Dr. Reddy's Laboratories, SA

STATISTICAL ANALYSIS PLAN

Protocol No. PPC-06-CD-004
Novella Study No. OYAA4621

A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, MULTICENTER, 24-WEEK STUDY TO ASSESS THE EFFICACY AND SAFETY OF PPC-06 (TEPILAMIDE FUMARATE) EXTENDED RELEASE TABLETS IN SUBJECTS WITH MODERATE-TO-SEVERE PLAQUE PSORIASIS

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Date	Reason for update	Section Updated (Current)
2018-11-15	**Creation of initial version**	**NA**
2019-04-15	**Creation of amendment 1**	• **Section 8 Analysis Population: PP exclusion criteria updated** • **Section 9 Handling of Missing Data: PSSI final score imputation method updated** • **Section 11.4 Analysis Visit Windows updated** • **Section 12.7.2 Secondary Efficacy Endpoints: PSSI final score range updated**

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List of Abbreviations and Definitions of Terms

Abbreviation	Definition
ADaM	Analysis dataset model
AE	Adverse event
ANOVA	Analysis of variance
ANCOVA	Analysis of covariance
ATC	Anatomical Therapeutic Chemical Classification System
BDM	Biostatistics and Data Management Group
BID	Twice a day
BMI	Body mass index
BSA	Body surface area
DLQI	Dermatology Life Quality Index
ECG	Electrocardiogram
eCRF	Electronic Case Report Form
EOS	End of study
ETV	Early termination visit
FAS	Full analysis set
HEOR	Health Economics and Outcomes Research
IP	Investigational product
IGA	Investigator's Global Assessment
LOCF	Last observation carried forward
MCMC	Markov Chain Monte Carlo method
MedDRA	Medical Dictionary for Regulatory Activities
MI	Multiple imputation
NAPSI	Nail Psoriasis Severity Index
m-NRI	Modified non-responder imputation
NRS	Numeric rating scale
OC	Observed-cases
PASI	Psoriasis Area and Severity Index
PASI-50	At least 50% reduction in PASI score
PASI-75	At least 75% reduction in PASI score
PD	Pharmacodynamic/pharmacodynamics
PGA	Physician's Global Assessment
PP	Per protocol
PP PGA	Palmoplantar Psoriasis Physician's Global Assessment
PSSI	Psoriasis Scalp Score Index
PT	Preferred Term
QD	Once daily

Abbreviation	Definition
QIDS-SR16	Quick Inventory of Depressive Symptomatology-Self Report (16 Items)
QoL	Quality of Life
SAE	Serious adverse event
SAP	Statistical analysis plan
SD	Standard deviation
SDTM	Study data tabulation model
SF-12	12-item Short Form Survey
SOC	System Organ Class
TEAE	Treatment-emergent adverse event
WPAI:PSO	Work Productivity and Activity Impairment Questionnaire: Psoriasis

1. INTRODUCTION

This Statistical Analysis Plan (SAP) is based on the study Protocol Amendment 2 Final v3.0 dated October 26th, 2018.

This document provides additional details concerning the statistical analyses outlined in the protocol and reflects any changes to the protocol from any amendments. This plan will not repeat all the definitions given in the protocol but will provide further details of the summaries and analyses planned therein.

2. STUDY OBJECTIVES

The co-primary objectives are:

- To demonstrate the efficacy of PPC-06 with respect to Psoriasis Area and Severity Index (PASI) for the treatment of moderate-to-severe plaque psoriasis, as compared to placebo at 24 weeks.
- To demonstrate the efficacy of PPC-06 with respect to Investigator's Global Assessment (IGA) at 24 weeks.

The secondary objectives are:

- To assess the efficacy of PPC-06 as it relates to psoriasis-related symptoms and health-related quality of life (QoL) measures.
- To assess the safety and tolerability of PPC-06 in subjects with moderate-to-severe plaque psoriasis.
- To evaluate the pharmacodynamics (PD) of PPC-06 through immunological analysis of peripheral blood samples. The PD analysis will be covered in a separate report.

3. STUDY DESIGN

This is a randomized, double-blind, placebo-controlled, multicenter study designed to assess the safety and efficacy of PPC-06 (tepilamide fumarate) extended release [ER] tablets in subjects with moderate-to-severe plaque psoriasis. Study subjects will be enrolled at approximately 75 sites in the United States (US). The study will be comprised of 4 study periods: 1) Screening Period, 2) Double-Blind Titration Period 3) Double-Blind Treatment Period and 4) Post-treatment Follow-Up Period.

Following completion of the pre-randomization Screening Period (up to 4 weeks), approximately 400 eligible subjects will be randomly assigned in a 1:1:1:1 ratio to one of the 4 arms (PPC-06 400 mg QD, PPC-06 400 mg BID, PPC-06 600 mg BID, or placebo BID) and the subjects will enter the 5-week Double-Blind Titration Period. At Visit 3 (Week 4), the subjects will continue one

more week of titration dose (Week 5 of blister wallets) and will also be given a kit of bottles which will allow dosing until Visit 4 (Week 8).

Subjects will receive double-blind treatment from Week 6 through Week 24. Subjects will return to the clinic every 4 weeks (±3 days) thereafter, until Week 24, for drug accountability and to undergo safety and efficacy evaluations. Subjects will return at Week 25 for an End of Study (EOS) Safety Follow-Up Visit. There are nine expected visits total per subject.

Blood samples for pharmacodynamics (PD) assessments will be collected at Baseline and at Weeks 4, 8, 12, 16, 20, and 24. PD assessments will be conducted for all subjects, with the intent of evaluating psoriasis-associated inflammatory markers.

The Early Termination Visit (ETV) will be scheduled if the study drug is permanently discontinued for any reason (for example: due to meeting the protocol-mandated safety monitoring criteria or unresolved gastrointestinal [GI]-related intolerability).

The EOS Safety Follow-up Period will consist of 1 visit 1-week (± 3 days) following the Week 24 Visit or the ETV. In the event that the Week 24 Visit or the ETV occurs > 1 week following the last dose of the study drug, the EOS Safety Follow-up Visit may not be required. The ETV and/or EOS Safety Follow-Up Visit are not expected to be completed for subjects who withdraw full consent or are lost to follow up.

If necessary, the Investigator may decide to extend the follow-up visits beyond one week to monitor recovery of safety parameters (e.g., lymphopenia).

4. HARDWARE AND SOFTWARE

Statistical analysis will be performed following Novella standard operating procedures and on the Novella computer network. All statistical analysis will be performed using SAS Version 9.3 or higher with program code prepared specifically for the project by qualified Novella statisticians and SAS programmers.

5. DATABASE CLOSURE

After completion of all data review and cleaning procedures and approval by the sponsor, the clinical database will be closed, and the study will be unblinded. Any change to the clinical database after this time will require written authorization, with explanation, by the Sponsor and the Biostatistician. After final approval of analysis methodologies, population assignments, and database closure, the study will be unblinded.

6. RANDOMIZATION

IWRS will be used for randomization. The randomization scheme will be reviewed and approved by a member of the sponsor's Biostatistics and Data Management (BDM) group or designee. The sites will randomize eligible subjects by contacting IWRS at Visit 2 after all the relevant Baseline

procedures are completed and assessed as appropriate. A subject who fulfills the study eligibility requirements will be randomly assigned to treatment. The randomization will be stratified by prior biologic use.

The IWRS will assign a randomization number to the subject, which will be used to link the subject to the treatment group and will specify a unique Blister Wallet IP kit number for the IP to be dispensed to the subject at Visit 2 for the Titration Period. The sites will log in to IWRS during each subsequent subject visit to obtain the kit numbers of the Bottle Kits to be dispensed at study Visits 3-7.

7. SAMPLE SIZE DETERMINATION

It was determined that a sample size of 100 subjects per treatment group would detect a significant difference in proportion of PASI-75 and IGA responders from Baseline to Week 24 between each dose group of PPC-06 and placebo group, assuming a 15% response rate for the placebo group and 45% for PPC-06 at Week 24. To provide sufficient evidence of treatment effect, both PASI and IGA based response rate must reject at the same significance level. The hypothesis testing for the three dose groups will be conducted sequentially from high to low dose (600 mg BID, 400 mg BID and 400 mg QD); therefore, the 2-sided Type I error rate from a chi-squared test remains at the 0.05 level. Assuming 50% dropout rate, about 100 subjects per treatment arm will be randomized to get approximately 50 completers in each treatment arm. The total sample size of 400 subjects will yield at least 84% power for hypothesis testing of the co-primary endpoints of a difference in PASI-75 and IGA responders from Baseline to Week 24 between PPC-06 doses and placebo.

8. ANALYSIS POPULATIONS

The following analysis sets/populations will be used in this trial:

- Safety population: include all subjects who receive at least one dose of IP. The safety population is the population used for all safety analyses.
- Full analysis set (FAS) – All randomized subjects who receive at least one dose of investigational product and have at least one post dose efficacy assessment. The FAS population will be the primary population for the efficacy analyses
- Per Protocol (PP) population: include subjects in the FAS population who complete the study without any major protocol violations that are considered likely to affect the efficacy analysis outcomes of the study. Major protocol violations will include but not be restricted to the following:
    - Failure to meet the inclusion/exclusion criteria that are considered likely to affect the efficacy analysis outcomes of the study
    - Randomization error

- Usage of any prohibited concomitant medications or procedures
- Failure to have Week 24 assessment within the allowable window for either of the co-primary endpoints
- Failure to be compliant with treatment regimen

Additional criteria may be added to determine PP population. The composition of the PP population will be determined and documented in blind reviews of the database conducted prior to unblinding the study database. Subjects who used rescue medications or who discontinued due to unsatisfactory therapeutic effect will be included in the PP population. These subjects will be considered as treatment failures (i.e., non-responder for both PASI-75 and IGA) for all time points after the initiation of rescue medications or subject discontinuation.

9. HANDLING OF MISSING DATA

All imputations specified in this section will be performed for the Double-Blind Treatment and titration Period only; the Post-treatment Follow-Up Period data will be analyzed as observed.

For the analyses of the co-primary endpoints (PASI-75 and IGA), multiple imputation (MI) will be the primary imputation method. The modified non-responder imputation (m-NRI) and last observation carried (LOCF) method will be used as sensitivity analyses.

Details of the imputation methods are as following:

- **MI**: Missing data will be imputed using multiple imputations, a simulation-based approach where missing values are replaced by multiple Bayesian draws from the conditional distribution of missing data given the observed data and covariates, creating multiple completed data sets. These completed datasets can then be analyzed using standard analysis methods. MI will be implemented for all subjects with missing data, included those who used rescue medications or discontinued due to unsatisfactory therapeutic effect.

  Multiple Imputation procedures for missing PASI scores:

  Intermittent missing values of PASI scores will be imputed separately for each treatment group using the Markov Chain Monte Carlo (MCMC) method, generating 50 copies of the imputed dataset with monotonic missing pattern. For each of the 50 datasets, missing values at scheduled visits (Weeks 4, 8, 12, 16, 20 and 24) will be imputed using a linear regression model. The imputations will include the following variables: baseline BMI, baseline PASI score, and PASI scores at the previous scheduled visits. SAS Proc MI will be used. Imputed PASI-75 response (Yes/No) will be derived for each imputed dataset.

  Example SAS code is as follows:

```
PROC MI DATA = PASI1 OUT = PASI2 SEED = 132138 NIMPUTE = 50 NOPRINT;
   BY TRT01PN;
```

```
   MCMC IMPUTE = MONOTONE;
   VAR BASEBMI BASEPASI _3 _4 _5 _6 _7 _8;
RUN;

PROC MI DATA = PASI2 OUT= PASI3 SEED = 132138 NIMPUTE = 1 NOPRINT;
   BY TRT01PN _IMPUTATION_;
   MONOTONE REGRESSION;
   VAR BASEBMI BASEPASI _3 _4 _5 _6 _7 _8;
RUN;
```

Multiple Imputation procedures for missing IGA scores:

The imputation of post-baseline IGA scores will be performed following a similar approach as described for PASI scores. Intermittent missing IGA scores will be imputed separately for each treatment group using the Markov Chain Monte Carlo (MCMC) method where 50 copies of the dataset with monotonic missing pattern will be generated. For each of the 50 datasets, missing values at scheduled visits (Weeks 4, 8, 12, 16, 20 and 24) will be imputed using a logistic regression model including baseline BMI, baseline IGA score, and IGA scores at the previous scheduled visits. SAS Proc MI using the logistic regression method for monotone data will be used for the imputation. IGA Treatment Success status (Yes/No) will then be derived for each imputed dataset.

Example SAS code is as follows:

```
PROC MI DATA = IGA1 OUT = IGA2 SEED = 132138 NIMPUTE = 50 NOPRINT;
   BY TRT01PN;
   MCMC IMPUTE = MONOTONE;
   VAR BASEBMI _3 _4 _5 _6 _7 _8;
RUN;

PROC MI DATA = IGA2 OUT= IGA3 SEED = 132138 NIMPUTE = 1 NOPRINT;
   BY TRT01PN _IMPUTATION_;
   MONOTONE LOGISTIC;
   VAR BASEBMI _3 _4 _5 _6 _7 _8;
RUN;
```

The imputation of missing post-baseline BSA, PSSI final score, NAPSI, and NRS scores will be performed using a similar method as described for PASI. The imputation of missing post-baseline PP PGA scores will be performed using a similar method as described for IGA. A pre-specified seed number of 132138 will be used in all imputation procedures. No imputation will be done to the health-related quality of life endpoints or safety endpoints.

- **Observed cases (OC)**: No imputation will be performed, only observed values will be analyzed.

- **m-NRI (response endpoint only)**: Subjects who used rescue medications or discontinued due to unsatisfactory therapeutic effect are considered as treatment failures (i.e., non-responder) for all time points after the initiation of rescue medications or subject discontinuation. For example, if a subject discontinued due to lack of efficacy, all visits

after the last planned visits will be imputed to non-responders. If a subject used rescue medication during the study, all visits after the start of the rescue medication will be imputed to non-responders regardless if the subject had an assessment or not. Other subjects with missing data will be kept as missing (i.e., no imputation). Discontinuation due to unsatisfactory therapeutic effect will be identified by discontinuation reason = "Other" with a comment "lack of efficacy" on the eCRF.

- **LOCF**: The last observed value will be carried forward for any subsequent missing values. Baseline values will not be carried forward.

A summary of the imputation methods for all efficacy endpoints is shown below:

Endpoint	**Analysis Population**	**Imputation Methods**
PASI-75 at Week 24	FAS	MI, m-NRI, LOCF, OC
	PP	m-NRI
IGA score of clear or almost clear at Week 24	FAS	MI, m-NRI, LOCF, OC
	PP	m-NRI
Change from Baseline and percent change from Baseline in PASI Total Score by Visit	FAS	MI, LOCF, OC
	PP	OC
PASI-50 and PASI-75 by Visit	FAS	MI, m-NRI, LOCF, OC
	PP	m-NRI
IGA score of clear or almost clear by Visit	FAS	MI, m-NRI, LOCF, OC
	PP	m-NRI
Change from Baseline and percent change from Baseline in BSA by Visit	FAS	MI, LOCF, OC
	PP	OC
Change from Baseline in NAPSI by Visit	FAS	MI, LOCF, OC
	PP	OC
Change from Baseline in PSSI by Visit	FAS	MI, LOCF, OC
	PP	OC
Change from Baseline in PP PGA by Visit	FAS	MI, LOCF, OC
	PP	OC
Change from Baseline in NRS by Visit	FAS	MI, LOCF, OC
	PP	OC
Time to PASI-75	FAS	OC
Time to achieving an IGA score of clear or almost clear	FAS	OC
QIDS-SR 16	FAS	OC
DLQI	FAS	OC
SF-12	FAS	OC
WPAI:PSO	FAS	OC

HEOR	FAS	OC

10. INTERIM ANALYSIS

The overall response rate for PASI-75 and IGA success at Week 16 and 24, will be reported when 50, 100 and 200 subjects complete the treatment period. The interim will be performed on blinded data using the m-NRI, OC and LOCF imputation method. All subjects in full analysis set (FAS) that have completed Week 24 assessments or early terminated by the interim data cut date will be included in the analysis. No formal shell is required.

11. DATA CONVENTIONS FOR ANALYSIS

11.1 General Statistical Principles

All statistical tests will be performed at the unadjusted 0.05 (two-sided) level of significance.

All observed and derived variables (e.g., change from baseline, percentage change from baseline, response status) used in the summaries of analyses will be presented in by-subject listings. Descriptive statistics will be used to provide an overview of the efficacy and safety results. For categorical parameters, the number and percentage of subjects in each category will be presented. The denominator for percentage will be based on the number of subjects appropriate for the purpose of analysis. For continuous parameters, descriptive statistics will include number of subjects, mean, standard deviation (SD), median, minimum, and maximum.

11.2 Study Day

Day 1 is defined as the date of first study drug administration. For subjects who used any study drug but did not have a recorded date of first study drug administration (e.g., due to missing Week 4 visit), Day 1 is defined as randomization date + 1. Study day is calculated relative to the date of Day 1.

11.3 Baseline and Change from Baseline

Baseline value is defined as the last non-missing value prior to the first dose of study drug. Change from baseline is defined as the post-baseline value minus the baseline value unless otherwise specified. Percent change from baseline is calculated as follows: Percent change = (Change from baseline / Baseline) * 100.

11.4 Analysis Visit Window

Efficacy and safety endpoints will be analyzed according to their windowed visits defined by actual study day. If more than one visit occurs within a single visit window, then the analysis will take the one closest to the target day. If the 2 visits are equidistant from the target day, the later visit will be used. A later visit within the window will be used for LOCF.

The following analysis visit windows will apply:

Visit	**Week**	**Target Day**	**Efficacy Assessment Window**	**Safety Assessment Window**
2	Baseline	0	On or prior to date of first dose	On or prior to date of first dose
3	4	28	Post-dose – Day 42	Post-dose – Day 42
4	8	56	Day 43 – Day 70	Day 43 – Day 70
5	12	84	Day 71 – Day 98	Day 71 – Day 98
6	16	112	Day 99 – Day 126	Day 99 – Day 126
7	20	140	Day 127 – Day 154	Day 127 – Day 154
8	24	168	≥Day 155	≥Day 155
9 (Follow-Up)	25	LD+7	> LD+15	> LD+15

LD = Last dose date

Visits 3 through 8 are on-treatment visits. Therefore, only on-drug assessments or assessments performed within 15 days post last dose are to be analyzed within those windows, according to their actual study day. Visit 9 is an off-treatment visit, which will be analyzed according to their number of days after last dose, regardless of the actual study day. For example, a subject who has Visit 4 on Day 56, then discontinues with last dose on Day 84 and returns for Early Termination on Day 100 will have no data within the Visit 6 window. The Early Termination visit must be analyzed as Visit 9. For this subject, data for Visits 5, 6, 7, and 8 would be carried forward from Visit 4 in an LOCF analysis. If the last dose date is unknown, then all visits will be analyzed as on-treatment based on actual study day (i.e., no Visit 9 will be identified for the subject).

Subjects who permanently discontinue the study drug for any reason or who withdraw from the study prematurely prior to the end of the Double-Blind Treatment Period should undergo the ETV followed by the EOS Safety Follow-up Period Visit. In the event that the ETV or Week 24 Visit occurs > 1 week following the last dose of the study drug, the EOS Safety Follow-up Visit may not be required. If necessary, the Investigator may decide to extend the EOS Safety Follow-up Visits beyond 1 week to monitor recovery of safety parameters (eg, lymphopenia).

11.5 Pooled Analysis Centers

There will be approximately 75 trial sites in the United States. Pooling of trial sites, based on insufficient number of subjects, will be performed when any site does not have a minimum number (e.g., 5 subjects per site per arm) of subjects in the FAS population. Sites with insufficient number

of subjects will be combined in order of geographical proximity. The exact composition of these "analysis sites" will be determined and documented prior to breaking the trial blind.

Descriptive summaries of the co-primary efficacy endpoints will be provided for each analysis site. Any notable site heterogeneity will be further investigated. Exploratory analyses of the co-primary endpoints may be performed excluding analysis sites whose results differ appreciably from other analysis sites.

12. STATISTICAL EVALUATION

12.1 Subject Disposition

The number and percentage of subjects screened, randomized, included in each analysis population, completing the study, withdrawing from the study (together with the reasons for withdrawal), and subjects excluded from PP population (together with the reasons for exclusion) will be summarized using frequencies and percentages by treatment group. A by-subject listing will be presented for all subject enrollment and disposition. Screen failures and subjects not randomized will also be presented in by-subject listings.

The number of days in the study (date of study completion / discontinuation minus date of Day 1 plus 1) will be summarized using descriptive statistics for each treatment group.

12.2 Protocol Deviation

Protocol deviations will be provided in a by-subject listing.

12.3 Demographic and Baseline Characteristics

Demographics and baseline characteristics will be summarized overall and by treatment for the FAS, PP and Safety populations. The following demographic and baseline variables will be included:

- Age
- Gender
- Race
- Ethnicity
- Weight
- Height
- Waist circumference
- BMI
- Baseline PASI score
- Baseline BSA
- Baseline IGA

12.4 Study Medication Exposure and Compliance

The following exposure and compliance parameters will be summarized by treatment group and study period (overall, titration, and treatment as applicable) using descriptive statistics:

- Total number of days exposed to study medication, defined as date of last dose of study drug during the study minus date of first dose of study drug plus 1.
- Total number of tablets taken during the titration period (Week 1 – 5), defined as number of dispensed tablets from blister wallets minus number of returned tablets from blister wallets.
- Total number of tablets taken during the treatment period (Week 6 – 24), defined as total number of dispensed tablets from bottles minus total number of returned tablets from bottles.
- Number of tablets per bottle taken during the treatment period (Week 6 – 24), defined as number of dispensed tablets per bottle (total of 4 bottles per visit) minus number of returned tablets per bottle.
- Total number of tablets taken, defined as the summation of number of tablets taken during the titration and treatment period.
- Percent compliance will be calculated as the number of tablets taken divided by the expected number of tablets, defined for the titration period, treatment period, and overall. The expected number of tablets are as following:

Period	**Number of Tablets Dispensed Per Dosing Regimen**	**Expected Total Number of Tablets**
Titration (Week 1 – 5)	Week 1 – 4: 28 per week Week 5: 35 per week	28*4 + 35 = 147
Treatment (Week 6 – 24)	42 per week	42*19 = 798
Overall (Week 1 – 24)		945

- Subject compliance, defined as 80% - 120% (inclusive) in percent compliance. If the percentage of study medication compliance is unknown, the subject is assumed to be non-compliant with study medication. Subject compliance is summarized by periods and overall. Overall compliance will be the main determinant of compliance.
- Average daily dose of IP received can be calculated as the number of tablets divided by the number of days exposed to study medication. The average daily dose of IP received by each subject will be summarized by treatment group using summary statistics for the overall period.

12.5 Prior and Concomitant Medications

Prior (within the previous 30 days and with stop dates prior to first dose of study drug) and concomitant (ongoing or with stop dates on or after first dose of study drug) medications will be presented for the safety population in a by-subject listing for each treatment group. If the medication is ongoing or the stop year is missing, the medication will be considered as received for the entire duration of the study. Medications will be coded using WHO-DD terminology.

For the determination of prior vs concomitant medications, the following rules regarding the stop date will be applied:

- If only year was recorded, and it is before Baseline, it is a prior medication; if year is same or after Baseline, it is assumed to be a concomitant medication.
- If day is missing, but month and year are before Baseline, it is a prior medication; if month and year are the same as Baseline, it is assumed to be a concomitant medication; if month and year are after Baseline, it is a concomitant medication.
- If start date is after Baseline, it is a concomitant medication regardless.

In addition, prior and concomitant medications will be summarized by treatment, WHO-DD Anatomical-Therapeutic-Chemical (ATC) classification and preferred term (PT).

12.6 Medical History and Concurrent Procedures

Medical history (including previous and ongoing medical conditions) will be coded using MedDRA and presented in a by-subject listing.

Psoriasis Medical History, Prior Psoriasis Treatment History and Other Medical/Surgical History will be presented in separate by-subject listings.

Concurrent procedures will be coded using MedDRA and presented in a by-subject listing.

12.7 Efficacy Endpoints

12.7.1 Primary Efficacy Endpoint

The co-primary efficacy endpoints are as follows:

- The proportion of subjects who achieve a reduction of 75% or greater from Baseline in the Psoriasis Area and Severity Index (PASI-75) at the end of Week 24
- The proportion of subjects who achieve an IGA score of clear or almost clear (IGA score 0 or 1) at the end of Week 24

12.7.2 Secondary Efficacy Endpoints

The secondary endpoints are the following:

- Change from Baseline and percent change from Baseline in total PASI Score by Visit in the Double-Blind Treatment Period
- Proportion of subjects who achieve PASI-50 and PASI-75 at each visit in the Double-Blind Treatment Period
- Proportion of subjects who achieve an IGA score of clear or almost clear at each visit in the Double-Blind Treatment Period
- Change from Baseline and percent change from Baseline in percent of affected BSA at each visit in the Double-Blind Treatment Period
- For applicable subjects present with non-zero baseline NAPSI score (score range 0-8) in target nail, change from baseline in Nail Psoriasis Severity Index (NAPSI) of the target fingernail at Weeks 12, 16 and 24
    - All fingernails will be scored at Baseline and the target nail will be selected as the one with the worst (highest) score by investigator; Only the target nail will be evaluated in the subsequent visits.
    - If a target nail was not identified on the CRF, for purpose of analysis, it will be selected programmatically as the fingernail with the worst score at Baseline. If more than 1 nail has the same worst score, then the target nail will be the first nail according to the order of digit collected on the CRF (i.e., digit 1/thumb, digit 2…digit 5). If the same digit from both hands have the same worst score, the target nail will be selected from the left hand.
    - If score is 0 at Baseline, then the respective assessments at future visits would not be required.
- For applicable subjects present with non-zero baseline score, change from baseline by visit in Psoriasis Scalp Score Index (PSSI, score range 0-72) and Palmoplantar Psoriasis Physician's Global Assessment (PP PGA, score range 0-4) in the Double-Blind Treatment Period;
    - If score is 0 for PSSI and PP PGA at Baseline, then the respective assessments at future visits would not be required;
- Change from Baseline and percent change from Baseline in pruritus Numeric rating scale (NRS) score (score range 0-10) at each visit in the Double-Blind Treatment Period
- Time to achieving a PASI-75 response, defined as time in days from baseline to first achieving a reduction of 75% or greater from Baseline in PASI. Subjects who did not achieve PASI-75 by the last assessment or withdrew prior to the last study visit will be censored at their last PASI assessment

- Time to achieving an IGA score of clear or almost clear, defined as time in days from baseline to first achieving an IGA score of 0 or 1. Subjects who did not achieve an IGA of 0 or 1 at the last assessment or withdrew prior to the last study visit will be censored at their last IGA assessment

12.7.3 Health-related Quality of Life Endpoints

The Health Outcome/Quality of Life endpoints are the change from baseline in the following health outcome/QoL assessments at Weeks 12, 16, and 24:

- Quick Inventory of Depressive Symptomatology-Self Report (16 Items) (QIDS-SR16) total score. The total score (range 0-27) is calculated as the sum of the following 9 items: Highest score on any sleep items (Q1-Q4), Q5, highest score on any appetite/weight items (Q6-Q9), Q10, Q11, Q12, Q13, Q14, highest score on either psychomotor items (Q15 & Q16). The total score will be considered as missing if any of the component score is missing.
- The Dermatology Life Quality Index (DLQI) total score (0-30) will be calculated as the sum of 10 questions with each ranging from 0 to 3. The scoring of each answer is as follows:

Very much	Scored 3
A lot	Scored 2
A little	Scored 1
Not at all	Scored 0
Not relevant	Scored 0
Question unanswered	Scored 0
Question 7: "prevented work or studying"	Scored 3

If one question is left unanswered this is scored 0 and the scores are summed and expressed as usual out of a maximum of 30. If two or more questions are left unanswered the total DLQI score is missing. If question 7a is answered 'no' or 'not relevant', then the answer of 7b will be ignored. Additionally, the score of each of 6 domains (daily activities, personal relationships, symptoms and feelings, leisure, work/school, and treatment) will be summarized separately.

- The SF-12 summary scales will be calculated using the SF-12 Health Survey Standard Scoring software. Summary scores will be computed for Physical Summary (PCS) and Mental Summary (MCS). Subscores will also be computed for the following 8 domains:
  - Physical Functioning (PF)
  - Role-Physical (RP)
  - Bodily Pain (BP)

- Social Functioning (SF)
- Mental Health (MH)
- Role-Emotional (RE)
- Vitality (VT)
- General Health (GH)

- Work Productivity and Activity Impairment Questionnaire: Psoriasis (WPAI:PSO) score. WPAI-PSO outcomes are expressed as impairment percentages, with higher numbers indicating greater impairment and less productivity, i.e., worse outcomes as follows

  - The percent work time missed due to psoriasis will be summarized for all subjects who answer "Yes" to Question 1, "Are you currently employed?". This will be calculated using the following formula: 100 * ((Question 2) / (Question 2 + Question 4))
  - The percent impairment while working due to psoriasis will be summarized for all subjects who have worked at least 1 hour in the past 7 days (ie, response to Question 4 is greater than zero). This will be calculated as 100 * (Question 5 / 10)
  - The percent overall work impairment due to psoriasis will be summarized for subjects who answer "Yes" to Question 1 and response >0 to Question 4. This will be calculated as 100 * {Question 2 / (Question 2 + Question 4) + (1- Question 2 / (Question 2 + Question 4)) * Question 5 / 10)}
  - The percent activity impairment due to psoriasis will be summarized for all subjects with a non-missing response to Question 6. This will be calculated as 100 * (Question 6 / 10).

  Any of the impairment percentage will be considered as missing if the contributing question is missing.

- Health Economics and Outcome Research (HEOR) evaluation. Responses to each of the following 3 questions will be summarized separately by visit:

  - Number of times to any physician's office or urgent care clinic
  - Number of times to a nurse practitioner, a physician assistant, a psychologist, a naturopath, an acupuncturist, a chiropractor, or other healthcare professional (HCP)
  - Number of times received care from a health professional in your home

12.8 Efficacy Analyses

12.8.1 Primary Efficacy Analyses

For each of the co-primary efficacy endpoints, proportion of subjects who achieved PASI-75 and IGA success at Week 24, will be tested to compare the difference between the subjects treated with PPC-06 and placebo, separately. To provide sufficient evidence of treatment effect, both PASI and

IGA based response rate must be rejected at the same significance level. The hypothesis testing for the three dose groups will be conducted sequentially from high to low dose; therefore, the 2-sided Type I error rate remains at the 0.05 level.

The primary efficacy analyses will be based on the FAS population using MI. Each multiple imputed dataset will be analyzed using a logistic regression model with treatment group, baseline BMI, and pooled analysis center as factors. The primary treatment comparisons will be the contrasts between the PPC-06 doses and placebo. The estimates and standard errors (SEs) of the log (odds ratio) based on the 50 imputed datasets will be combined by applying Rubin's rules for multiple imputed datasets. The combined log (odds ratio), odds ratio and associated 95% CI, and the resulting p-value will be provided. SAS Proc MI, Proc LOGISTIC, and Proc MIANALYZE will be utilized for these analyses. The averaged proportion of PASI-75 responders and IGA Success Rates over the 50 imputed datasets will also be presented.

Sensitivity analyses will be conducted using m-NRI and LOCF, following a same method as described above for each multiple imputed dataset. For each of the co-primary efficacy endpoints, proportion of subjects who achieved PASI-75 and IGA success at Week 24, will be tested to compare the difference between the subjects treated with PPC-06 and placebo, separately. PASI-75 and IGA Success Rates will be analyzed using a logistic regression model with treatment group, baseline BMI, and pooled analysis center as factors. The odds ratio between each PPC-06 group and placebo, along with the 95% CI and p-value will be reported.

Supporting analysis of the primary endpoints will also be performed using m-NRI based on the PP population.

12.8.2 Secondary Efficacy Analyses

All secondary efficacy analyses will be performed on the FAS and PP populations.

The following categorical secondary efficacy endpoints will be summarized using the number and percentage of subjects within each category for each treatment group. A same logistic regression model as used for the primary endpoint will be performed. Each PPC-06 group will be compared to placebo separately as described in the primary analysis.

- Proportion of subjects who achieve PASI-50 and PASI-75 by visit in the Double-Blind Treatment Period
- Proportion of subjects who achieve an IGA score of clear or almost clear by visit in the Double-Blind Treatment Period

The observed values and change from baseline in PP PGA will be summarized as categorical endpoint using frequency counts and percentages. The change from baseline in severity categories will be compared between treatment groups using a Wilcoxon rank sum test.

The following continuous secondary efficacy endpoints will be summarized descriptively and analyzed using an Analysis of Covariance (ANCOVA) including factors for treatment, baseline

BMI, and pooled analysis center. Each PPC-06 group will be compared to placebo separately. The least square mean (LSM) difference, along with the 95% CI and p-value will be reported.

- Change from Baseline and percent change from Baseline in total PASI Score by visit in the Double-Blind Treatment Period
- Change from Baseline and percent change from Baseline in percent of affected BSA by Visit in the Double-Blind Treatment Period
- For applicable subjects, change from baseline in NAPSI of the target fingernail at Weeks 12, 16 and 24
- For applicable subjects, change from baseline by visit in PSSI in the Double-Blind Treatment Period
- Change from Baseline and percent change from Baseline in pruritus NRS score by Visit in the Double-Blind Treatment Period

The following time to event variables will be analyzed using the Kaplan-Meier (KM) method. Subjects who have not achieved treatment response by the last visit or discontinue the study will be censored at their last visit. The mean, 25th, 50th, and 75th percentile time to achieving a treatment success will be reported; log-rank test will be performed for the comparison between each PPC-06 arm and placebo.

- Time to achieving PASI-75 response
- Time to achieving IGA 0 or 1

12.8.3 Health-related Quality of Life Analyses

All QoL endpoints will be summarized by visit and treatment group using descriptive statistics on the FAS population.

12.8.4 Subgroup Analyses

The co-primary efficacy endpoints will be analyzed for the following subgroups:

- Baseline hsCRP (< 5 mg/L, >=5 mg/L)
- Baseline BMI (<30, >=30)
- Occurrence of diarrhea (Subjects reported diarrhea as adverse event by Week 24, subject did not report diarrhea by Week 24)

The same method as described in Section 12.8.1 will be used for the subgroup analyses, except that no formal hypothesis testing will be performed.

12.9 Safety Analysis

12.9.1 Adverse Events

AE terms will be coded using MedDRA dictionary. A treatment-emergent AE (TEAE) is defined as an AE that starts after the first dose of study medication through 5 days after the last dose. If relationship to treatment is missing, the event will be conservatively considered as being related to study drug. If severity is missing, a separate category of missing severity will be included in the summary table, and no imputation of severity will be performed. Through the data cleaning process, all attempts will be made to avoid missing values for relationship and severity.

All AEs will be presented in a by-treatment and by-subject listing, detailing the verbatim term given by the investigator, the preferred term (PT), system organ class (SOC), onset date and time, end date and time, intensity, outcome, relationship to study drug/treatment, action taken with study drug/treatment, other action taken to treat the event, seriousness and criteria for seriousness. Serious AEs (SAEs) and TEAEs leading to study discontinuation will also be presented in a separate listing. Deaths and non-fatal SAEs will be listed by subject and tabulated by PT.

Each TEAE will be identified as titration period AE or treatment period AE according to the following rules:

- PPC-06 400 mg QD:
    - Any TEAE starting before Day 15 is considered as a titration period AE
    - Any TEAE starting on or after Day 15 is considered as a treatment period AE
- PPC-06 400 mg BID, PPC-06 600 mg BID:
    - Any TEAE starting before Day 36 is considered as a titration period AE
    - Any TEAE starting on or after Day 36 is consider as a treatment period AE
- Placebo BID:
    - No study period will be further designated for this group. They should match equivalent phases to calculate therapeutic effect for eg: for 400 mg it should be Day 15 and >15 days, for other doses it should be Day 36 and >36 days.

An overall summary of AEs will be presented by treatment and overall, for the titration period, treatment period, and overall. The summary will include the total number of events, frequency counts and percentages, and exposure-adjusted incidence rate for:

- Any AE
- Any TEAE
- Any serious TEAE
- Any treatment-related TEAE, including definitely, probably, and possibly related
- Any TEAE leading to study drug discontinuation
- Any SAEs (non-Fatal)
- Any Deaths

For the 3 arms receiving active treatment, exposure-adjusted incidence rate will be defined for both titration and treatment periods as number of subjects with AEs divided by total number of subject-days with exposure to study medication. Total number of subject-days with exposure in each period = sum of durations in days across all subjects in each period. Duration in each period is defined as following:

- PPC-06 400 mg QD:
    - Titration period = Number of days between date of first study application and the earlier of date of last study medication and Day 14 inclusive
    - Treatment period = Number of days between Day 15 and date of last study application inclusive
- PPC-06 400 mg BID, PPC-06 600 mg BID:
    - Titration period = Number of days between date of first study application and the earlier of date of last study medication and Day 35 inclusive
    - Treatment period = Number of days between Day 36 and date of last study application inclusive

Summaries of the incidence of TEAEs will be displayed by treatment according to the following:

- All TEAEs by SOC in alphabetical order and PT in descending order of frequency (the combined frequency in the three active treatments)
- All TEAEs by SOC, PT, and maximum severity (mild, moderate, or severe)
- All TEAEs by SOC, PT, and maximum causality (not related, related) to the study drug

At each level of summarization, a subject will be counted once if he/she reported one or more events. In the counts of subjects with TEAEs, each subject will contribute only once (maximum severity) regardless of the number of occurrences (events).

The severity of TEAEs and relationship to study drug will be summarized in a similar manner. For summaries of relationship to study drug, a subject will be classified according to the closest relationship. For summaries of TEAE severity, a subject will be classified according to the highest severity.

12.9.2 Clinical Laboratory Testing

Clinical laboratory values will be reported as complete listings of individual subject data. All laboratory values will be classified as normal, low, or high based on normal ranges supplied by the laboratory. Subjects with values outside the normal range will be flagged and summarized using shift tables. A separate listing and table will identify and summarize subjects with markedly abnormal values. For quantitative measures, observed and changes in clinical laboratory values will be analyzed descriptively by time of collection and treatment group.

Additionally, lymphocyte counts will be summarized by clinical response of PASI-50 and PASI-75 (Yes/No) at Week 24. Lymphocyte counts and hs-CRP will also be plotted against PASI scores by visit and treatment. The correlation coefficient will be reported.

12.9.3 Vital Signs

Change in vital sign data will be classified as normal, low, high, based on a reference range. Observed and changes in vital sign parameters will be analyzed descriptively by visit and treatment group. Subjects with markedly abnormal changes will be listed and tabulated separately.

	Low	Normal	High	Abnormal (Absolute) Change from Baseline	Markedly Abnormal (Absolute) Change from Baseline
SBP	<90 mmHg	90-140 mmHg	>140 mmHg	≥ 20 mmHg	≥ 40 mmHg
DBP	<50 mmHg	50-90 mmHg	>90 mmHg	≥ 10 mmHg	≥ 20 mmHg
Pulse	<50 bpm	50-100 bpm	>100 bpm	≥ 10 bpm	≥ 30 bpm

12.9.4 Physical Examination

Abnormal findings of physical examination will be presented in a by-subject listing.

12.9.5 Electrocardiogram (ECG)

Data will be listed, notable values will be flagged, and any other information collected will be listed as appropriate. Subjects with markedly abnormal ECG changes will be listed and tabulated separately. Observed changes will be analyzed descriptively by time of collection and treatment group.

12.10 Pharmacodynamic Analyses

Blood samples for pharmacodynamics (PD) assessments will be collected at Baseline and at Weeks 4, 8, 12, 16, 20, and 24. PD assessments will be conducted for all subjects, with the intent of evaluating psoriasis-associated inflammatory markers. PD analysis will be covered in a separate report

13.CHANGES FROM THE PROTOCOL AND PLANNED ANALYSES

Protocol states PP PGA will be analyzed using a similar method as NAPSI, PSSI. The SAP summarizes PP PGA using frequency counts and percentages. Wilcoxon rank sum test will be used to compare the change from baseline in PP PGA between treatment groups.

14.FORMATTING

Each page of the analysis will show the sponsor's name, the investigational product, and the protocol number. Report tables will be embedded in the MS Word report document from SAS program output without change. The footer of each table will show the name of the SAS program module which generated it, the names of all data sets providing input data in the program and the date and time the table was generated.

The SAS programs will generate rich-text-formatted (RTF) output with the "RTF" extension using the SAS Output Delivery System (ODS). The summary tables and listings will be formatted using the Times New Roman 9-point font. The RTF output is included in report documents prepared with Microsoft Word and converted to PDF format without typographical change.

Datasets will be created and taken as input to validated SAS programs to generate the report-ready tables, listings, and figures. Each output display will show the names of the data sets and SAS program used to produce it.

15.ARCHIVING AND RETENTION OF DOCUMENTS

After finalization of the analysis, the following will be archived at Novella Clinical and/or with the study sponsor:

- SAP and any amendments
- All SAS code used in the project for statistical analysis, report tables generation, and analysis data set creation
- Tables, listings and figures as included in the clinical study report
- SAS study data tabulation model (SDTM) and analysis dataset model (ADaM) datasets

16.OUTLINE OF PROPOSED TABLES, FIGURES AND LISTINGS

Tables	
14.1	**Summary of Disposition, Demographic, and Exposure Tables**
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14.1.2.1	Summary of Subject Demographics and Baseline Characteristics; Full Analysis Set
14.1.2.2	Summary of Subject Demographics and Baseline Characteristics; Safety Population
14.1.2.3	Summary of Subject Demographics and Baseline Characteristics; PP Population
14.1.3.1	Summary of Exposure and Compliance, Overall, Safety Population
14.1.3.2	Summary of Exposure and Compliance; Titration Period (Week 1—5), Safety Population
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14.1.4.1	Summary of Prior Medications by Anatomical Therapeutic Chemical Class (ATC) and Preferred Term; Safety Population
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14.2.1	**Summary of Primary Efficacy and Sensitivity Analysis Tables**
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14.2.1.1.4	Analysis of Co-Primary Efficacy Outcome, Sensitivity Analysis, PASI-75 Response Rate at Week 24, Full Analysis Set, LOCF
14.2.1.1.5	Analysis of Co-Primary Efficacy Outcome, Sensitivity Analysis, PASI-75 Response Rate at Week 24, Full Analysis Set, OC
14.2.1.2.1	Analysis of Co-Primary Efficacy Outcome, IGA Treatment Success Rate at Week 24, Full Analysis Set, Multiple Imputation
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14.2.1.2.3	Analysis of Co-Primary Efficacy Outcome, Sensitivity Analysis, IGA Treatment Success Rate at Week 24, Full Analysis Set, m-NRI
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14.2.1.3.1	Analysis of Co-Primary Efficacy Outcome, Subgroup Analysis, PASI-75 Response Rate at Week 24 by Baseline hsCRP (mg/L), Full Analysis Set, Multiple Imputation
14.2.1.3.2	Analysis of Co-Primary Efficacy Outcome, Subgroup Analysis, PASI-75 Response Rate at Week 24 by Baseline BMI, Full Analysis Set, Multiple Imputation
14.2.1.3.3	Analysis of Co-Primary Efficacy Outcome, Subgroup Analysis, PASI-75 Response Rate at Week 24 by Occurrence of Diarrhea, Full Analysis Set, Multiple Imputation
14.2.1.4.1	Analysis of Co-Primary Efficacy Outcome, Subgroup Analysis, IGA Treatment Success Rate at Week 24 by Baseline hsCRP (mg/L), Full Analysis Set, Multiple Imputation
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14.2.1.4.3	Analysis of Co-Primary Efficacy Outcome, Subgroup Analysis, IGA Treatment Success at Week 24 by Occurrence of Diarrhea, Full Analysis Set, Multiple Imputation
14.2.1.5.1	Analysis of Co-Primary Efficacy Outcome, PASI-75 Response Rate at Week 24 by Visit and Analysis Sites, Full Analysis Set, Multiple Imputation
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14.2.2.1.1.2	Analysis of Secondary Efficacy Outcome - Percent Change from Baseline in Total PASI Score by Visit, Double-Blind Treatment Period, Full Analysis Set, Multiple Imputation

14.2.2.1.2.1	Analysis of Secondary Efficacy Outcome - Change from Baseline in Total PASI Score by Visit, Double-Blind Treatment Period, Full Analysis Set, LOCF
14.2.2.1.2.2	Analysis of Secondary Efficacy Outcome - Percent Change from Baseline in Total PASI Score by Visit, Double-Blind Treatment Period, Full Analysis Set, LOCF
14.2.2.1.3.1	Analysis of Secondary Efficacy Outcome - Change from Baseline in Total PASI Score by Visit, Double-Blind Treatment Period, Full Analysis Set, OC
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14.2.2.1.4.2	Analysis of Secondary Efficacy Outcome - Percent Change from Baseline in Total PASI Score by Visit, Double-Blind Treatment Period, PP Population, OC
14.2.2.2.1	Analysis of Secondary Efficacy Outcome: PASI-50 Response Rate by Visit, Double-Blind Treatment Period, Full Analysis Set, Multiple Imputation
14.2.2.2.2	Analysis of Secondary Efficacy Outcome: PASI-50 Response Rate by Visit, Double-Blind Treatment Period, Full Analysis Set, LOCF
14.2.2.2.3	Analysis of Secondary Efficacy Outcome: PASI-50 Response Rate by Visit, Double-Blind Treatment Period, Full Analysis Set, m-NRI
14.2.2.2.4	Analysis of Secondary Efficacy Outcome: PASI-50 Response Rate by Visit, Double-Blind Treatment Period, Full Analysis Set, OC
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14.2.2.3.1	Analysis of Secondary Efficacy Outcome: PASI-75 Response Rate by Visit, Double-Blind Treatment Period, Full Analysis Set, Multiple Imputation
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14.2.2.3.3	Analysis of Secondary Efficacy Outcome: PASI-75 Response Rate by Visit, Double-Blind Treatment Period, Full Analysis Set, m-NRI
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14.2.2.3.5	Analysis of Secondary Efficacy Outcome: PASI-75 Response Rate by Analysis Site and Visit, Double-Blind Treatment Period, PP Population, m-NRI
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14.2.2.4.3	Analysis of Secondary Efficacy Outcome: IGA Success Rate by Visit, Double-Blind Treatment Period, Full Analysis Set, m-NRI
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14.2.2.4.5	Analysis of Secondary Efficacy Outcome: IGA Success Rate by Visit, Double-Blind Treatment Period, PP Population, m-NRI
14.2.2.5.1.1	Analysis of Secondary Efficacy Outcome: Change From Baseline in Percent of Affected Body Surface Area (BSA) by Visit, Double-Blind Treatment Period, Full Analysis Set, Multiple Imputation
14.2.2.5.1.2	Analysis of Secondary Efficacy Outcome: Percent Change from Baseline in Percent of Affected Body Surface Area (BSA) by Visit, Double-Blind Treatment Period, Full Analysis Set, Multiple Imputation
14.2.2.5.2.1	Analysis of Secondary Efficacy Outcome: Change From Baseline in Percent of Affected Body Surface Area (BSA) by Visit, Double-Blind Treatment Period, Full Analysis Set, LOCF
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14.2.2.5.3.1	Analysis of Secondary Efficacy Outcome: Change From Baseline in Percent of Affected Body Surface Area (BSA) by Visit, Double-Blind Treatment Period, Full Analysis Set, OC
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14.2.2.5.4.2	Analysis of Secondary Efficacy Outcome: Percent Change from Baseline in Percent of Affected Body Surface Area (BSA) by Visit, Double-Blind Treatment Period, PP Population, OC

14.2.2.6.1	Analysis of Secondary Efficacy Outcome: Change from Baseline in Nail Psoriasis Severity Index (NAPSI) of the target fingernail visit, Double-Blind Treatment Period, Full Analysis Set, Multiple Imputation
14.2.2.6.2	Analysis of Secondary Efficacy Outcome: Change from Baseline in Nail Psoriasis Severity Index (NAPSI) of the target fingernail visit, Double-Blind Treatment Period, Full Analysis Set, LOCF
14.2.2.6.3	Analysis of Secondary Efficacy Outcome: Change from Baseline in Nail Psoriasis Severity Index (NAPSI) of the target fingernail visit, Double-Blind Treatment Period, Full Analysis Set, OC
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14.2.2.7.3	Analysis of Secondary Efficacy Outcome: Change from Baseline in Psoriasis Scalp Severity Index (PSSI) by visit, Double-Blind Treatment Period, Full Analysis Set, OC
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14.2.2.8.2	Analysis of Secondary Efficacy Outcome: Change from Baseline in Palmoplantar Psoriasis Physician's Global Assessment (PP PGA) by Visit, Double-Blind Treatment Period, Full Analysis Set, LOCF
14.2.2.8.3	Analysis of Secondary Efficacy Outcome: Change from Baseline in Palmoplantar Psoriasis Physician's Global Assessment (PP PGA) by Visit, Double-Blind Treatment Period, Full Analysis Set, OC
14.2.2.8.4	Analysis of Secondary Efficacy Outcome: Change from Baseline in Palmoplantar Psoriasis Physician's Global Assessment (PP PGA) by Visit, Double-Blind Treatment Period, PP Population, OC
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14.2.2.9.1.2	Analysis of Secondary Efficacy Outcome: Percent Change from Baseline in Pruritus Numeric Rating Scale (NRS) Score by Visit, Double-Blind Treatment Period, Full Analysis Set, Multiple Imputation
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14.2.2.10	Analysis of Secondary Efficacy Outcome, Time to Achieving PASI-75 Response, Full Analysis Set, OC
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14.3.2.1	Plot of Mean Change from Baseline by Visit, hsCRP vs PASI scores, Safety Population, PPC-06 400 mg QD
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14.3.2.3	Plot of Mean Change from Baseline by Visit, hsCRP vs PASI scores, Safety Population, PPC-06 600 mg BID
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16.2.4.1	Demographics and Baseline Characteristics, All Randomized Subjects
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16.2.6.3	Investigator's Assessment of the Body Surface Area (BSA) Involvement of Psoriasis, All Randomized Subjects
16.2.6.4.1	Nail Psoriasis Severity Index (NAPSI) at Baseline, All Randomized Subjects
16.2.6.4.2	Target Nail Psoriasis Severity Index (NAPSI) , All Randomized Subjects
16.2.6.5	Psoriasis Scalp Severity Index (PSSI), All Randomized Subjects
16.2.6.6	Palmoplantar Physician's Global Assessment of Disease Severity (PP PGA), All Randomized Subjects
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Table 14.1.1: Summary of Subject Disposition

	PPC-06 400 mg QD	PPC-06 400 mg BID	PPC-06 600 mg BID	Placebo	Overall
Number of Subjects Screened					XX
Number of Subjects Randomized	XX	XX	XX	XX	XX
Number of Subjects in Full Analysis (FAS) Population, n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Number of Subjects in Safety (SAF) Population, n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Number of Subjects in Per Protocol (PP) Population, n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Number of Subjects Excluded from PP Population	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Reason for Exclusion from PP					
Failure to meet key Inclusion/Exclusion criteria	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Randomization error	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Usage of any prohibited concomitant medications or procedures	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Failure to have Week 24 assessment within the allowable window for either of the co-primary endpoints	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Noncompliance with the trial treatment regimen	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

Note: Denominator for percentages is the number of subjects randomized.

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Table 14.1.1: Summary of Subject Disposition

	PPC-06 400 mg QD	PPC-06 400 mg BID	PPC-06 600 mg BID	Placebo	Overall
Number of Subjects Completing the Study, n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Number of Subjects Discontinued, Overall, n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Reason for discontinuation, n (%)					
Adverse event(s)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Protocol violation	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Voluntary withdrawal by subject	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Lost to follow-up	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Pregnancy	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Study terminated by sponsor	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Investigator decision	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Non-compliance with study drug	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Loss of ability to freely provide consent	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Unblinding of a subject for any reason	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Lack of efficacy	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Other [1]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Number of Days in the Study [2]					
N	XX	XX	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X	XX.X	XX.X
Minimum, Maximum	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX

Note: Denominator for percentages is the number of subjects randomized.
[1] This does not include those whose discontinuation reason is "Other" with a comment "lack of efficacy" on the eCRF.
[2] The number of days in the study (date of study completion / discontinuation minus date of Day 1 plus 1)

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Table 14.1.2.X: Summary of Subject Demographics and Baseline Characteristics
[Full Analysis Set] [Safety Population] [PP Population]

	PPC-06 400 mg QD (N=XX)	**PPC-06 400 mg BID (N=XX)**	**PPC-06 600 mg BID (N=XX)**	**Placebo (N=XX)**	**Overall (N=XX)**
Age (years)					
N	XX	XX	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X	XX.X	XX.X
Minimum, Maximum	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX
Gender, n(%)					
N	XX	XX	XX	XX	XX
Female	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Male	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Race, n(%)					
N	XX	XX	XX	XX	XX
White	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Black or African American	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Asian	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
American Indian or Alaska Native	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Native Hawaiian or Other Pacific Islander	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Other [1]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Ethnicity, n(%)					
N	XX	XX	XX	XX	XX
Hispanic or Latino	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Not Hispanic or Latino	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

[1] See listing 16.2.4.1 for other races.
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Table 14.1.2.X: Summary of Subject Demographics and Baseline Characteristics
[Full Analysis Set] [Safety Population] [PP Population]

	PPC-06 400 mg QD (N=XX)	**PPC-06 400 mg BID (N=XX)**	**PPC-06 600 mg BID (N=XX)**	**Placebo (N=XX)**	**Overall (N=XX)**
Height (cm)					
N	XX	XX	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X	XX.X	XX.X
Minimum, Maximum	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX
Weight (kg)					
N	XX	XX	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X	XX.X	XX.X
Minimum, Maximum	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX
Waist Circumference (cm)					
N	XX	XX	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X	XX.X	XX.X
Minimum, Maximum	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX
BMI (kg/m^2)					
N	XX	XX	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X	XX.X	XX.X
Minimum, Maximum	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX

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Table 14.1.2.X: Summary of Subject Demographics and Baseline Characteristics
[Full Analysis Set] [Safety Population] [PP Population]

	PPC-06 400 mg QD (N=XX)	PPC-06 400 mg BID (N=XX)	PPC-06 600 mg BID (N=XX)	Placebo (N=XX)	Overall (N=XX)
Baseline PASI score					
N	XX	XX	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X	XX.X	XX.X
Minimum, Maximum	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX
Baseline BSA (%)					
N	XX	XX	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X	XX.X	XX.X
Minimum, Maximum	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX
Baseline IGA					
N	XX	XX	XX	XX	XX
3 – Moderate	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
4 – Severe	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

Note: PASI = Psoriasis Area Severity Index. BSA = Body Surface Area. IGA = Investigator's Global Assessment.
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Table 14.1.3.1: Summary of Exposure and Compliance
Overall
Safety Population

	PPC-06 400 mg QD (N=XX)	PPC-06 400 mg BID (N=XX)	PPC-06 600 mg BID (N=XX)	Placebo (N=XX)
Total Number of Days Exposed [1]				
N	XX	XX	XX	XX
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median	XX.X	XX.X	XX.X	XX.X
Minimum, Maximum	XX, XX	XX, XX	XX, XX	XX, XX
Total Number of Tablets Taken [2]				
N	XX	XX	XX	XX
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median	XX.X	XX.X	XX.X	XX.X
Minimum, Maximum	XX, XX	XX, XX	XX, XX	XX, XX
Average Daily Dose of IP [3]				
N	XX	XX	XX	XX
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median	XX.X	XX.X	XX.X	XX.X
Minimum, Maximum	XX, XX	XX, XX	XX, XX	XX, XX
Percent Compliance (%) [4]				
N	XX	XX	XX	XX
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median	XX.X	XX.X	XX.X	XX.X
Minimum, Maximum	XX, XX	XX, XX	XX, XX	XX, XX
80-120% Compliant (Inclusive), n (%)				
N	XX	XX	XX	XX
Yes	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
No	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

[1] Date of last dose of study drug during the study minus date of first dose of study drug plus 1
[2] Summation of number of tablets taken during the titration and treatment period
[3] Number of tablets taken divided by the number of days exposed to study medication.
[4] Number of tablets taken / number of expected tablets *100. The expected total number of tablets is 945 for the whole study.

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Table 14.1.3.2: Summary of Exposure and Compliance
Titration Period (Week 1—5)
Safety Population

	PPC-06 400 mg QD (N=XX)	PPC-06 400 mg BID (N=XX)	PPC-06 600 mg BID (N=XX)	Placebo (N=XX)
Total Number of Tablets Taken [1]				
N	XX	XX	XX	XX
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median	XX.X	XX.X	XX.X	XX.X
Minimum, Maximum	XX, XX	XX, XX	XX, XX	XX, XX
Percent Compliance (%) [2]				
N	XX	XX	XX	XX
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median	XX.X	XX.X	XX.X	XX.X
Minimum, Maximum	XX, XX	XX, XX	XX, XX	XX, XX
80-120% Compliant (Inclusive), n (%)				
N	XX	XX	XX	XX
Yes	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
No	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

[1] Number of dispensed tablets from blister wallets minus number of returned tablets from blister wallets.
[3] Number of used tablets / number of expected tablets for the titration period *100. The expected total number of tablets is 147 for the titration period.

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Table 14.1.3.3: Summary of Exposure and Compliance
Treatment Period (Week 6 – 24)
Safety Population

	PPC-06 400 mg QD (N=XX)	PPC-06 400 mg BID (N=XX)	PPC-06 600 mg BID (N=XX)	Placebo (N=XX)
Total Number of Tablets Taken [1]				
N	XX	XX	XX	XX
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median	XX.X	XX.X	XX.X	XX.X
Minimum, Maximum	XX, XX	XX, XX	XX, XX	XX, XX
Percent Compliance (%) [2]				
N	XX	XX	XX	XX
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median	XX.X	XX.X	XX.X	XX.X
Minimum, Maximum	XX, XX	XX, XX	XX, XX	XX, XX
80-120% Compliant (Inclusive), n (%)				
N	XX	XX	XX	XX
Yes	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
No	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

[1] Number of dispensed tablets from bottles minus number of returned tablets from bottles.
[2] Number of used tablets / number of expected tablets for the treatment period *100. The expected total number of tablets is 798 for the treatment period

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Table 14.1.4.1: Summary of Prior Medications
by Anatomical Therapeutic Chemical Class (ATC) and Preferred Term
Safety Population

	PPC-06 400 mg QD (N=XX)	**PPC-06 400 mg BID (N=XX)**	**PPC-06 600 mg BID (N=XX)**	**Placebo (N=XX)**
Subjects with any Prior Medication, n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
<< Anatomical Therapeutic Chemical Class >>				
<< Medication Preferred Term >>	XXXXX	XXXXX	XXXXX	XXXXX
<< Medication Preferred Term >>	XXXXX	XXXXX	XXXXX	XXXXX
<< Medication Preferred Term >>	XXXXX	XXXXX	XXXXX	XXXXX
<< Anatomical Therapeutic Chemical Class >>				
<< Medication Preferred Term >>	XXXXX	XXXXX	XXXXX	XXXXX
<< Medication Preferred Term >>	XXXXX	XXXXX	XXXXX	XXXXX
<< Medication Preferred Term >>	XXXXX	XXXXX	XXXXX	XXXXX

Note: Any medication with stop date prior to first dose of study drug is a prior medication. Counts reflect number of subjects in each treatment group reporting one or more prior medication that map to the WHO Drug anatomical therapeutic chemical or preferred term. A subject may be counted once only in each row of the table.

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Table 14.1.4.2: Summary of Concomitant Medications
by Anatomical Therapeutic Chemical Class (ATC) and Preferred Term
Safety Population

	PPC-06 400 mg QD (N=XX)	**PPC-06 400 mg BID (N=XX)**	**PPC-06 600 mg BID (N=XX)**	**Placebo (N=XX)**
Subjects with any Concomitant Medication, n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
<< Anatomical Therapeutic Chemical Class >>				
<< Medication Preferred Term >>	XXXXX	XXXXX	XXXXX	XXXXX
<< Medication Preferred Term >>	XXXXX	XXXXX	XXXXX	XXXXX
<< Medication Preferred Term >>	XXXXX	XXXXX	XXXXX	XXXXX
<< Anatomical Therapeutic Chemical Class >>				
<< Medication Preferred Term >>	XXXXX	XXXXX	XXXXX	XXXXX
<< Medication Preferred Term >>	XXXXX	XXXXX	XXXXX	XXXXX
<< Medication Preferred Term >>	XXXXX	XXXXX	XXXXX	XXXXX

Note: Any medication ongoing or with stop date on or after first dose of study drug is a concomitant medication. Counts reflect number of subjects in each treatment group reporting one or more prior medication that map to the WHO Drug anatomical therapeutic chemical or preferred term. A subject may be counted once only in each row of the table.

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Table 14.2.1.1.1: Analysis of Co-Primary Efficacy Outcome
PASI-75 Response Rate at Week 24
Full Analysis Set, Multiple Imputation

	PPC-06 400 mg QD (N=XX)	**PPC-06 400 mg BID (N=XX)**	**PPC-06 600 mg BID (N=XX)**	**Placebo (N=XX)**
PASI-75 Response Rate (%) [1]	XX.X	XX.X	XX.X	XX.X
Logistic Regression [2]				
Log (Odds Ratio) (SE), PPC-06 vs. Placebo	X.XX (X.XX)	X.XX (X.XX)	X.XX (X.XX)	
Odds Ratio	X.XX	X.XX	X.XX	
Odds Ratio 95% CI	X.XX, X.XX	X.XX, X.XX	X.XX, X.XX	
p-value [3]	0.XXXX	0.XXXX	0.XXXX	
Pairwise Comparisons Between PPC-06 Treatments				
Log (Odds Ratio) (SE), PPC-06 vs. PPC-06 600 mg BID	X.XX (X.XX)	X.XX (X.XX)		
Odds Ratio	X.XX	X.XX		
Odds Ratio 95% CI	X.XX, X.XX	X.XX, X.XX		
p-value [3]	0.XXXX	0.XXXX		
Log (Odds Ratio) (SE), PPC-06 vs. PPC-06 400 mg BID	X.XX (X.XX)			
Odds Ratio	X.XX			
Odds Ratio 95% CI	X.XX, X.XX			
p-value [3]	0.XXXX			

Note: PASI=Psoriasis Area and Severity Index; SE=Standard Error; CI=Confidence Interval. PASI-75 Response is defined as achieving a reduction of 75% or greater from Baseline in PASI at the end of Week 24.

[1] Average PASI75 response rate over 50 imputed datasets.

[2] Logistic model includes treatment group, baseline BMI, and pooled analysis center as factors.

[3] p-value is for null hypothesis that the combined log (Odds Ratio) equals 0.

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Table 14.2.1.1.2: Analysis of Co-Primary Efficacy Outcome
PASI-75 Response Rate at Week 24
PP Population, m-NRI

	PPC-06 400 mg QD (N=XX)	**PPC-06 400 mg BID (N=XX)**	**PPC-06 600 mg BID (N=XX)**	**Placebo (N=XX)**
PASI-75 Response Rate, n / N (%) [1]	XX / XX (XX.X)	XX / XX (XX.X)	XX / XX (XX.X)	XX / XX (XX.X)
Logistic Regression [2]				
Odds Ratio, PPC-06 vs. Placebo	X.XX	X.XX	X.XX	
Odds Ratio 95% CI	X.XX, X.XX	X.XX, X.XX	X.XX, X.XX	
p-value	0.XXXX	0.XXXX	0.XXXX	
Pairewise Comparisons Between PPC-06 Treatments				
Odds Ratio, PPC-06 vs. PPC-06 600 mg BID	X.XX	X.XX		
Odds Ratio 95% CI	X.XX, X.XX	X.XX, X.XX		
p-value	0.XXXX	0.XXXX		
Odds Ratio, PPC-06 vs. PPC-06 400 mg BID	X.XX			
Odds Ratio 95% CI	X.XX, X.XX			
p-value	0.XXXX			

Note: PASI=Psoriasis Area and Severity Index; m-NRI=modified non-responder imputation; CI=Confidence Interval. PASI-75 response is defined as achieving a reduction of 75% or greater from Baseline in PASI at the end of Week 24.
m-NRI: subjects who used rescue medications or discontinued due to unsatisfactory therapeutic effect are considered as treatment failures for all time points after the initiation of rescue medications or subject discontinuation.
[1] n = Number of responders at Week 24. N = Number of subjects with a Week 24 assessment.
[1] Logistic model includes treatment group, baseline BMI, and pooled analysis center as factors.

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< Repeat Table 14.2.1.1.2 for>

Table 14.2.1.1.3: Analysis of Co-Primary Efficacy Outcome, Sensitivity Analysis
PASI-75 Response Rate at Week 24
Full Analysis Set, m-NRI

Table 14.2.1.1.4: Analysis of Co-Primary Efficacy Outcome, Sensitivity Analysis
PASI-75 Response Rate at Week 24
Full Analysis Set, LOCF

Programming note: modify the Note accordingly for the definition of LOCF

Table 14.2.1.1.5: Analysis of Co-Primary Efficacy Outcome, Sensitivity Analysis
PASI-75 Response Rate at Week 24
Full Analysis Set, OC

Programming note: modify the Note accordingly for the definition of OC

Table 14.2.1.2.1: Analysis of Co-Primary Efficacy Outcome
IGA Treatment Success Rate at Week 24
Full Analysis Set, Multiple Imputation

	PPC-06 400 mg QD (N=XX)	**PPC-06 400 mg BID (N=XX)**	**PPC-06 600 mg BID (N=XX)**	**Placebo (N=XX)**
IGA Treatment Success Rate (%) [1]	XX.X	XX.X	XX.X	XX.X
Logistic Regression [2]				
Log (Odds Ratio) (SE), PPC-06 vs. Placebo	X.XX (X.XX)	X.XX (X.XX)	X.XX (X.XX)	
Odds Ratio	X.XX	X.XX	X.XX	
Odds Ratio 95% CI	X.XX, X.XX	X.XX, X.XX	X.XX, X.XX	
p-value [3]	0.XXXX	0.XXXX	0.XXXX	
Pairewise Comparisons Between PPC-06 Treatments				
Log (Odds Ratio) (SE), PPC-06 vs. PPC-06 600 mg BID	X.XX (X.XX)	X.XX (X.XX)		
Odds Ratio	X.XX	X.XX		
Odds Ratio 95% CI	X.XX, X.XX	X.XX, X.XX		
p-value [3]	0.XXXX	0.XXXX		
Log (Odds Ratio) (SE), PPC-06 vs. PPC-06 400 mg BID	X.XX (X.XX)			
Odds Ratio	X.XX			
Odds Ratio 95% CI	X.XX, X.XX			
p-value [3]	0.XXXX			

Note: IGA= Investigator's Global Assessment; SE=Standard Error; CI=Confidence Interval. IGA Treatment Success is defined as achieving an IGA score of clear or almost clear (IGA score 0 or 1) at the end of Week 24.

[1] Average IGA treatment success rate over 50 imputed datasets.

[2] Logistic model includes treatment group, baseline BMI, and pooled analysis center as factors.

[3] p-value is for null hypothesis that the combined log (Odds Ratio) equals 0.

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Table 14.2.1.2.2: Analysis of Co-Primary Efficacy Outcome
IGA Treatment Success Rate at Week 24
PP Population, m-NRI

	PPC-06 400 mg QD (N=XX)	**PPC-06 400 mg BID (N=XX)**	**PPC-06 600 mg BID (N=XX)**	**Placebo (N=XX)**
IGA Treatment Success Rate, n / N (%) [1]	XX / XX (XX.X)	XX / XX (XX.X)	XX / XX (XX.X)	XX / XX (XX.X)
Logistic Regression [2]				
Odds Ratio, PPC-06 vs. Placebo	X.XX	X.XX	X.XX	
Odds Ratio 95% CI	X.XX, X.XX	X.XX, X.XX	X.XX, X.XX	
p-value	0.XXXX	0.XXXX	0.XXXX	
Pairewise Comparisons Between PPC-06 Treatments				
Odds Ratio, PPC-06 vs. PPC-06 600 mg BID	X.XX	X.XX		
Odds Ratio 95% CI	X.XX, X.XX	X.XX, X.XX		
p-value	0.XXXX	0.XXXX		
Odds Ratio, PPC-06 vs. PPC-06 400 mg BID	X.XX			
Odds Ratio 95% CI	X.XX, X.XX			
p-value	0.XXXX			

Note: IGA= Investigator's Global Assessment; m-NRI=modified non-responder imputation; CI=Confidence Interval. IGA Treatment Success is defined as achieving an IGA score of clear or almost clear (IGA score 0 or 1) at the end of Week 24.
[1] n = Number of responders at Week 24. N = Number of subjects with a Week 24 assessment.
[2] Logistic model includes treatment group, baseline BMI, and pooled analysis center as factors.

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< Repeat Table 14.2.1.2.2 for>

Table 14.2.1.2.3: Analysis of Co-Primary Efficacy Outcome, Sensitivity Analysis
IGA Treatment Success Rate at Week 24
Full Analysis Set, m-NRI

Table 14.2.1.2.4: Analysis of Co-Primary Efficacy Outcome, Sensitivity Analysis
IGA Treatment Success Rate at Week 24
Full Analysis Set, LOCF

Programming note: modify the Note accordingly for the definition of LOCF

Table 14.2.1.2.5: Analysis of Co-Primary Efficacy Outcome, Sensitivity Analysis
IGA Treatment Success Rate at Week 24
Full Analysis Set, OC

Programming note: modify the Note accordingly for the definition of OC

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Table 14.2.1.3.1: Analysis of Co-Primary Efficacy Outcome, Subgroup Analysis
PASI-75 Response Rate at Week 24 by Baseline hsCRP
Full Analysis Set, Multiple Imputation
[Baseline hsCRP < 5mg/L][Baseline hsCRP >= 5mg/L]

	PPC-06 400 mg QD (N=XX)	**PPC-06 400 mg BID (N=XX)**	**PPC-06 600 mg BID (N=XX)**	**Placebo (N=XX)**
PASI-75 Response Rate				
N	XX	XX	XX	XX
Response Rate [1]	XX.X	XX.X	XX.X	XX.X
Logistic Regression [2]				
Log (Odds Ratio) (SE), PPC-06 vs. Placebo	X.XX (X.XX)	X.XX (X.XX)	X.XX (X.XX)	
Odds Ratio	X.XX	X.XX	X.XX	
Odds Ratio 95% CI	X.XX, X.XX	X.XX, X.XX	X.XX, X.XX	
p-value [3]	X.XXXX	X.XXXX	X.XXXX	

Note: PASI=Psoriasis Area and Severity Index; SE=Standard Error; CI=Confidence Interval. PASI-75 Response is defined as achieving a reduction of 75% or greater from Baseline in the Psoriasis Area and Severity Index (PASI-75) at the end of Week 24.
[1] Average PASI-75 response rate over 50 imputed datasets.
[2] Logistic model includes treatment group, baseline BMI, and pooled analysis center as factors.
[3] p-value is for null hypothesis that the combined log (Odds Ratio) equals 0.

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<Repeat for>

Table 14.2.1.3.2: Analysis of Co-Primary Efficacy Outcome, Subgroup Analysis
PASI-75 Response Rate at Week 24 by Baseline BMI
Full Analysis Set, Multiple Imputation
[Baseline BMI < 30kg/m2] [Baseline BMI >= 30kg/m2]

Table 14.2.1.3.3: Analysis of Co-Primary Efficacy Outcome, Subgroup Analysis
PASI-75 Response Rate at Week 24 by Occurrence of Diarrhea
Full Analysis Set, Multiple Imputation
[Subjects Reporting any Diarrhea by Week 24] [Subjects Not Reporting any Diarrhea by Week 24]

Table 14.2.1.4.1: Analysis of Co-Primary Efficacy Outcome, Subgroup Analysis
IGA Treatment Success Rate at Week 24 by Baseline hsCRP (mg/L)
Full Analysis Set, Multiple Imputation
[Baseline hsCRP < 5mg/L] [Baseline hsCRP >= 5mg/L]

Programming note: modify the Note accordingly for the definition of IGA treatment success

Table 14.2.1.4.2: Analysis of Co-Primary Efficacy Outcome, Subgroup Analysis
IGA Treatment Success Rate at Week 24 by Baseline BMI
Full Analysis Set, Multiple Imputation
[Baseline BMI < 30kg/m2] [Baseline BMI >= 30kg/m2]

Programming note: modify the Note accordingly for the definition of IGA treatment success

Table 14.2.1.4.3: Analysis of Co-Primary Efficacy Outcome, Subgroup Analysis
IGA Treatment Success at Week 24 by Occurrence of Diarrhea
Full Analysis Set, Multiple Imputation
[Subjects Reporting any Diarrhea by Week 24] [Subjects Not Reporting any Diarrhea by Week 24]

Programming note: modify the Note accordingly for the definition of IGA treatment success

Dr Reddy's Laboratories, SA
Protocol Number: PPC-06-CD-004

Table 14.2.1.5.1: Analysis of Co-Primary Efficacy Outcome
PASI-75 Response Rate at Week 24 by Visit and Analysis Sites
Full Analysis Set, Multiple Imputation

	PPC-06 400 mg QD (N=XX)	PPC-06 400 mg BID (N=XX)	PPC-06 600 mg BID (N=XX)	Placebo (N=XX)
Pooled Analysis Site (Clinical Sites)				
A01 (112 113 114)				
N	XX	XX	XX	XX
Response Rate [1]	XX.X	XX.X	XX.X	XX.X
A02 (101 102 105)				
N	XX	XX	XX	XX
Response Rate [1]	XX.X	XX.X	XX.X	XX.X
XXX				
N	XX	XX	XX	XX
Response Rate [1]	XX.X	XX.X	XX.X	XX.X

<include all pooled *Analysis Site*>

Note: PASI=Psoriasis Area and Severity Index. PASI-75 Response is defined as achieving a reduction of 75% or greater from Baseline.
[1] Average PASI-75 response rate over 50 imputed datasets.

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<Repeat for>

Table 14.2.1.5.2: Analysis of Co-Primary Efficacy Outcome
IGA Treatment Success Rate at Week 24 by Visit and Analysis Sites
Full Analysis Set, Multiple Imputation

Programming note: modify the Note accordingly for the definition of IGA treatment success

Table 14.2.2.1.1.1: Analysis of Secondary Efficacy Outcome
Change from Baseline in Total PASI Score by Visit
Double-Blind Treatment Period
Full Analysis Set, Multiple Imputation

	PPC-06 400 mg QD (N=XX)	**PPC-06 400 mg BID (N=XX)**	**PPC-06 600 mg BID (N=XX)**	**Placebo (N=XX)**
Week 8				
Change from baseline [1]				
N	XX	XX	XX	XX
Mean	XX.X	XX.X	XX.X	XX.X
Analysis of Covariance (ANCOVA) [2]				
LSM (SE)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
LSM, 95% CI	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X
LSM Difference (SE), PPC-06 vs. Placebo	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	
95% CI	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	
p-value	X.XXXX	X.XXXX	X.XXXX	

<*Repeat for other visits:* Week 12, Week 16, Week 20, and Week 24>

Note: PASI=Psoriasis Area and Severity Index, SE=Standard Error.
[1] Average based on 50 imputed datasets.
[2] ANCOVA model includes treatment as factor, baseline BMI and pooled analysis centers as covariates.
Generated on XX/XX/XX:XXXX by XXXXX / Uses: XXXX / Reference: Listings XXXX

<Repeat for>

Table 14.2.2.1.1.2: Analysis of Secondary Efficacy Outcome
Percent Change from Baseline in Total PASI Score by Visit
Double-Blind Treatment Period
Full Analysis Set, Multiple Imputation

Dr Reddy's Laboratories, SA
Protocol Number: PPC-06-CD-004

Table 14.2.2.1.2.1: Analysis of Secondary Efficacy Outcome
Change from Baseline in Total PASI Score by Visit
Double-Blind Treatment Period
Full Analysis Set, LOCF

	PPC-06 400 mg QD (N=XX)	**PPC-06 400 mg BID (N=XX)**	**PPC-06 600 mg BID (N=XX)**	**Placebo (N=XX)**
Baseline				
N	XX	XX	XX	XX
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median	XX	XX	XX	XX
Minimum, Maximum	XX, XX	XX, XX	XX, XX	XX, XX
Week 8				
N	XX	XX	XX	XX
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median	XX	XX	XX	XX
Minimum, Maximum	XX, XX	XX, XX	XX, XX	XX, XX
Change from baseline				
N	XX	XX	XX	XX
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median	XX	XX	XX	XX
Minimum, Maximum	XX, XX	XX, XX	XX, XX	XX, XX
Analysis of Covariance (ANCOVA) [1]				
LSM (SE)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
LSM, 95% CI	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X
LSM Difference (SE), PPC-06 vs. Placebo	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	
95% CI	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	
p-value	X.XXXX	X.XXXX	X.XXXX	

<*Repeat for other visits* Week 12, Week 16, Week 20, and Week 24>

Note: PASI=Psoriasis Area and Severity Index; LOCF=Last Observation Carried Forward; SD=Standard Deviation; SE=Standard Error.
[1] ANCOVA model includes treatment as factor, baseline BMI and pooled analysis centers as covariates.
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<Repeat table for >

Table 14.2.2.1.2.2: Analysis of Secondary Efficacy Outcome
Percent Change from Baseline in Total PASI Score by Visit
Double-Blind Treatment Period
Full Analysis Set, LOCF

Table 14.2.2.1.3.1: Analysis of Secondary Efficacy Outcome
Change from Baseline in total PASI Score by Visit
Double-Blind Treatment Period
Full Analysis Set, OC

Programming note: modify the Note accordingly for the definition of OC

Table 14.2.2.1.3.2: Analysis of Secondary Efficacy Outcome
Percent Change from Baseline in total PASI Score by Visit
Double-Blind Treatment Period
Full Analysis Set, OC

Programming note: modify the Note accordingly for the definition of OC

Table 14.2.2.1.4.1: Analysis of Secondary Efficacy Outcome
Change from Baseline in Total PASI Score by Visit
Double-Blind Treatment Period
PP Population, OC

Programming note: modify the Note accordingly for the definition of OC

Table 14.2.2.1.4.2: Analysis of Secondary Efficacy Outcome
Percent Change from Baseline in Total PASI Score by Visit
Double-Blind Treatment Period
PP Population, OC

Programming note: modify the Note accordingly for the definition of OC

Dr Reddy's Laboratories, SA
Protocol Number: PPC-06-CD-004

Table 14.2.2.2.1: Analysis of Secondary Efficacy Outcome
PASI-50 Response Rate by Visit
Double-Blind Treatment Period
Full Analysis Set, Multiple Imputation

	PPC-06 400 mg QD (N=XX)	**PPC-06 400 mg BID (N=XX)**	**PPC-06 600 mg BID (N=XX)**	**Placebo (N=XX)**
Week 8				
N	XX	XX	XX	XX
% [1]	XX.X	XX.X	XX.X	XX.X
Logistic Regression [2]				
Log (Odds Ratio) (SE), PPC-06 vs. Placebo	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	
Odds Ratio	XX.X	XX.X	XX.X	
Odds Ratio 95% CI	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	
p-value [3]	X.XXXX	X.XXXX	X.XXXX	

<*Repeat for other visits:* Week 12, Week 16, Week 20, and Week 24>

Note: PASI=Psoriasis Area and Severity Index; SE=Standard Error; CI=Confidence Interval. PASI-50 Treatment Success is defined as achieving a reduction of 50% or greater from Baseline.

[1] Average PASI-50 response rate over 50 imputed datasets.

[2] Logistic model includes treatment group, baseline BMI, and pooled analysis center as factors.

[3] p-value is for null hypothesis that the combined log (Odds Ratio) equals 0.

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Dr Reddy's Laboratories, SA
Protocol Number: PPC-06-CD-004

Table 14.2.2.2.2: Analysis of Secondary Efficacy Outcome
PASI-50 Response Rate by Visit
Double-Blind Treatment Period
Full Analysis Set, LOCF

	PPC-06 400 mg QD (N=XX)	**PPC-06 400 mg BID (N=XX)**	**PPC-06 600 mg BID (N=XX)**	**Placebo (N=XX)**
Baseline				
n / N (%)	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)
Week 8				
n / N (%)	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)
Logistic Regression [1]				
Odds Ratio, PPC-06 vs. Placebo	XX.X	XX.X	XX.X	
Odds Ratio 95% CI	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	
p-value	X.XXXX	X.XXXX	X.XXXX	

<*Repeat for other visits:* Week 12, Week 16, Week 20, and Week 24>

Note: PASI=Psoriasis Area and Severity Index; LOCF=Last Observation Carried Forward; CI=Confidence Interval. PASI-50 Treatment Success is defined as achieving a reduction of 50% or greater from Baseline. n = Number of responders at each visit. N = Number of subjects available for analysis at each visit.
[1] Logistic model includes treatment group, baseline BMI, and pooled analysis center as factors.

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<Repeat for tables:>

Table 14.2.2.2.3: Analysis of Secondary Efficacy Outcome
PASI-50 Response Rate by Visit in the Double-Blind Treatment Period
Full Analysis Set, m-NRI

Programming note: modify the Note accordingly for the definition of m-NRI

Table 14.2.2.2.4: Analysis of Secondary Efficacy Outcome
PASI-50 Response Rate by Visit in the Double-Blind Treatment Period
Full Analysis Set, OC

Programming note: modify the Note accordingly for the definition of OC

Table 14.2.2.2.5: Analysis of Secondary Efficacy Outcome
PASI-50 Response Rate by Visit in the Double-Blind Treatment Period
PP Population, m-NRI

Programming note: modify the Note accordingly for the definition of m-NRI

Dr Reddy's Laboratories, SA
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Table 14.2.2.3.1: Analysis of Secondary Efficacy Outcome
PASI-75 Response Rate by Visit
Double-Blind Treatment Period
Full Analysis Set, Multiple Imputation

	PPC-06 400 mg QD (N=XX)	**PPC-06 400 mg BID (N=XX)**	**PPC-06 600 mg BID (N=XX)**	**Placebo (N=XX)**
Week 8				
N	XX	XX	XX	XX
% [1]	XX.X	XX.X	XX.X	XX.X
Logistic Regression [2]				
Log (Odds Ratio) (SE), PPC-06 vs. Placebo	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	
Odds Ratio	XX.X	XX.X	XX.X	
Odds Ratio 95% CI	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	
p-value [3]	X.XXXX	X.XXXX	X.XXXX	

<*Repeat for other visits*: Week 12, Week 16, Week 20>

Note: PASI=Psoriasis Area and Severity Index; SE=Standard Error; CI=Confidence Interval. PASI-75 Response is defined as achieving a reduction of 75% or greater from Baseline.
[1] Average PASI-75 response rate over 50 imputed datasets.
[2] Logistic model includes treatment group, baseline BMI, and pooled analysis center as factors.
[3] p-value is for null hypothesis that the combined log (Odds Ratio) equals 0.

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[programming note: no need to present Week 24 in this table]

Dr Reddy's Laboratories, SA
Protocol Number: PPC-06-CD-004

Table 14.2.2.3.2: Analysis of Secondary Efficacy Outcome
PASI-75 Response Rate by Visit
Double-Blind Treatment Period
Full Analysis Set, LOCF

	PPC-06 400 mg QD (N=XX)	**PPC-06 400 mg BID (N=XX)**	**PPC-06 600 mg BID (N=XX)**	**Placebo (N=XX)**
Baseline				
n / N (%)	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)
Week 8				
n / N (%)	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)	XX/XX (XX.X)
Logistic Regression [1]				
Odds Ratio, PPC-06 vs. Placebo	XX.X	XX.X	XX.X	
Odds Ratio 95% CI	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	
p-value	X.XXXX	X.XXXX	X.XXXX	

<*Repeat for other visits*: Week 12, Week 16, Week 20>

Note: PASI=Psoriasis Area and Severity Index; CI=Confidence Interval; LOCF=Last Observation Carried Forward. PASI-75 Response is defined as achieving a reduction of 75% or greater from Baseline. n = Number of responders at each visit. N = Number of subjects available for analysis at each visit.
[1] Logistic model includes treatment group, baseline BMI, and pooled analysis center as factors.

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[programming note: no need to present Week 24 in the table]

Repeat for tables:

Table 14.2.2.3.3: Analysis of Secondary Efficacy Outcome
PASI-75 Response Rate by Visit
Double-Blind Treatment Period
Full Analysis Set, m-NRI

Programming note: modify the Note accordingly for the definition of m-NRI

Table 14.2.2.3.4: Analysis of Secondary Efficacy Outcome
PASI-75 Response Rate by Visit
Double-Blind Treatment Period
Full Analysis Set, OC

Programming note: modify the Note accordingly for the definition of OC

Table 14.2.2.3.5: Analysis of Secondary Efficacy Outcome
PASI-75 Response Rate by Visit
Double-Blind Treatment Period
PP Population, m-NRI

Programming note: modify the Note accordingly for the definition of m-NRI

Dr Reddy's Laboratories, SA
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Table 14.2.2.4.1: Analysis of Secondary Efficacy Outcome
IGA Success Rate by Visit
Double-Blind Treatment Period
Full Analysis Set, Multiple Imputation

	PPC-06 400 mg QD (N=XX)	**PPC-06 400 mg BID (N=XX)**	**PPC-06 600 mg BID (N=XX)**	**Placebo (N=XX)**
Week 8				
N	XX	XX	XX	XX
% [1]	XX.X	XX.X	XX.X	XX.X
Logistic Regression [2]				
Log (Odds Ratio) (SE), PPC-06 vs. Placebo	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	
Odds Ratio	XX.X	XX.X	XX.X	
Odds Ratio 95% CI	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	
p-value [3]	X.XXXX	X.XXXX	X.XXXX	

<*Repeat for other visits:* Week 12, Week 16, Week 20>

Note: IGA= Investigator's Global Assessment; SE=Standard Error; CI=Confidence Interval. IGA Success Rate is defined as achieving an IGA score of clear or almost clear (IGA score 0 or 1).
[1] Average IGA Success Rate over 50 imputed datasets.
[2] Logistic model includes treatment group, baseline BMI, and pooled analysis center as factors.
[3] p-value is for null hypothesis that the combined log (Odds Ratio) equals 0.

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[programming note: no need to present Week 24 in the table]

Dr Reddy's Laboratories, SA
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Table 14.2.2.4.2: Analysis of Secondary Efficacy Outcome
IGA Success Rate by Visit
Double-Blind Treatment Period
Full Analysis Set, LOCF

	PPC-06 400 mg QD (N=XX)	**PPC-06 400 mg BID (N=XX)**	**PPC-06 600 mg BID (N=XX)**	**Placebo (N=XX)**
Baseline				
N	XX	XX	XX	XX
4 – Severe	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
3 - Moderate	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Week 8				
N	XX	XX	XX	XX
4 – Severe	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
3 – Moderate	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
2 – Mild	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
1 – Almost clear	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
0 – Clear	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
IGA Success Rate, n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Logistic Regression [1]				
Odds Ratio, PPC-06 vs. Placebo	XX.X	XX.X	XX.X	
Odds Ratio 95% CI	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	
p-value	X.XXXX	X.XXXX	X.XXXX	

<Repeat for other visits>

Note: IGA= Investigator's Global Assessment; CI=Confidence Interval. IGA Success Rate is defined as achieving an IGA score of clear or almost clear (IGA score 0 or 1).
[1] Logistic model includes treatment group, baseline BMI, and pooled analysis center as factors.

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[programming note: no need to present Week 24 in the table]

Repeat for tables:

Table 14.2.2.4.3: Analysis of Secondary Efficacy Outcome
IGA Success Rate by Visit
Double-Blind Treatment Period
Full Analysis Set, m-NRI

Programming note: modify the Note accordingly for the definition of m-NRI

Table 14.2.2.4.4: Analysis of Secondary Efficacy Outcome
IGA Success Rate by Visit
Double-Blind Treatment Period
Full Analysis Set, OC

Programming note: modify the Note accordingly for the definition of OC

Table 14.2.2.4.5: Analysis of Secondary Efficacy Outcome
IGA Success Rate by Visit
Double-Blind Treatment Period
PP Population, m-NRI

Programming note: modify the Note accordingly for the definition of m-NRI

Table 14.2.2.5.1.1: Analysis of Secondary Efficacy Outcome
Change from Baseline in Affected Body Surface Area (BSA) by Visit
Double-Blind Treatment Period
Full Analysis Set, Multiple Imputation

	PPC-06 400 mg QD (N=XX)	**PPC-06 400 mg BID (N=XX)**	**PPC-06 600 mg BID (N=XX)**	**Placebo (N=XX)**
Week 8				
Change from baseline [1]				
N	XX	XX	XX	XX
Mean	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Analysis of Covariance (ANCOVA) [2]				
LSM (SE)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
LSM, 95% CI	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X
LSM Difference (SE), PPC-06 vs. Placebo	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	
95% CI	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	
p-value	X.XXXX	X.XXXX	X.XXXX	
<*Repeat for* Week 12, Week 16, Week 20, Week 24>				

[1] Average based on 50 imputed datasets.
[2] ANCOVA model includes treatment as factor, baseline BMI and pooled analysis centers as covariates.

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Repeat for

Table 14.2.2.5.1.2: Analysis of Secondary Efficacy Outcome
Percent Change from Baseline in Affected Body Surface Area (BSA) by Visit
Double-Blind Treatment Period
Full Analysis Set, Multiple Imputation
Programming note: same structure as the change from baseline table, replace change from baseline with percent change from baseline

Table 14.2.2.5.2.1: Analysis of Secondary Efficacy Outcome
Change from Baseline in Affected Body Surface Area (BSA) by Visit
Double-Blind Treatment Period
Full Analysis Set, LOCF

	PPC-06 400 mg QD (N=XX)	**PPC-06 400 mg BID (N=XX)**	**PPC-06 600 mg BID (N=XX)**	**Placebo (N=XX)**
Baseline				
N	XX	XX	XX	XX
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median	XX	XX	XX	XX
Minimum, Maximum	XX, XX	XX, XX	XX, XX	XX, XX
Week 8				
N	XX	XX	XX	XX
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median	XX	XX	XX	XX
Minimum, Maximum	XX, XX	XX, XX	XX, XX	XX, XX
Change from baseline				
N	XX	XX	XX	XX
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median	XX	XX	XX	XX
Minimum, Maximum	XX, XX	XX, XX	XX, XX	XX, XX
Analysis of Covariance (ANCOVA) [1]				
LSM (SE)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
LSM, 95% CI	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X
LSM Difference (SE), PPC-06 vs. Placebo	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	
95% CI	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	
p-value	X.XXXX	X.XXXX	X.XXXX	

<*Repeat for other visits:* Week 12, Week 16, Week 20, Week 24>

Note: LOCF = Last Observation Carried Forward.
[1] ANCOVA model includes treatment as factor, baseline BMI and pooled analysis centers as covariates.

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Repeat for tables:

Table 14.2.2.5.2.2: Analysis of Secondary Efficacy Outcome
Percent Change from Baseline in Affected Body Surface Area (BSA) by Visit
Double-Blind Treatment Period
Full Analysis Set, LOCF
Programming note: same structure as the change from baseline table, replace change from baseline with percent change from baseline. Update footnote for the defection of OC

Table 14.2.2.5.3.1: Analysis of Secondary Efficacy Outcome
Change from Baseline in Affected Body Surface Area (BSA) by Visit
Double-Blind Treatment Period
Full Analysis Set, OC
Programming note: Update footnote for the defection of OC

Table 14.2.2.5.3.2: Analysis of Secondary Efficacy Outcome
Percent Change from Baseline in Affected Body Surface Area (BSA) by Visit
Double-Blind Treatment Period
Full Analysis Set, OC

Programming note: same structure as the change from baseline table, replace change from baseline with percent change from baseline. Update footnote for the defection of OC

Table 14.2.2.5.4.1: Analysis of Secondary Efficacy Outcome
Change from Baseline in Affected Body Surface Area (BSA) by Visit
Double-Blind Treatment Period
PP Population, OC

Programming note: Update footnote for the defection of OC

Table 14.2.2.5.4.2: Analysis of Secondary Efficacy Outcome
Percent Change from Baseline in Affected Body Surface Area (BSA) by Visit
Double-Blind Treatment Period
PP Population, OC

Programming note: same structure as the change from baseline table, replace change from baseline with percent change from baseline. Update footnote for the defection of OC

Table 14.2.2.6.1: Analysis of Secondary Efficacy Outcome
Change from Baseline in Nail Psoriasis Severity Index (NAPSI) of Target Fingernail by Visit
Double-Blind Treatment Period
Full Analysis Set, Multiple Imputation

	PPC-06 400 mg QD (N=XX)	**PPC-06 400 mg BID (N=XX)**	**PPC-06 600 mg BID (N=XX)**	**Placebo (N=XX)**
Week 12				
Change from baseline [1]				
N	XX	XX	XX	XX
Mean	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Analysis of Covariance (ANCOVA) [2]				
LSM (SE)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
LSM, 95% CI	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X
LSM Difference (SE), PPC-06 vs. Placebo	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	
95% CI	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	
p-value	X.XXXX	X.XXXX	X.XXXX	
<*Repeat for* Week 16 and Week 24>				

Note: This analysis excludes subjects with baseline NAPSI score of 0.
[1] Average based on 50 imputed datasets.
[2] ANCOVA model includes treatment as factor, baseline BMI and pooled analysis centers as covariates.

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Table 14.2.2.6.2: Analysis of Secondary Efficacy Outcome
Change from Baseline in Nail Psoriasis Severity Index (NAPSI) of Target Fingernail by Visit
Double-Blind Treatment Period
Full Analysis Set, LOCF

	PPC-06 400 mg QD (N=XX)	**PPC-06 400 mg BID (N=XX)**	**PPC-06 600 mg BID (N=XX)**	**Placebo (N=XX)**
Baseline				
N	XX	XX	XX	XX
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median	XX	XX	XX	XX
Minimum, Maximum	XX, XX	XX, XX	XX, XX	XX, XX
Week 12				
N	XX	XX	XX	XX
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median	XX	XX	XX	XX
Minimum, Maximum	XX, XX	XX, XX	XX, XX	XX, XX
Change from baseline				
N	XX	XX	XX	XX
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median	XX	XX	XX	XX
Minimum, Maximum	XX, XX	XX, XX	XX, XX	XX, XX
Analysis of Covariance (ANCOVA) [1]				
LSM (SE)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
LSM, 95% CI	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X
LSM Difference (SE), PPC-06 vs. Placebo	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	
95% CI	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	
p-value	X.XXXX	X.XXXX	X.XXXX	

<*Repeat for* Week 16 and Week 24>

Note: This analysis excludes subjects with baseline NAPSI score of 0. LOCF = Last Observation Carried Forward.
[1] ANCOVA model includes treatment as factor, baseline BMI and pooled analysis centers as covariates.
Generated on XX/XX/XX:XXXX by XXXXX / Uses: XXXX / Reference: Listings XXXX

Repeat for tables:

Table 14.2.2.6.3: Analysis of Secondary Efficacy Outcome
Change from Baseline in Nail Psoriasis Severity Index (NAPSI) of Target Fingernail by Visit
Double-Blind Treatment Period
Full Analysis Set, OC

Programming note: Update footnote for the defection of OC

Table 14.2.2.6.4: Analysis of Secondary Efficacy Outcome
Change from Baseline in Nail Psoriasis Severity Index (NAPSI) of Target Fingernail by Visit
Double-Blind Treatment Period
PP Population, OC

Programming note: Update footnote for the defection of OC

Table 14.2.2.7.1: Analysis of Secondary Efficacy Outcome
Change from Baseline in Psoriasis Scalp Severity Index (PSSI) Total Score by Visit
Double-Blind Treatment Period
Full Analysis Set, Multiple Imputation

	PPC-06 400 mg QD (N=XX)	**PPC-06 400 mg BID (N=XX)**	**PPC-06 600 mg BID (N=XX)**	**Placebo (N=XX)**
Week 8				
Change from baseline [1]				
N	XX	XX	XX	XX
Mean	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Analysis of Covariance (ANCOVA) [2]				
LSM (SE)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
LSM, 95% CI	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X
LSM Difference (SE), PPC-06 vs. Placebo	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	
95% CI	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	
p-value	X.XXXX	X.XXXX	X.XXXX	
<*Repeat for* Week12, Week16, Week20, Week24>				

Note: This analysis excludes subjects with baseline PSSI score of 0.
[1] Average based on 50 imputed datasets.
[2] ANCOVA model includes treatment as factor, baseline BMI and pooled analysis centers as covariates.

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Table 14.2.2.7.2: Analysis of Secondary Efficacy Outcome
Change from Baseline in Psoriasis Scalp Severity Index (PSSI) Total Score by Visit
Double-Blind Treatment Period
Full Analysis Set, LOCF

	PPC-06 400 mg QD (N=XX)	**PPC-06 400 mg BID (N=XX)**	**PPC-06 600 mg BID (N=XX)**	**Placebo (N=XX)**
Baseline				
N	XX	XX	XX	XX
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median	XX	XX	XX	XX
Minimum, Maximum	XX, XX	XX, XX	XX, XX	XX, XX
Week 8				
N	XX	XX	XX	XX
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median	XX	XX	XX	XX
Minimum, Maximum	XX, XX	XX, XX	XX, XX	XX, XX
Change from baseline				
N	XX	XX	XX	XX
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median	XX	XX	XX	XX
Minimum, Maximum	XX, XX	XX, XX	XX, XX	XX, XX
Analysis of Covariance (ANCOVA) [1]				
LSM (SE)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
LSM, 95% CI	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X
LSM Difference (SE), PPC-06 vs. Placebo	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	
95% CI	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	
p-value	X.XXXX	X.XXXX	X.XXXX	

<*Repeat for* Week12, Week16, Week20, Week24>

Note: This analysis excludes subjects with baseline PSSI score of 0. LOCF = Last Observation Carried Forward.
[1] ANCOVA model includes treatment as factor, baseline BMI and pooled analysis centers as covariates.
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Repeat for tables:

Table 14.2.2.7.3: Analysis of Secondary Efficacy Outcome
Change from Baseline in Psoriasis Scalp Severity Index (PSSI) Total Score by Visit
Double-Blind Treatment Period
Full Analysis Set, OC

Programming note: Update footnote for the defection of OC

Table 14.2.2.7.4: Analysis of Secondary Efficacy Outcome
Change from Baseline in Psoriasis Scalp Severity Index (PSSI) Total Score by Visit
Double-Blind Treatment Period
PP Population, OC

Programming note: Update footnote for the defection of OC

Table 14.2.2.8.1: Analysis of Secondary Efficacy Outcome
Change from Baseline in Palmoplantar Psoriasis Physician's Global Assessment (PP PGA) by Visit
Double-Blind Treatment Period
Full Analysis Set, Multiple Imputation

	PPC-06 400 mg QD (N=XX)	PPC-06 400 mg BID (N=XX)	PPC-06 600 mg BID (N=XX)
Wilcoxon Rank Sum Test p-value, PPC-06 vs. Placebo [1]			
Week 8	X.XXXX	X.XXXX	X.XXXX
Week 12	X.XXXX	X.XXXX	X.XXXX
Week 16	X.XXXX	X.XXXX	X.XXXX
Week 20	X.XXXX	X.XXXX	X.XXXX
Week 24	X.XXXX	X.XXXX	X.XXXX

Note: This analysis excludes subjects with baseline PP PGA score of 0.
[1] Average based on 50 imputed datasets.

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[*Programming note: Use the following syntax to perform Wilcoxon Rank Sum test for MI*

```
Proc NPAR1WAY data=indata Wilcoxon hl;
        By _imputation_;
        Var Chg;
        ODS OUTPUT WilcoxonTest=wilcox HodgesLehmann=hl;
Run;

Proc Mianalyze data=hl;
        Modeleffects shift;
        Stderr stderr;
        ODS OUTPUT ParameterEstimates=stats;
Run;
```

]

Table 14.2.2.8.2: Analysis of Secondary Efficacy Outcome
Change from Baseline in Palmoplantar Psoriasis Physician's Global Assessment (PP PGA) by Visit
Double-Blind Treatment Period
Full Analysis Set, LOCF

	PPC-06 400 mg QD (N=XX)	**PPC-06 400 mg BID (N=XX)**	**PPC-06 600 mg BID (N=XX)**	**Placebo (N=XX)**
Baseline, n (%)				
1 - Almost clear	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
2 - Mild	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
3 - Moderate	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
4 - Severe	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Week 8, n (%)				
0 - Clear	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
1 - Almost clear	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
2 - Mild	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
3 - Moderate	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
4 - Severe	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Change from baseline				
4 – Worsen by 4 grades	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
3 – Worsen by 3 grades	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
2 – Worsen by 2 grades	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
1 – Worsen by 1 grade	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
0 – No change	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
-1 – Improved by 1 grade	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
-2 – Improved by 2 grades	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
-3 – Improved by 3 grades	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
-4 – Improved by 4 grades	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Wilcoxon Rank Sum Test, PPC-06 vs. Placebo p-value	X.XXXX	X.XXXX	X.XXXX	

<*Repeat for* Week12, Week16, Week20, Week24>

Note: This analysis excludes subjects with baseline PP PGA score of 0. LOCF = Last Observation Carried Forward.

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XXXX / Reference: Listings XXXX

Repeat for tables:

Table 14.2.2.8.3: Analysis of Secondary Efficacy Outcome
Change from Baseline in Palmoplantar Psoriasis Physician's Global Assessment (PP PGA) by Visit
Double-Blind Treatment Period
Full Analysis Set OC

Programming note: Update footnote for the defection of OC

Table 14.2.2.8.4: Analysis of Secondary Efficacy Outcome
Change from Baseline in Palmoplantar Psoriasis Physician's Global Assessment (PP PGA) by Visit
Double-Blind Treatment Period
PP Population, OC

Programming note: Update footnote for the defection of OC

Table 14.2.2.9.1.1: Analysis of Secondary Efficacy Outcome
Change from Baseline in Pruritus Numeric Rating Scale (NRS) Score by Visit
Double-Blind Treatment Period
Full Analysis Set, Multiple Imputation

	PPC-06 400 mg QD (N=XX)	**PPC-06 400 mg BID (N=XX)**	**PPC-06 600 mg BID (N=XX)**	**Placebo (N=XX)**
Week 8				
Change from baseline [1]				
N	XX	XX	XX	XX
Mean	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Analysis of Covariance (ANCOVA) [2]				
LSM (SE)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
LSM, 95% CI	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X
LSM Difference (SE), PPC-06 vs. Placebo	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	
95% CI	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	
p-value	X.XXXX	X.XXXX	X.XXXX	
<*Repeat for* Week12, Week16, Week20, Week24>				

[1] Average based on 50 imputed datasets.
[2] ANCOVA model includes treatment as factor, baseline BMI and pooled analysis centers as covariates.

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Repeat for

Table 14.2.2.9.1.2: Analysis of Secondary Efficacy Outcome
Percent Change from Baseline in Pruritus Numeric Rating Scale (NRS) Score by Visit
Double-Blind Treatment Period
Full Analysis Set, Multiple Imputation
Programming note: same structure as change from baseline table, but replace change from baseline with percent change from baseline.

Table 14.2.2.9.2.1: Analysis of Secondary Efficacy Outcome
Change from Baseline in Pruritus Numeric Rating Scale (NRS) Score by Visit
Double-Blind Treatment Period
Full Analysis Set, LOCF

	PPC-06 400 mg QD (N=XX)	PPC-06 400 mg BID (N=XX)	PPC-06 600 mg BID (N=XX)	Placebo (N=XX)
Baseline				
N	XX	XX	XX	XX
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median	XX	XX	XX	XX
Minimum, Maximum	XX, XX	XX, XX	XX, XX	XX, XX
Week 8				
N	XX	XX	XX	XX
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median	XX	XX	XX	XX
Minimum, Maximum	XX, XX	XX, XX	XX, XX	XX, XX
Change from baseline				
N	XX	XX	XX	XX
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median	XX	XX	XX	XX
Minimum, Maximum	XX, XX	XX, XX	XX, XX	XX, XX
Analysis of Covariance (ANCOVA) [1]				
LSM (SE)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
LSM, 95% CI	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X
LSM Difference (SE), PPC-06 vs. Placebo	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	
95% CI	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	
p-value	X.XXXX	X.XXXX	X.XXXX	
<*Repeat for* Week12, Week16, Week20, Week24>				

Note: LOCF = Last Observation Carried Forward.
[1] ANCOVA model includes treatment as factor, baseline BMI and pooled analysis centers as covariates.
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Repeat for tables:

Table 14.2.2.9.2.2: Analysis of Secondary Efficacy Outcome
Percent Change from Baseline in Pruritus Numeric Rating Scale (NRS) Score by Visit
Double-Blind Treatment Period
Full Analysis Set, LOCF
Programming note: same structure as change from baseline table, but replace change from baseline with percent change from baseline.

Table 14.2.2.9.3.1: Analysis of Secondary Efficacy Outcome
Change from Baseline in Pruritus Numeric Rating Scale (NRS) Score by Visit
Double-Blind Treatment Period
Full Analysis Set, OC

Programming note: update footnote for definition of OC

Table 14.2.2.9.3.2: Analysis of Secondary Efficacy Outcome
Percent Change from Baseline in Pruritus Numeric Rating Scale (NRS) Score by Visit
Double-Blind Treatment Period
Full Analysis Set, OC

Programming note: same structure as change from baseline table, but replace change from baseline with percent change from baseline. update footnote for definition of OC

Table 14.2.2.9.4.1: Analysis of Secondary Efficacy Outcome
Change from Baseline in Pruritus Numeric Rating Scale (NRS) Score by Visit
Double-Blind Treatment Period
PP Population, OC

Programming note: update footnote for definition of OC

Table 14.2.2.9.4.2: Analysis of Secondary Efficacy Outcome
Percent Change from Baseline in Pruritus Numeric Rating Scale (NRS) Score by Visit
Double-Blind Treatment Period
PP Population, OC

Programming note: same structure as change from baseline table, but replace change from baseline with percent change from baseline. update footnote for definition of OC

Table 14.2.2.10: Analysis of Secondary Efficacy Outcome
Time to Achieving PASI-75 Response
Full Analysis Set, OC

	PPC-06 400 mg QD (N=XX)	**PPC-06 400 mg BID (N=XX)**	**PPC-06 600 mg BID (N=XX)**	**Placebo (N=XX)**
Time to Achieving PASI-75 Response [1]				
Kaplan-Meier Estimates				
N	XX	XX	XX	XX
25th percentile	XX	XX	XX	XX
Median	XX	XX	XX	XX
75th percentile	XX	XX	XX	XX
Log Rank Test p-Values				
PPC-06 vs. Placebo	0.XXX	0.XXX	0.XXX	
PPC-06 vs. PPC-06 600 mg BID	0.XXX	0.XXX		
PPC-06 vs. PPC-06 400 mg BID	0.XXX			

Note: PASI= Psoriasis Area and Severity Index
[1] Days from baseline to first achieving a reduction of 75% or greater from Baseline in PASI. Subjects who did not achieve PASI-75 by the last assessment or withdrew prior to the last study visit will be censored at their last PASI assessment.

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Table 14.2.2.11: Analysis of Secondary Efficacy Outcome
Time to Achieving an IGA Score of Clear or Almost Clear
Full Analysis Set, OC

	PPC-06 400 mg QD (N=XX)	PPC-06 400 mg BID (N=XX)	PPC-06 600 mg BID (N=XX)	Placebo (N=XX)
Time to Achieving an IGA Score of Clear or Almost Clear [1]				
Kaplan-Meier Estimates				
N	XX	XX	XX	XX
25th percentile	XX	XX	XX	XX
Median	XX	XX	XX	XX
75th percentile	XX	XX	XX	XX
Log Rank Test p-Values				
PPC-06 vs. Placebo	0.XXX	0.XXX	0.XXX	
PPC-06 vs. PPC-06 600 mg BID	0.XXX	0.XXX		
PPC-06 vs. PPC-06 400 mg BID	0.XXX			

Note: IGA= Investigator's Global Assessment
[1] Days from baseline to first achieving an IGA score of 0 or 1. Subjects who did not achieve an IGA of 0 or 1 at the last assessment or withdrew prior to the last study visit will be censored at their last IGA assessment.

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Table 14.2.3.1: Analysis of Quality of Life Outcome
Change from Baseline in QIDS-SR16 Total Score by Visit
Full Analysis Set, OC

	PPC-06 400 mg QD (N=XX)	**PPC-06 400 mg BID (N=XX)**	**PPC-06 600 mg BID (N=XX)**	**Placebo (N=XX)**
Baseline				
N	XX	XX	XX	XX
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median	XX	XX	XX	XX
Minimum, Maximum	XX, XX	XX, XX	XX, XX	XX, XX
Week 12				
N	XX	XX	XX	XX
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median	XX	XX	XX	XX
Minimum, Maximum	XX, XX	XX, XX	XX, XX	XX, XX
Change from baseline				
N	XX	XX	XX	XX
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median	XX	XX	XX	XX
Minimum, Maximum	XX, XX	XX, XX	XX, XX	XX, XX
<*Repeat for* Week 16, Week 24>				

Note: QIDS-SR16=Quick Inventory of Depressive Symptomatology-Self Report (16 Items). OC = Observed Cases.

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Dr Reddy's Laboratories, SA
Protocol Number: PPC-06-CD-004

Table 14.2.3.2.1: Analysis of Quality of Life Outcome
Change from Baseline in DLQI Total Score by Visit
Full Analysis Set, OC

	PPC-06 400 mg QD (N=XX)	**PPC-06 400 mg BID (N=XX)**	**PPC-06 600 mg BID (N=XX)**	**Placebo (N=XX)**
Baseline				
N	XX	XX	XX	XX
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median	XX	XX	XX	XX
Minimum, Maximum	XX, XX	XX, XX	XX, XX	XX, XX
Week 12				
N	XX	XX	XX	XX
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median	XX	XX	XX	XX
Minimum, Maximum	XX, XX	XX, XX	XX, XX	XX, XX
Change from baseline				
N	XX	XX	XX	XX
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median	XX	XX	XX	XX
Minimum, Maximum	XX, XX	XX, XX	XX, XX	XX, XX
<*Repeat for* Week 16, Week 24>				

Note: DLQI= Dermatology Life Quality Index. OC= Observed Cases.

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Table 14.2.3.2.2: Analysis of Quality of Life Outcome
Change from Baseline in DLQI Individual Domains by Visit
Full Analysis Set, OC

	PPC-06 400 mg QD (N=XX)	PPC-06 400 mg BID (N=XX)	PPC-06 600 mg BID (N=XX)	Placebo (N=XX)
Symptoms and Feelings				
Baseline				
N	XX	XX	XX	XX
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median	XX	XX	XX	XX
Minimum, Maximum	XX, XX	XX, XX	XX, XX	XX, XX
Week 12				
N	XX	XX	XX	XX
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median	XX	XX	XX	XX
Minimum, Maximum	XX, XX	XX, XX	XX, XX	XX, XX
Change from baseline				
N	XX	XX	XX	XX
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median	XX	XX	XX	XX
Minimum, Maximum	XX, XX	XX, XX	XX, XX	XX, XX
<*Repeat for* Week 16, Week 24>				
<*Repeat for other domains:* Daily Activities, Leisure, Personal Relationships >				

Note: DLQI= Dermatology Life Quality Index. OC = Observed Cases.

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XXXX / Reference: Listings XXXX

Table 14.2.3.2.2: Analysis of Quality of Life Outcome
Change from Baseline in DLQI Individual Domains by Visit
Full Analysis Set, OC

	PPC-06 400 mg QD (N=XX)	**PPC-06 400 mg BID (N=XX)**	**PPC-06 600 mg BID (N=XX)**	**Placebo (N=XX)**
Work and School				
Baseline, n (%)				
Yes	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
No	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Not relevant	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Week 12, n (%)				
Yes	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
No	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Not relevant	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
<*Repeat for* Week 16, Week 24>				

Note: DLQI= Dermatology Life Quality Index. OC = Observed Cases.

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Table 14.2.3.2.2: Analysis of Quality of Life Outcome
Change from Baseline in DLQI Individual Domains by Visit
Full Analysis Set, OC

	PPC-06 400 mg QD (N=XX)	**PPC-06 400 mg BID (N=XX)**	**PPC-06 600 mg BID (N=XX)**	**Placebo (N=XX)**
Treatment				
Baseline, n (%)				
Very much	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
A lot	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
A little	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Not at all	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Not relevant	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Week 12, n (%)				
Very much	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
A lot	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
A little	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Not at all	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Not relevant	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

<*Repeat for* Week 16, Week 24>

Note: DLQI= Dermatology Life Quality Index. OC = Observed Cases.

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XXXX / Reference: Listings XXXX

Table 14.2.3.3.1: Analysis of Quality of Life Outcome
Change from Baseline in SF-12 Subdomains by Visit
Full Analysis Set, OC

	PPC-06 400 mg QD (N=XX)	PPC-06 400 mg BID (N=XX)	PPC-06 600 mg BID (N=XX)	Placebo (N=XX)
Physical Functioning (PF)				
Baseline				
N	XX	XX	XX	XX
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median	XX	XX	XX	XX
Minimum, Maximum	XX, XX	XX, XX	XX, XX	XX, XX
Week 12				
N	XX	XX	XX	XX
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median	XX	XX	XX	XX
Minimum, Maximum	XX, XX	XX, XX	XX, XX	XX, XX
Change from baseline				
N	XX	XX	XX	XX
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median	XX	XX	XX	XX
Minimum, Maximum	XX, XX	XX, XX	XX, XX	XX, XX

<*Repeat for* Week 16, Week 24>

<*Repeat for the other scores in order:,* Role-Physical (RP), Bodily Pain (BP), Social Functioning (SF), Mental Health (MH), Role-Emotional (RE), Vitality (VT), General Health (GH) >

Note: OC = Observed Cases.
Generated on XX/XX/XX:XXXX by XXXXX / Uses: XXXX / Reference: Listings XXXX

<Repeat for>

Table 14.2.3.3.2: Analysis of Quality of Life Outcome
Change from Baseline in SF-12 Summary Scores by Visit
Full Analysis Set, OC

[Programming Note: include the two summary scores: Physical Summary (PCS) and Mental Summary (MCS)]

Table 14.2.3.4: Analysis of Quality of Life Outcome
Change from Baseline in WPAI: PSO Score by Visit
Full Analysis Set, OC

[Programming Note: include summaries for questions "The percent work time missed due to psoriasis", "The percent impairment while working due to psoriasis", "The percent overall work impairment due to psoriasis" and "The percent activity impairment due to psoriasis"]

Table 14.2.3.5: Analysis of Quality of Life Outcome
Summary of HEOR Score by Visit
Full Analysis Set, OC

	PPC-06 400 mg QD (N=XX)	**PPC-06 400 mg BID (N=XX)**	**PPC-06 600 mg BID (N=XX)**	**Placebo (N=XX)**
# of times visited physician's office or urgent care clinic				
Baseline				
N	XX	XX	XX	XX
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median	XX	XX	XX	XX
Minimum, Maximum	XX, XX	XX, XX	XX, XX	XX, XX
Week 12				
N	XX	XX	XX	XX
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median	XX	XX	XX	XX
Minimum, Maximum	XX, XX	XX, XX	XX, XX	XX, XX

<*Repeat for* Week 16, Week 24>
< *Repeat for:* "# of times visited other health care professionals", and "# of times received care from a health professional in your home">

Note: HEOR = Health Economics and Outcomes Research. OC = Observed Cases.

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XXXX / Reference: Listings XXXX

Dr Reddy's Laboratories, SA
Protocol Number: PPC-06-CD-004

Table 14.3.1.1.1: Overall Summary of Adverse Events by Treatment
Titration Period
Safety Population

	PPC-06 400 mg QD (N=XX)[1]	**Placebo– Definition 1 (N=XX) [1]**	**PPC-06 400 mg BID (N=XX)[2]**	**PPC-06 600 mg BID (N=XX)[2]**	**Placebo– Definition 2 (N=XX) [2]**
Adverse Events					
Number of Events	XX	XX	XX	XX	XX
Number of Subjects, n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Exposure-adjusted incidence rate [3]	XX	XX	XX	XX	XX
Treatment-Emergent Adverse Events (TEAEs)					
Number of Events	XX	XX	XX	XX	XX
Number of Subjects, n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Exposure-adjusted incidence rate [3]	XX	XX	XX	XX	XX
Treatment-Related TEAEs					
Number of Events	XX	XX	XX	XX	XX
Number of Subjects, n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Exposure-adjusted incidence rate [3]	XX	XX	XX	XX	XX
Serious TEAEs					
<etc.>					
Serious AEs (non-Fatal)					
<etc.>					
Death					
<etc.>					
AEs Leading to Study Drug Discontinuation					
<etc.>					

Note: For each treatment, a subject will be counted once only within each AE category.
[1] Titration period TEAEs include all AEs starting or worsening after the first dose of study drug and before Day 15. Titration period duration is number of days between date of first study medication and the earlier of date of last study medication and Day 14 inclusive.
[2] Titration period TEAEs include all AEs starting or worsening after the first dose of study drug and before Day 36. Titration period duration is number of days between date of first study medication and the earlier of date of last study medication and Day 35 inclusive.
[3] Number of subjects with AEs divided by total number of subject-days with exposure to study medication, defined as sum of duration in days across all subjects in titration period.

Generated on XX/XX/XX:XXXX by SMYAE / Uses: XXXX / Reference: Listing XXXX

Repeat for

Table 14.3.1.1.2: Overall Summary of Adverse Events by Treatment
Treatment Period
Safety Population

Programming note: modify footnotes as following:

[1] Treatment period TEAEs include all AEs starting or worsening on or after Day 15. Treatment period duration is number of days between Day 15 and date of last study medication inclusive.
[2] Treatment period TEAEs include all AEs starting or worsening on or after Day 36. Treatment period duration is number of days between Day 36 and date of last study medication inclusive.
[3] Number of subjects with AEs divided by total number of subject-days with exposure to study medication, defined as sum of duration in days across all subjects in treatment period.

Dr Reddy's Laboratories, SA
Protocol Number: PPC-06-CD-004

Table 14.3.1.1.3: Overall Summary of Adverse Events by Treatment
Overall
Safety Population

	PPC-06 400 mg QD (N=XX)	**PPC-06 400 mg BID (N=XX)**	**PPC-06 600 mg BID (N=XX)**	**Placebo (N=XX)**
Adverse Events				
Number of Events	XX	XX	XX	XX
Number of Subjects, n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Exposure-adjusted incidence rate [1]	XX	XX	XX	XX
Treatment-Emergent Adverse Events (TEAEs)				
Number of Events	XX	XX	XX	XX
Number of Subjects, n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Exposure-adjusted incidence rate [1]	XX	XX	XX	XX
Treatment-Related TEAEs				
Number of Events	XX	XX	XX	XX
Number of Subjects, n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Exposure-adjusted incidence rate [1]	XX	XX	XX	XX
Serious TEAEs				
Number of Events	XX	XX	XX	XX
Number of Subjects, n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Exposure-adjusted incidence rate [1]	XX	XX	XX	XX
Serious AEs (non-Fatal)				
<etc.>				
Death				
<etc.>				
AEs Leading to Study Drug Discontinuation				
<etc.>				

Note: For each treatment, a subject will be counted once only within each AE category. TEAEs include all AEs starting or worsening after the first dose of study drug.
[1] Number of subjects with AEs divided by total number of subject-days with exposure to study medication, defined as sum of duration in days across all subjects during the study period.

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Table 14.3.1.2: Summary of Treatment-emergent Adverse Events
by System Organ Class and Preferred Term in Descending Frequency
Safety Population

System Organ Class **Preferred Term**	**PPC-06 400 mg QD** **(N=XX)**	**PPC-06 400 mg BID** **(N=XX)**	**PPC-06 600 mg BID** **(N=XX)**	**Placebo** **(N=XX)**
Subjects with any TEAE, n (%)	**XX (XX.X)**	**XX (XX.X)**	**XX (XX.X)**	**XX (XX.X)**
<< Adverse Event System Organ Class >>	**XX (XX.X)**	**XX (XX.X)**	**XX (XX.X)**	**XX (XX.X)**
<< Adverse Event Preferred Term >>	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
<< Adverse Event Preferred Term >>	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
<< Adverse Event Preferred Term >>	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
<< Adverse Event System Organ Class >>	**XX (XX.X)**	**XX (XX.X)**	**XX (XX.X)**	**XX (XX.X)**
<< Adverse Event Preferred Term >>	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
<< Adverse Event Preferred Term >>	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
<< Adverse Event Preferred Term >>	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

Note: Counts reflect numbers of subjects reporting one or more adverse events that map to MedDRA system organ class or preferred term. A subject may be counted once only in each row of the table.

Generated on XX/XX/XX:XXXX by SMYTEAEPT / Uses: XXXX / Reference: Listings XXXX

<*Programming Note: sort by SOC in alphabetical order and PT in descending order of the combined frequency in the three active treatments*>

Dr Reddy's Laboratories, SA
Protocol Number: PPC-06-CD-004

Table 14.3.1.3: Summary of Treatment-emergent Adverse Events
by System Organ Class, Preferred Term, and Maximum Severity
Safety Population

System Organ Class Preferred Term	Severity	PPC-06 400 mg QD (N=XX)	PPC-06 400 mg BID (N=XX)	PPC-06 600 mg BID (N=XX)	Placebo (N=XX)
Subjects with any TEAE, n (%)	**Total**	**XX (XX.X)**	**XX (XX.X)**	**XX (XX.X)**	**XX (XX.X)**
	Mild	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Moderate	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Severe	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
<< Adverse Event System Organ Class >>	**Total**	**XX (XX.X)**	**XX (XX.X)**	**XX (XX.X)**	**XX (XX.X)**
	Mild	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Moderate	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Severe	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
<< Adverse Event Preferred Term >>	Total	XX (XX.X)	XX (XX.X)	XX (XX.X)	**XX (XX.X)**
	Mild	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Moderate	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Severe	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

Note: Counts reflect numbers of subjects reporting one or more adverse events that map to MedDRA system organ class or preferred term. A subject may be counted only once at the highest severity.

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Dr Reddy's Laboratories, SA
Protocol Number: PPC-06-CD-004

Table 14.3.1.4: Summary of Treatment-emergent Adverse Events
by System Organ Class, Preferred Term, and Maximum Causality
Safety Population

System Organ Class Preferred Term	Causality Assessment[1]	PPC-06 400 mg QD (N=XX)	PPC-06 400 mg BID (N=XX)	PPC-06 600 mg BID (N=XX)	Placebo (N=XX)
Subjects with any TEAE, n (%)	**Total**	**XX (XX.X)**	**XX (XX.X)**	**XX (XX.X)**	**XX (XX.X)**
	Related	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Not Related	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
<< Adverse Event System Organ Class >>	**Total**	**XX (XX.X)**	**XX (XX.X)**	**XX (XX.X)**	**XX (XX.X)**
	Related	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Not Related	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
<< Adverse Event Preferred Term >>	**Total**	**XX (XX.X)**	**XX (XX.X)**	**XX (XX.X)**	**XX (XX.X)**
	Related	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
	Not Related	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

Note: Counts reflect numbers of subjects reporting one or more adverse events that map to MedDRA system organ class or preferred term. A subject may be counted only once at the highest causality.
[1] Related includes definitely related, probably related, and possibly related events. If relationship to treatment is missing, the event will be conservatively summarized as being related to study drug

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Dr Reddy's Laboratories, SA
Protocol Number: PPC-06-CD-004

Table 14.3.2.1: Summary of Clinical Laboratory Results by Treatment and Visit
Chemistry
Safety Population
[Lab Tests Name (Units)]

	PPC-06 400 mg QD (N=XX)	**PPC-06 400 mg BID (N=XX)**	**PPC-06 600 mg BID (N=XX)**	**Placebo (N=XX)**
Baseline				
Observed Values				
N	XX	XX	XX	XX
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median	XX	XX	XX	XX
Minimum, Maximum	XX, XX	XX, XX	XX, XX	XX, XX
Week 4				
Observed Values				
N	XX	XX	XX	XX
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median	XX	XX	XX	XX
Minimum, Maximum	XX, XX	XX, XX	XX, XX	XX, XX
Change from Baseline				
N	XX	XX	XX	XX
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median	XX	XX	XX	XX
Minimum, Maximum	XX, XX	XX, XX	XX, XX	XX, XX

<*Repeat for other visits:* Week 8, Week 12, Week 16, Week 20, Week 24>

Note: Baseline is the last available measurement prior to the first dose of study drug on Day 1.

Generated on XX/XX/XX:XXXX by XXX / Uses: XXXX / Reference: Listing XXXX
<*Programming Note: Page break after each lab parameter.*>

<Repeat for>

Table 14.3.2.2: Summary of Clinical Laboratory Results by Treatment and Visit
Hematology
Safety Population

Table 14.3.2.3.1: Lymphocyte Counts by Clinical Response of PASI-50 at Week 24
Safety Population

	PPC-06 400 mg QD (N=XX)	**PPC-06 400 mg BID (N=XX)**	**PPC-06 600 mg BID (N=XX)**	**Placebo (N=XX)**
PASI-50 Responders: Yes	N=XX	N=XX	N=XX	N=XX
Baseline				
N	XX	XX	XX	XX
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median	XX	XX	XX	XX
Minimum, Maximum	XX, XX	XX, XX	XX, XX	XX, XX
Week 24				
N	XX	XX	XX	XX
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median	XX	XX	XX	XX
Minimum, Maximum	XX, XX	XX, XX	XX, XX	XX, XX
Change from Baseline				
N	XX	XX	XX	XX
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median	XX	XX	XX	XX
Minimum, Maximum	XX, XX	XX, XX	XX, XX	XX, XX

Note: PASI-50 responder is defined as achieving a reduction of 50% or greater from baseline. Baseline is the last available measurement prior to the first dose of study drug on Day 1.
Generated on XX/XX/XX:XXXX by XXX / Uses: XXXX / Reference: Listing XXXX

Table 14.3.2.3.1: Lymphocyte Counts by Clinical Response of PASI-50 at Week 24
Safety Population

	PPC-06 400 mg QD (N=XX)	**PPC-06 400 mg BID (N=XX)**	**PPC-06 600 mg BID (N=XX)**	**Placebo (N=XX)**
PASI-50 Responders: No	N=XX	N=XX	N=XX	N=XX
Baseline				
N	XX	XX	XX	XX
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median	XX	XX	XX	XX
Minimum, Maximum	XX, XX	XX, XX	XX, XX	XX, XX
Week 24				
N	XX	XX	XX	XX
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median	XX	XX	XX	XX
Minimum, Maximum	XX, XX	XX, XX	XX, XX	XX, XX
Change from baseline				
N	XX	XX	XX	XX
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median	XX	XX	XX	XX
Minimum, Maximum	XX, XX	XX, XX	XX, XX	XX, XX

Note: PASI-50 responder is defined as achieving a reduction of 50% or greater from baseline. Baseline is the last available measurement prior to the first dose of study drug on Day 1.

Generated on XX/XX/XX:XXXX by XXX / Uses: XXXX / Reference: Listing XXXX

<Repeat for>

Table 14.3.2.3.2: Lymphocyte Counts by Clinical Response of PASI-75 at Week 24
Safety Population

Note: PASI-75 responder is defined as achieving a reduction of 75% or greater from baseline. Baseline is the last available measurement prior to the first dose of study drug on Day 1.

Table 14.3.2.4.1: Clinical Laboratory Results, Shifts from Baseline by Visit
Chemistry
Safety Population
[Lab Tests Name (Units)]

	PPC-06 400 mg QD (N=XX)	**PPC-06 400 mg BID (N=XX)**	**PPC-06 600 mg BID (N=XX)**	**Placebo (N=XX)**
Baseline - > Week 4, n (%)				
N [1]	XX	XX	XX	XX
Low -> Normal	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Normal -> Normal	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
High -> Normal	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
<Include all possible shifts as rows>				
Baseline - > Week 8, n (%)				
N [1]	XX	XX	XX	XX
Low -> Normal	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Normal -> Normal	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
High -> Normal	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
<Include all possible shifts as rows>				
Baseline - > Week 12, n (%)				
N [1]	XX	XX	XX	XX
Low -> Normal	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Normal -> Normal	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
High -> Normal	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
<Include all possible shifts as rows>				

<continue with:: Week 16, Week 20, Week 24>

[1] # of subjects with both baseline and post-baseline visits, this is the denominator for calculating the percentage.

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<Repeat table for>

Table 14.3.2.4.2: Clinical Laboratory Results, Shifts from Baseline by Visit
Hematology
Safety Population
[Lab Tests Name (Units)]

Table 14.3.3.1: Summary of Vital Signs by Treatment and Visit
Safety Population
[Pulse Rate (bpm)][Systolic Blood Pressure (mmHg)][Diastolic Blood Pressure (mmHg)]

	PPC-06 400 mg QD (N=XX)	**PPC-06 400 mg BID (N=XX)**	**PPC-06 600 mg BID (N=XX)**	**Placebo (N=XX)**
Baseline				
Observed Values				
N	XX	XX	XX	XX
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median	XX	XX	XX	XX
Minimum, Maximum	XX, XX	XX, XX	XX, XX	XX, XX
Week 4				
Observed Values				
N	XX	XX	XX	XX
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median	XX	XX	XX	XX
Minimum, Maximum	XX, XX	XX, XX	XX, XX	XX, XX
Change from Baseline				
N	XX	XX	XX	XX
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median	XX	XX	XX	XX
Minimum, Maximum	XX, XX	XX, XX	XX, XX	XX, XX

<*Repeat for* Week 8, Week 12, Week 16, Week 20, Week 24>

Note: Baseline is the last available measurement prior to the first dose of study drug on Day 1.

Generated on XX/XX/XX:XXXX by XXX / Uses: XXXX / Reference: Listing XXXX

Table 14.3.3.2: Summary of Vital Signs, Shifts from Baseline by Visit
Safety Population
[Pulse Rate (bpm)][Systolic Blood Pressure (mmHg)][Diastolic Blood Pressure (mmHg)]

	PPC-06 400 mg QD (N=XX)	**PPC-06 400 mg BID (N=XX)**	**PPC-06 600 mg BID (N=XX)**	**Placebo (N=XX)**
Baseline - > Week 4, n (%)				
N [1]	XX	XX	XX	XX
Low -> Normal	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Normal -> Normal	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
High -> Normal	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
<Include all possible shifts as rows>				
Abnormal Change from Baseline	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Markedly Abnormal Change from Baseline	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Baseline - > Week 8, n (%)				
N [1]	XX	XX	XX	XX
Low -> Normal	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Normal -> Normal	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
High -> Normal	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
<Include all possible shifts as rows>				
Abnormal Change from Baseline	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Markedly Abnormal Change from Baseline	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

<*continue with other visits:* Week 12, Week 16, Week 20, Week 24>

Note: Pulse Rate: Low=<50bpm; Normal=50-100bpm; High=>100bpm; Abnormal change from baseline: >=10bpm; Markedly abnormal change from baseline: >=30bpm.
Systolic Blood Pressure: Low= <90mmHg; Normal= 90-140mmHg; High= >140mmHg; Abnormal change from baseline: >=20mmHg; Markedly abnormal change from baseline: >=40mmHg. Diastolic Blood Pressure: Low= <50mmHg; Normal= 50-90mmHg; High= >90mmHg; Abnormal change from baseline: >=10mmHg; Markedly abnormal change from baseline: >=20mmHg.
[1] # of subjects with both baseline and post-baseline visits, this is the denominator for calculating the percentage.

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XXXX / Reference: Data Listings XXXX

Table 14.3.4: Summary of ECG Results by Treatment and Visit
Safety Population
[Lab Tests Name (Units)]

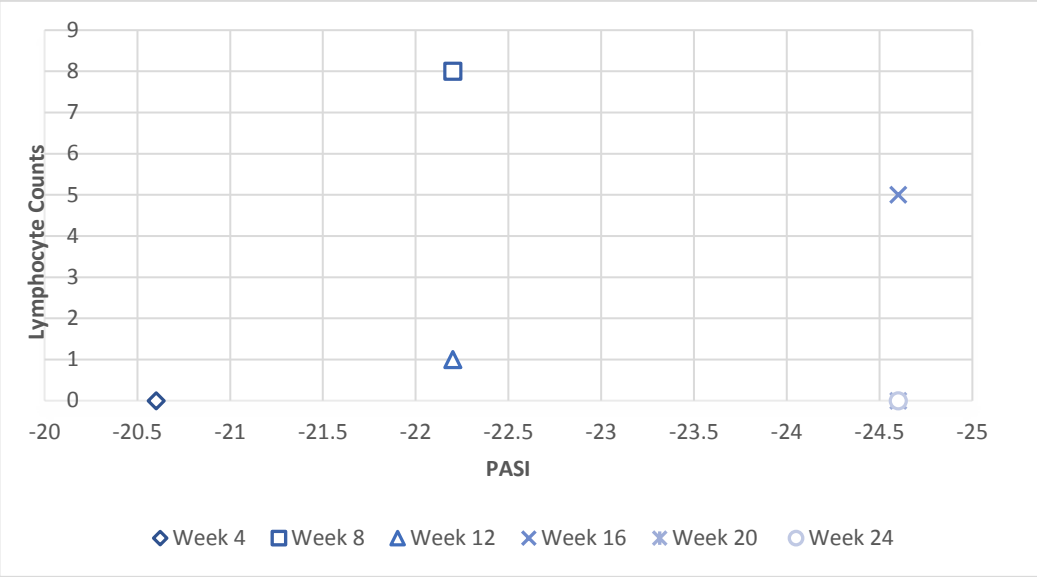
	PPC-06 400 mg QD (N=XX)	**PPC-06 400 mg BID (N=XX)**	**PPC-06 600 mg BID (N=XX)**	**Placebo (N=XX)**
Baseline				
Observed Values				
N	XX	XX	XX	XX
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median	XX	XX	XX	XX
Minimum, Maximum	XX, XX	XX, XX	XX, XX	XX, XX
Week 4				
Observed Values				
N	XX	XX	XX	XX
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median	XX	XX	XX	XX
Minimum, Maximum	XX, XX	XX, XX	XX, XX	XX, XX
Change from Baseline				
N	XX	XX	XX	XX
Mean (SD)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)	XX.X (XX.X)
Median	XX	XX	XX	XX
Minimum, Maximum	XX, XX	XX, XX	XX, XX	XX, XX

<*Repeat for other visits:* Week 8, Week 12, Week 16, Week 20, Week 24>

Note: Baseline is the last available measurement prior to the first dose of study drug on Day 1.

Generated on XX/XX/XX:XXXX by XXX / Uses: XXXX / Reference: Listing XXXX

Figure 14.3.1.1: Plot of Mean Change from Baseline by Visit, Lymphocyte Counts vs PASI scores
Safety Population
PPC-06 400 mg QD



Generated on XX/XX/XX XX:XX by XXXX / Uses: XXXX, XXXX, XXXX / Reference: XXXX

[Programming note: y-axis is the mean change from baseline in lymphocyte counts by visit. X-axis is the mean change from baseline in PASI scores by visit. Use different symbols for different visits, limit color just to black and white.]

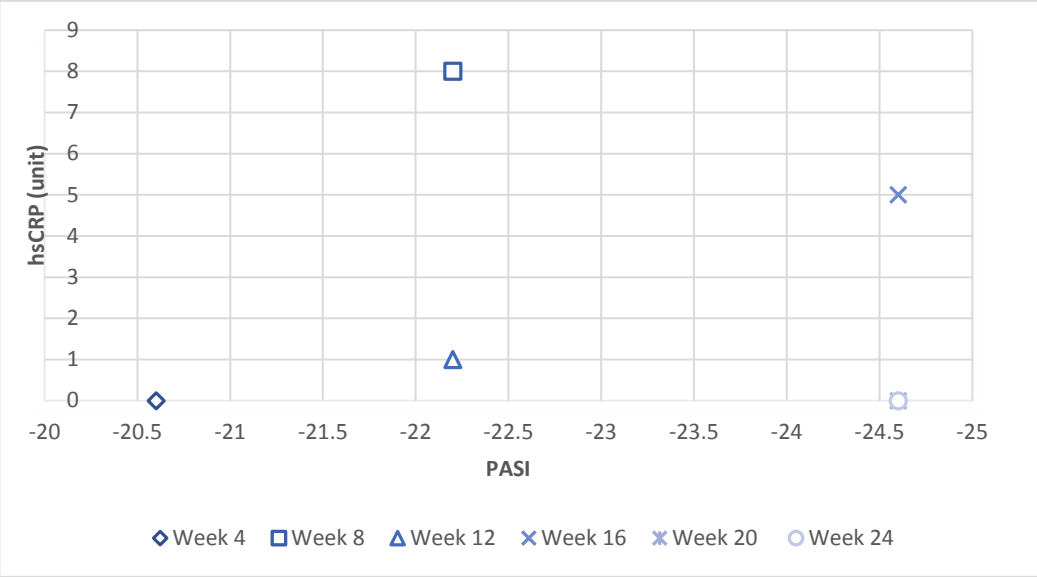
Repeat the figure for

Figure 14.3.1.2: Plot of Mean Change from Baseline by Visit, Lymphocyte Counts vs PASI scores
Safety Population
PPC-06 400 mg BID

Figure 14.3.1.3: Plot of Mean Change from Baseline by Visit, Lymphocyte Counts vs PASI scores
Safety Population
PPC-06 600 mg BID

Figure 14.3.1.4: Plot of Mean Change from Baseline by Visit, Lymphocyte Counts vs PASI scores
Safety Population
Placebo

Figure 14.3.2.1: Plot of Mean Change from Baseline by Visit, hsCRP (unit) vs PASI scores
Safety Population
PPC-06 400 mg QD



Generated on XX/XX/XX XX:XX by XXXX / Uses: XXXX, XXXX, XXXX / Reference: XXXX

[Programming note: y-axis is the mean change from baseline in hsCRP by visit. X-axis is the mean change from baseline in PASI scores by visit. Use different symbols for different visits, limit color just to black and white.]

Figure 14.3.2.2: Plot of Mean Change from Baseline by Visit, hs-CRP (unit) vs PASI scores
Safety Population
PPC-06 400 mg BID

Figure 14.3.2.3: Plot of Mean Change from Baseline by Visit, hs-CRP (unit) vs PASI scores
Safety Population
PPC-06 600 mg BID

Figure 14.3.2.4: Plot of Mean Change from Baseline by Visit, hs-CRP (unit) vs PASI scores
Safety Population
Placebo

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Listing 16.1.7: Subject Enrollment and Randomization
All Randomized Subjects

Subject Number	Date of Informed Consent	Require Washout Period?	Washout Period Completed? If No, Reason	Randomization Date	Randomization Number	Randomized Treatment	Actual Treatment
XX-XXX	DDMMMYYYY	Yes	Yes	DDMMMYYYY	XXXXXXX	PPC-06 400 mg QD	PPC-06 400 mg QD
XX-XXX	DDMMMYYYY	No	--	DDMMMYYYY	XXXXXXX	PPC-06 400 mg BID	PPC-06 400 mg BID
XX-XXX	DDMMMYYYY	Yes	No: XXXX	DDMMMYYYY	XXXXXXX	PPC-06 600 mg BID	Not Treated

Generated on XX/XX/XX:XXXX by XXXX / Uses: XXXX

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Listing 16.2.1.1: Screen Failures
All Screen Failure Subjects

Subject Number	Date of Informed Consent	Date of Screening	Date of Birth	Age (Years)	Sex	Primary Reason for Screen Failure
XX-XXX	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	XX	X	I/E criteria not met: Inclusion 2
XX-XXX	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	XX	X	Other: XXXXXXX
XX-XXX	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	XX	X	XXXXXXXXXXX
XX-XXX	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	XX	X	XXXXXXXXXXX
XX-XXX	DDMMMYYYY	DDMMMYYYY	DDMMMYYYY	XX	X	XXXXXXXXXXX

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Listing 16.2.1.2: Subject Disposition
All Randomized Subjects
[PPC-06 400 mg QD] [PPC-06 400 mg BID] [PPC-06 600 mg BID] [Placebo]

	Date (Day) of [1]						
Subject Number	**Screening**	**Randomization**	**First Dose**	**Last Dose**	**Last Visit**	**Last Contact**	**Completion Status / Discontinuation Reason**
XX-XXX	DDMMMYYYY(XX)	DDMMMYYYY(XX)	DDMMMYYYY(XX)	DDMMMYYYY(XX)	DDMMMYYYY(XX)	DDMMMYYYY(XX)	XXXXX
XX-XXX	DDMMMYYYY(XX)	DDMMMYYYY(XX)	DDMMMYYYY(XX)	DDMMMYYYY(XX)	DDMMMYYYY(XX)	DDMMMYYYY(XX)	XXXXX
001-001	19JUN2017(-10)	29JUN2017(1)	29JUN2017(1)	--	06JUL2017(8)	--	Completed

[1] Study day is calculated relative to the date of first study drug administration (Day 1).

Generated on XX/XX/XX:XXXX by XXXX/ Uses: XXXX

Listing 16.2.2: Protocol Deviation
All Randomized Subjects
[PPC-06 400 mg QD] [PPC-06 400 mg BID] [PPC-06 600 mg BID] [Placebo]

Subject Number	Category	Protocol Deviation
XX-XXX	XXXX	XXXX
	XXXXX	XXXX

Generated on XX/XX/XX:XXXX by XXXX/ Uses: XXXX

<Programming Note: The format of protocol deviation listing depends on the actual protocol deviation report form layout. Additional columns may be added, such as "Reference" "Type". If site deviation or deviation for SF subjects are also available, include those at the very end of this listing.>

Dr Reddy's Laboratories, SA
Protocol Number: PPC-06-CD-004

Listing 16.2.3: Population Datasets
All Randomized Subjects
[PPC-06 400 mg QD] [PPC-06 400 mg BID] [PPC-06 600 mg BID] [Placebo]

Subject Number	In Full Analysis Set?	In Safety Population?	In PP Population?	Reason for Exclusion from PP Population
XX-XXX	Yes	Yes	Yes	XXX
XX-XXX	Yes	No	No	XXX
XX-XXX	No	No	No	NA

Generated on XX/XX/XX:XXXX by XXXX/ Uses: XXXX

Listing 16.2.4.1: Demographics and Baseline Characteristics
All Randomized Subjects
[PPC-06 400 mg QD] [PPC-06 400 mg BID] [PPC-06 600 mg BID] [Placebo]

Subject Number	Date of Birth	Age (years)	Sex	Race	Ethnicity	Weight (kg)	Height (cm)	BMI (kg/m2) [1]	Waist Circum-ference (cm)	PASI	BSA	IGA [2]
XX-XXX	DDMMMYYYY	XX	M	Asian	NH	XXX	XXX	XX.X	XXX	X	XX.X	X
XX-XXX	DDMMMYYYY	XX	F	White	H	XXX	XXX	XX.X	XXX	X	XX.X	X

Note: BMI = Body Mass Index; PASI = Psoriasis Area and Severity Index; BSA = Body Surface Area; IGA = Investigator's Global Assessment
NH=Not Hispanic or Latino; H=Hispanic or Latino
[1] Baseline BMI is calculated as baseline weight / baseline height^2.
[2] 0 = Clear; 1=Almost clear; 2=Mild; 3=Moderate; 4=Severe

Generated on XX/XX/XX:XXXX by XXXX/ Uses: XXXX

Listing 16.2.4.2: Prior and Concomitant Medication
All Randomized Subjects
[PPC-06 400 mg QD] [PPC-06 400 mg BID] [PPC-06 600 mg BID] [Placebo]

Subject Number	Category	WHO Preferred Term (Verbatim Term) / ATC Classification	Indication/ Total Daily Dose/ Unit/Frequency/Route	Start Date (Day)-Stop Date (Day)	Rescue Medication?/ Taken to treat an AE? AE #
XX-XXX	Prior	XXXXXX (xxxxx)/ XXXXXX	XXX/ XX/XX/XXX/XXXX	DDMMMYYYY (XX) – DDMMMYYYY (XX)	Yes/Yes: 2
XX-XXX	Concomitant	XXXXXX (xxxxx)/ XXXXXX	XXX/ XX/XX/XXX/XXXX	DDMMMYYYY (XX) – ONGOING	No/Yes: 3

Note: Study day is calculated relative to the date of first study drug administration (Day 1).

Generated on XX/XX/XX:XXXX by XXXX/ Uses: XXXX

<*Programming Note: List medication in ascending start date for each subject.*>

Listing 16.2.4.3: Psoriasis Treatment History
All Randomized Subjects
[PPC-06 400 mg QD] [PPC-06 400 mg BID] [PPC-06 600 mg BID] [Placebo]

Subject Number	Medication Name	Start Date (Day) - Stop Date (Day)
XX-XXX	XXXXXXXX	DDMMMYYYY (XX) – DDMMMYYYY (XX)
	XXXXXXXXXX	DDMMMYYYY (XX) – DDMMMYYYY (XX)
	XXXXXXXXX	DDMMMYYYY (XX) – ONGOING

Note: Study day is calculated relative to the date of first study drug administration (Day 1).

Generated on XX/XX/XX:XXXX by XXXX/ Uses: XXXX

<*Programming Note: List medication in ascending start date for each subject.*>

Listing 16.2.4.4: Concurrent Procedures
All Randomized Subjects
[PPC-06 400 mg QD] [PPC-06 400 mg BID] [PPC-06 600 mg BID] [Placebo]

Subject Number	Preferred Term/ System Organ Class/ Procedure	Diagnosis	Procedure Start Date (Day) - Stop Date (Day)
XX-XXX	XXXXXXXX/ XXXXX/ XXXXXX	XXXXXXX	DDMMMYYYY (XX) – DDMMMYYYY (XX)
XX-XXX	XXXXXXXX/ XXXXX/ XXXXXX	XXXXXXXXXXX	DDMMMYYYY (XX) – ONGOING

Note: Study day is calculated relative to the date of first study drug administration (Day 1).

Generated on XX/XX/XX:XXXX by XXXX/ Uses: XXXX

<*Programming Note: List medication in ascending start date for each subject.*>

Listing 16.2.4.5: Medical/Surgical History
All Randomized Subjects
[PPC-06 400 mg QD] [PPC-06 400 mg BID] [PPC-06 600 mg BID] [Placebo]

Subject Number	Condition/Surgery/Procedure	System Organ Class/ Preferred Term	Procedure Start Date (Day) - Stop Date (Day)
XX-XXX	XXXX	XXXXX/ XXXXXX	DDMMMYYYY (XX) – DDMMMYYYY (XX)
XX-XXX	XXXX	XXXXX/ XXXXXX	DDMMMYYYY (XX) – ONGOING

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XXXX

Listing 16.2.4.6: Psoriasis Medical History
All Randomized Subjects
[PPC-06 400 mg QD] [PPC-06 400 mg BID] [PPC-06 600 mg BID] [Placebo]

Subject Number	Date of Initial Diagnosis of Plaque Psoriasis	Other Anatomical Areas Affected by Psoriasis
XX-XXX	YYYY	Scalp
XX-XXX	YYYY	Other: XXXXX

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Dr Reddy's Laboratories, SA
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Listing 16.2.5.1: Study Drug Accountability – Blister Packs
All Randomized Subjects
[PPC-06 400 mg QD] [PPC-06 400 mg BID] [PPC-06 600 mg BID] [Placebo]

Subject Number	Kit Number	Blister Number	Date (Day) Returned [1]	Number of Tablets Returned
XX-XXX	XXXXXXX	Week 1	DDMMMYYYY(XX)	XX
		Week 2	DDMMMYYYY(XX)	XX
		Week 3	DDMMMYYYY(XX)	XX
		Week 4	DDMMMYYYY(XX)	XX
		Week 5	DDMMMYYYY(XX)	XX
XX-XXX	XXXXXXX	Week 1	DDMMMYYYY(XX)	XX
		Week 2	DDMMMYYYY(XX)	XX
		Week 3	DDMMMYYYY(XX)	XX
		Week 4	DDMMMYYYY(XX)	XX

[1] Study day is calculated relative to the date of first study drug administration (Day 1).

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XX

Listing 16.2.5.2 Study Drug Accountability – Bottles
All Randomized Subjects
[PPC-06 400 mg QD] [PPC-06 400 mg BID] [PPC-06 600 mg BID] [Placebo]

Subject Number	Kit Number	Bottle Number	Date (Day) Returned [1]	Number of Tablets		
				Dispensed	Returned	Used
XX-XXX	XXXXXXX	AM1	DDMMMYYYY(XX)	30	XX	XX
		AM2	DDMMMYYYY(XX)	60	XX	XX
		PM1	DDMMMYYYY(XX)	30	--	--
		PM2	DDMMMYYYY(XX)	60	XX	XX
XX-XXX	XXXXXXX	DDMMMYYYY(XX)	DDMMMYYYY(XX)	XX	XX	XX
		DDMMMYYYY(XX)	DDMMMYYYY(XX)	XX	XX	XX
		DDMMMYYYY(XX)	DDMMMYYYY(XX)	XX	XX	XX
		DDMMMYYYY(XX)	DDMMMYYYY(XX)	XX	XX	XX

[1] Study day is calculated relative to the date of first study drug administration (Day 1).

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XX

Listing 16.2.5.3: Study Drug Exposure and Compliance
All Randomized Subjects
[PPC-06 400 mg QD] [PPC-06 400 mg BID] [PPC-06 600 mg BID] [Placebo]

Subject Number	Study Period	Total # of Days Exposed [1]	Total # of Expected Tablets	Total # of Tablets Taken [2]	Average Daily Dose of IP [3]	Compliance	
						%Compliance [4]	Compliant?
XX-XXX	Overall	XX	945	XX	XX	XX.X	Yes
	Titration	-	147	XX	-	XX.X	No
	Treatment	-	798	XX	-	XX.X	Yes
XX-XXX	Overall	XX	945	XX	XX	XX.X	No
	Titration	-	147	XX	-	XX.X	Yes
	Treatment	-	798	XX	-	XX.X	Yes

Note: Titration Period: Week 1 – 5. Treatment Period: Week 6 – 24. Overall: Week 1 – 24.
[1] Defined as date of last dose of study drug during the study minus date of first dose of study drug plus 1.
[2] Defined as the summation of number of tablets taken during the titration, treatment, or overall period.
[3] Calculated as the number of tablets divided by the number of days exposed to study medication for the overall period.
[4] Calculated as the number of tablets taken divided by the expected number of tablets, defined for the titration period, treatment period, and overall.

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XX

Dr Reddy's Laboratories, SA
Protocol Number: PPC-06-CD-004

Listing 16.2.6.1.1: Psoriasis Area and Severity Index (PASI) Score
All Randomized Subjects
[PPC-06 400 mg QD] [PPC-06 400 mg BID] [PPC-06 600 mg BID] [Placebo]

Subject Number	Analysis Visit	Date (Study Day) [1]	Type	Head and Neck	Upper Limbs	Trunk	Lower Limbs	Scores
XXX-XXX	Baseline	DDMMMYYYY(XX)	Erythema	X	X	X	X	XX
			Induration	X	X	X	X	XX
			Scaling	X	X	X	X	XX
			Sum (E+I+S)	X	X	X	X	XX
			Area Involved	X	X	X	X	
			Sum X Area	XX	XX	XX	XX	XX.X
	Week 4	DDMMMYYYY(XX)	Erythema	X	X	X	X	XX
			Induration	X	X	X	X	XX
			Scaling	X	X	X	X	XX
			Sum (E+I+S)	X	X	X	X	XX
			Area Involved	X	X	X	X	
			Sum X Area	XX	XX	XX	XX	XX.X

< *continue for other visits*>

[1] Study day is calculated relative to the date of first study drug administration (Day 1).

Generated on XX/XX/XX:XXXX by XXXX / Uses: XX

Dr Reddy's Laboratories, SA
Protocol Number: PPC-06-CD-004

Listing 16.2.6.1.2: PASI Total Score and Change from Baseline and Responders
All Randomized Subjects
[PPC-06 400 mg QD] [PPC-06 400 mg BID] [PPC-06 600 mg BID] [Placebo]

Subject Number	Analysis Visit	Date (Study Day) [1]	Type	PASI Total Score			PASI-50? [2]	PASI-75? [2]
				Value	CFBL	%CFBL		
XXX-XXX	Baseline	DDMMMYYYY (XX)	Observed	60	-	-	-	-
	Week 4	DDMMMYYYY (XX)	Observed	52	-8	13.3	N	N
	Week 8	DDMMMYYYY (XX)	Observed	40	-20	33.4	N	N
	Week 12	-	LOCF	40	-20	33.4	N	N
		-	m-NRI	-	-	-	N	N

<continue for other visits>

Note: PASI=Psoriasis Area and Severity Index; LOCF=Last Observation Carried Forward; m-NRI= Modified Non-Responder Imputation. CFBL=Change from baseline calculated as post-baseline minus baseline.
[1] Study day is calculated relative to the date of first study drug administration (Day 1).
[2] PASI-50/PASI-75 responder is defined as achieving a reduction of 50%/75% or greater from baseline.

Generated on XX/XX/XX:XXXX by XXXX / Uses: XX

Listing 16.2.6.2: Investigator's Global Assessment (IGA) of Disease Severity
All Randomized Subjects
[PPC-06 400 mg QD] [PPC-06 400 mg BID] [PPC-06 600 mg BID] [Placebo]

Subject Number	Analysis Visit	Visit Date (Day) [1]	Type	IGA Score	IGA Responder?[2]
XX-XXX	Baseline	DDMMMYYYY(XX)	Observed	3 – Moderate	--
	Week 4	DDMMMYYYY(XX)	Observed	2 – Mild	N
	Week 8	-	LOCF	2 – Mild	N
		-	m-NRI	-	N
	Week 12	DDMMMYYYY(XX)	Observed	1 – Almost clear	Y
	Etc.				
	<continue for other visits>				

Note: LOCF=Last observation-carried forward; m-NRI= Modified Non-Responder Imputation.
[1] Study day is calculated relative to the date of first study drug administration (Day 1).
[2] IGA responder is defined as achieving an IGA score of clear or almost clear (IGA score 0 or 1).

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XXXX

Dr Reddy's Laboratories, SA
Protocol Number: PPC-06-CD-004

Listing 16.2.6.3: Investigator's Assessment of the Body Surface Area (BSA) Involvement of Psoriasis
All Randomized Subjects
[PPC-06 400 mg QD] [PPC-06 400 mg BID] [PPC-06 600 mg BID] [Placebo]

Subject Number	Analysis Visit	Visit Date (Day) [1]	Type	Skin Area Involved (Number of Palms)					
				Head and Neck	Upper Limbs	Trunk	Lower Limbs	Total	
								Value	CFBL
XX-XXX	Baseline	DDMMMYYYY(XX)	Observed	0	2	1	1	3	--
	Week 4	DDMMMYYYY(XX)	Observed	X	X	X	X	X	X
	Week 8	DDMMMYYYY(XX)	Observed	--	--	--	--	--	--
			LOCF	X	X	X	X	X	X
	<continue for other visits>								

Note: LOCF=Last observation-carried forward. CFBL=Change from baseline: calculated as post-baseline minus baseline.
[1] Study day is calculated relative to the date of first study drug administration (Day 1).

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XXXX

Listing 16.2.6.4.1: Nail Psoriasis Severity Index (NAPSI) at Baseline
All Randomized Subjects
[PPC-06 400 mg QD] [PPC-06 400 mg BID] [PPC-06 600 mg BID] [Placebo]

Subject Number	Visit Date	Hand/ Digit	Nail Bed					Nail Matrix					Total				
			1	2	3	4	5	1	2	3	4	5	1	2	3	4	5
XX-XXX	DDMMMYYYY	Left/1	X	X	X	X	X	X	X	X	X	X	X	X	X*	X	X
		Right/1	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XXXX

[Programming Note: put a star next to the total score of the selected target nail]

Listing 16.2.6.4.2: Target Nail Psoriasis Severity Index (NAPSI)
All Randomized Subjects
[PPC-06 400 mg QD] [PPC-06 400 mg BID] [PPC-06 600 mg BID] [Placebo]

Subject Number	Analysis Visit	Visit Date (Day) [1]	Nail Bed Score	Nail Matrix Score	Total score		CFBL	
					Observed	LOCF	Observed	LOCF
XX-XXX	Baseline	DDMMMYYYY(XX)	X	X	X	-	-	-
	Week 12	DDMMMYYYY(XX)	X	X	X	-	X	-
	Week 16	-	-	-	-	X	-	X
	Week 24	DDMMMYYYY(XX)	X	X	X	-	X	-
	Etc.							

CFBL=Change from baseline calculated as post-baseline minus baseline.
[1] Study day is calculated relative to the date of first study drug administration (Day 1).

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XXXX

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Listing 16.2.6.5: Psoriasis Scalp Severity Index (PSSI)
All Randomized Subjects
[PPC-06 400 mg QD][PPC-06 400 mg BID][PPC-06 600 mg BID][Placebo]

Subject Number	Analysis Visit	Visit Date (Day) [1]	Type	Erythema	Induration	Scaling	Area scoring	Total	
								Value	CFBL
XX-XXX	Baseline	DDMMMYYYY(XX)	Observed	0	2	1	1	3	--
	Week 4	DDMMMYYYY(XX)	Observed	X	X	X	X	X	X
	Week 8	-	LOCF	X	X	X	X	X	X
	Week 12	DDMMMYYYY(XX)	Observed	X	X	X	X	X	X
	Etc.								

Note LOCF=Last observation-carried forward; CFBL=Change from baseline: calculated as post-baseline minus baseline.
[1] Study day is calculated relative to the date of first study drug administration (Day 1).

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XXXX

Dr Reddy's Laboratories, SA
Protocol Number: PPC-06-CD-004

Listing 16.2.6.6: Palmoplantar Physician's Global Assessment of Disease Severity (PP PGA)
All Randomized Subjects
[PPC-06 400 mg QD] [PPC-06 400 mg BID] [PPC-06 600 mg BID] [Placebo]

Subject Number	Analysis Visit	Visit Date (Day) [1]	Type	Value	CFBL
XX-XXX	Baseline	DDMMMYYYY(XX)	Observed	3 – Moderate	--
	Week 4	DDMMMYYYY(XX)	Observed	2 – Mild	-1
	Week 8	DDMMMYYYY(XX)	Observed	2 – Mild	-1
	Week 12	DDMMMYYYY(XX)	Observed	1 – Almost clear	-2
	Week 16	DDMMMYYYY(XX)	Observed	1 – Almost clear	-2
XX-XXX	Baseline	DDMMMYYYY(XX)	Observed	3 – Moderate	--
	Week 4	DDMMMYYYY(XX)	Observed	3 – Moderate	X
	Week 8	DDMMMYYYY(XX)	Observed	2 – Mild	-1
	Week 12	--	LOCF	2 – Mild	-1
	Week 16	DDMMMYYYY(XX)	Observed	XXX	X
	Week 20	DDMMMYYYY(XX)	Observed	XXX	X
	Week 24	DDMMMYYYY(XX)	Observed	XXX	X

Note: LOCF=Last observation-carried forward. CFBL=Change from baseline calculated as post-baseline minus baseline.
[1] Study day is calculated relative to the date of first study drug administration (Day 1).
Generated on XX/XX/XX:XXXX by XXXXX / Uses: XXXX

Dr Reddy's Laboratories, SA
Protocol Number: PPC-06-CD-004

Listing 16.2.6.7: Itch by NRS
All Randomized Subjects
[PPC-06 400 mg QD] [PPC-06 400 mg BID] [PPC-06 600 mg BID] [Placebo]

Subject Number	Analysis Visit	Visit Date (Day) [1]	Type	Value	CFBL
XXX-XXX	Baseline	DDMMYYYY (XX)	Observed	X	-
	Week 4	DDMMYYYY (XX)	Observed	X	X
	Week 8	-	LOCF	X	X
	Week 12	DDMMYYYY (XX)	Observed	X	X
	Week 16	DDMMYYYY (XX)	Observed	X	X
	Week 20	DDMMYYYY (XX)	Observed	X	X
	Week 24	DDMMYYYY (XX)	Observed	X	X
	<Etc.>				

Note: NRS = Numerical Rating Scale. LOCF=Last observation-carried forward. CFBL=Change from baseline calculated as post-baseline minus baseline.
[1] Study day is calculated relative to the date of first study drug administration (Day 1).
Generated on XX/XX/XX:XXXX by XXXX/ Uses: XXXX

Listing 16.2.6.8: Self-Report Quick Inventory of Depressive Symptomatology (QIDS-SR16)
All Randomized Subjects
[PPC-06 400 mg QD] [PPC-06 400 mg BID] [PPC-06 600 mg BID] [Placebo]

Subject Number	Analysis Visit	Visit Date (Day) [1]	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12	Q13	Q14	Q15	Q16	Total Value	Total CFBL
XX-XXX	Baseline	DDMMMYYYY(XX)	0	0	0	2	1	1	1	3	0	1	1	1	1	1	1	1	X	X
	Week 12	DDMMMYYYY(XX)	1	1	1	3	2	1	1	3	1	1	1	1	1	1	1	1	X	X
	Week 16	DDMMMYYYY(XX)	1	0	0	1	0	0	0	1	1	0	0	0	0	0	0	0	X	X
	Week 24	DDMMMYYYY(XX)	1	0	0	1	0	0	0	1	1	0	0	0	0	0	0	0	X	X
	Etc.																			

Note: CFBL=Change from baseline calculated as post-baseline minus baseline.

1. Falling asleep; 2. Sleep during the night, 3. Waking up too early; 4. Sleeping too much 5. Feeling sad, 6. Decreased appetite, 7. Decreased appetite 8. Decreased weight (within the last two weeks), 9. Increased weight (within the Last two weeks), 10. Concentration/decision making, 11. View of myself, 12. Thoughts of death or suicide,13. General interest, 14. Energy level, 15. Feeling slowed down, 16. Feeling restless

[1] Study day is calculated relative to the date of first study drug administration (Day 1).

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XXXX

Dr Reddy's Laboratories, SA
Protocol Number: PPC-06-CD-004

Listing 16.2.6.9.1: Dermatology Life Quality Index (DLQI) Individual Questions
All Randomized Subjects
[PPC-06 400 mg QD] [PPC-06 400 mg BID] [PPC-06 600 mg BID] [Placebo]

Subject Number	Analysis Visit	Visit Date (Day) [1]	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10
XX-XXX	Baseline	DDMMMYYYY(XX)	X	X	X	X	X	X	X	X	X	X
	Week 12	DDMMMYYYY(XX)	X	X	X	X	X	X	X	X	X	X
	Week 16	DDMMMYYYY(XX)	X	X	X	X	X	X	X	X	X	X
	Week 24	DDMMMYYYY(XX)	X	X	X	X	X	X	X	X	X	X
	Etc.											

[1] Study day is calculated relative to the date of first study drug administration (Day 1).

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XXXX

Listing 16.2.6.9.2: Dermatology Life Quality Index (DLQI) Domains and Total Score
All Randomized Subjects
[PPC-06 400 mg QD] [PPC-06 400 mg BID] [PPC-06 600 mg BID] [Placebo]

Subject Number	Analysis Visit	Visit Date (Day) [1]	Symptoms and Feelings		Daily Activities		Leisure		Work and School	Personal Relationships		Treatment	Total	
			Value	CFBL	Value	CFBL	Value	CFBL	Value	Value	CFBL	Value	Value	CFBL
XX-XXX	Baseline	DDMMMYYYY(XX)	X	--	X	--	X	--	X	X	--	X	X	--
	Week 12	DDMMMYYYY(XX)	X	X	X	X	X	X	X	X	X	X	X	X
	Week 16	DDMMMYYYY(XX)	X	X	X	X	X	X	X	X	X	X	X	X
	Week 24	DDMMMYYYY(XX)	X	X	X	X	X	X	X	X	X	X	X	X
XX-XXX	Baseline	DDMMMYYYY(XX)	X	--	X	--	X	--	X	X	--	X	X	--
	Week 12	DDMMMYYYY(XX)	X	X	X	X	X	X	X	X	X	X	X	X
	Week 16	DDMMMYYYY(XX)	X	X	X	X	X	X	X	X	X	X	X	X
	Etc													

Note: CFBL=Change from baseline calculated as post-baseline minus baseline.
Symptoms and Feelings includes Q1 and Q2; Daily Activities includes Q3 and Q4; Leisure includes Q5 and Q6; Work and School includes Q7 and Q7a; Personal Relationships includes Q 8 and Q9; Treatment includes Q10

[1] Study day is calculated relative to the date of first study drug administration (Day 1).

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XXXX

Listing 16.2.6.10.1: SF-12 Subdomains
All Randomized Subjects
[PPC-06 400 mg QD] [PPC-06 400 mg BID] [PPC-06 600 mg BID] [Placebo]

Subject Number	Analysis Visit	Visit Date (Day) [1]	Type	PF	RP	BP	SF	MH	RE	VT	GH	PCS	MCS
XX-XXX	Baseline	DDMMMYYYY(XX)	Value	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX
			CFBL	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX
	Week 12	DDMMMYYYY(XX)	Value	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX
			CFBL	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX
	Week 16	DDMMMYYYY(XX)	Value	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX
			CFBL	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX
	Week 24	DDMMMYYYY(XX)	Value	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX
			CFBL	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX
	Etc.												

Note: PF =Physical Functioning, RP=Role-Physical, BP=Bodily Pain, SF=Social Functioning, MH=Mental Health, RE=Role-Emotional, VT=Vitality, GH=General Health, PCS =Physical Summary, MCS=Mental Summary. CFBL=Change from baseline calculated as post-baseline minus baseline.
[1] Study day is calculated relative to the date of first study drug administration (Day 1).

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XXXX

Listing 16.2.6.10.2: SF-12 Individual Questions
All Randomized Subjects
[PPC-06 400 mg QD] [PPC-06 400 mg BID] [PPC-06 600 mg BID] [Placebo]

Subject Number	Analysis Visit	Visit Date (Day) [1]	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12
XX-XXX	Baseline	DDMMMYYYY(XX)	X	X	X	X	X	X	X	X	X	X	X	X
	Week 12	DDMMMYYYY(XX)	X	X	X	X	X	X	X	X	X	X	X	X
	Week 16	DDMMMYYYY(XX)	X	X	X	X	X	X	X	X	X	X	X	X
	Week 24	DDMMMYYYY(XX)	X	X	X	X	X	X	X	X	X	X	X	X

[1] Study day is calculated relative to the date of first study drug administration (Day 1).

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XXXX

Dr Reddy's Laboratories, SA
Protocol Number: PPC-06-CD-004

Listing 16.2.6.11: Work Productivity and Activity Impairment Questionnaire: Psoriasis (WPAI: PSO)
All Randomized Subjects
[PPC-06 400 mg QD][PPC-06 400 mg BID][PPC-06 600 mg BID][Placebo]

Subject Number	Analysis Visit	Visit Date (Day) [1]	% work time missed		% impairment while working		% overall work impairment		% activity impairment	
			Value	CFBL	Value	CFBL	Value	CFBL	Value	CFBL
XX-XXX	Baseline	DDMMMYYYY(XX)	XX.X	--	XX.X	--	XX.X	--	XX.X	--
	Week 12	DDMMMYYYY(XX)	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	Week 16	DDMMMYYYY(XX)	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	Week 24	DDMMMYYYY(XX)	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
XX-XXX	Baseline	DDMMMYYYY(XX)	XX.X	--	XX.X	--	XX.X	--	XX.X	--
	Week 12	DDMMMYYYY(XX)	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	Week 16	DDMMMYYYY(XX)	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	Etc.									

Note: WPAI-PSO outcomes are expressed as impairment percentages, with higher numbers indicating greater impairment and less productivity, i.e., worse outcomes.
CFBL=Change from baseline calculated as post-baseline minus baseline.
[1] Study day is calculated relative to the date of first study drug administration (Day 1).

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XXXX

Dr Reddy's Laboratories, SA
Protocol Number: PPC-06-CD-004

Listing 16.2.6.12: Health Economics and Outcome Research (HEOR)
All Randomized Subjects
[PPC-06 400 mg QD] [PPC-06 400 mg BID] [PPC-06 600 mg BID] [Placebo]

Subject Number	Analysis Visit	Visit Date (Day) [1]	# Visits to Physician's Office or Urgent Care Clinic/ Reason	# Visits to Other Health Care Professionals / Reason	# Times Received Care from a Health Professional at Home /Reason
XX-XXX	Baseline	DDMMMYYYY(XX)	XX / XXXXXXXXXXXX	XX / XXXXXXXXXXXX	XX / XXXXXXXXXXXX
	Week 12	DDMMMYYYY(XX)	XX / XXXXXXXXXXXX	XX / XXXXXXXXXXXX	XX / XXXXXXXXXXXX
	Week 16	DDMMMYYYY(XX)	XX / XXXXXXXXXXXX	XX / XXXXXXXXXXXX	XX / XXXXXXXXXXXX
	Week 24	DDMMMYYYY(XX)	XX / XXXXXXXXXXXX	XX / XXXXXXXXXXXX	XX / XXXXXXXXXXXX

[1] Study day is calculated relative to the date of first study drug administration (Day 1).

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XXXX

Dr Reddy's Laboratories, SA
Protocol Number: PPC-06-CD-004

Listing 16.2.7.1: Adverse Events
All Randomized Subjects
[PPC-06 400 mg QD] [PPC-06 400 mg BID] [PPC-06 600 mg BID] [Placebo]

Subject Number	AE #	MedDRA SOC Term/ MedDRA Preferred Term/ (Verbatim Term)	Treatment-emergent? [1] Onset Date (Day) – End Date (Day) [2]	SAE: Criteria?	Outcome/ Action taken with IP	Severity	CTCAE Grade [3]/ Relationship to IP	Action taken to treat AE/ Withdraw due to AE?
XX-XXX	1	XXXXXXXX / XXXXXXXX / (XXXXXXXX)	Yes / DDMMMYYYY(XX) – DDMMMYYYY(XX)	Yes: Hospitalization	XXXXXXXX/ XXXXXXXX	Mild	-/ XXXXXXXX	XXXXXXXX / No
	2	XXXXXXXX / XXXXXXXX / (Diarrhea)	No / DDMMMYYYY(XX) – DDMMMYYYY(XX)	No	XXXXXXXX/ XXXXXXXX	XXXXXXXX	Grade 2/ XXXXXXXX	XXXXXXXX / No
XX-XXX	1	XXXXXXXX / XXXXXXXX / (XXXXXXXX)	XXX / DDMMMYYYY(XX) – DDMMMYYYY(XX)	No	XXXXXXXX/ XXXXXXXX	XXXXXXXX	-/ XXXXXXXX	XXXXXXXX / Yes

[1] A treatment-emergent AE (TEAE) is defined as an AE with a start date on or after the first application to trial medication.
[2] Study day is calculated relative to the date of first study drug administration (Day 1).
[3] Assessed for Lymphocytopenia or Diarrhea ONLY

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XX

Dr Reddy's Laboratories, SA
Protocol Number: PPC-06-CD-004

Listing 16.2.7.2: Serious Adverse Events
All Randomized Subjects
[PPC-06 400 mg QD][PPC-06 400 mg BID][PPC-06 600 mg BID][Placebo]

Subject Number	AE #	MedDRA SOC Term/ MedDRA Preferred Term/ (Verbatim Term)	Treatment-emergent? [1] Onset Date (Day) – End Date (Day) [2]	SAE: Criteria?	Outcome/ Action taken with IP	Severity	CTCAE Grade [3]/ Relationship to IP	Action taken to treat AE/ Withdraw due to AE?
XX-XXX	1	XXXXXXXX / XXXXXXXX / (XXXXXXXX)	Yes / DDMMMYYYY(XX) – DDMMMYYYY(XX)	Yes: Hospitalization	XXXXXXXX/ XXXXXXXX	Mild	-/ XXXXXXXX	XXXXXXXX / No
	2	XXXXXXXX / XXXXXXXX / (Diarrhea)	No / DDMMMYYYY(XX) – DDMMMYYYY(XX)	XX	XXXXXXXX/ XXXXXXXX	XXXXXXXX	Grade 2/ XXXXXXXX	XXXXXXXX / No
XX-XXX	1	XXXXXXXX / XXXXXXXX / (XXXXXXXX)	XXX / DDMMMYYYY(XX) – DDMMMYYYY(XX)	XX	XXXXXXXX/ XXXXXXXX	XXXXXXXX	-/ XXXXXXXX	XXXXXXXX / Yes

[1] A treatment-emergent AE (TEAE) is defined as an AE with a start date on or after the first application to trial medication.
[2] Study day is calculated relative to the date of first study drug administration (Day 1).
[3] Assessed for Lymphocytopenia or Diarrhea ONLY

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XX

Listing 16.2.7.3: Adverse Events Leading to Study Drug Discontinuation
All Randomized Subjects
[PPC-06 400 mg QD][PPC-06 400 mg BID][PPC-06 600 mg BID][Placebo]

Subject Number	AE #	MedDRA SOC Term/ MedDRA Preferred Term/ (Verbatim Term)	Treatment-emergent? [1] Onset Date (Day) – End Date (Day) [2]	SAE: Criteria?	Outcome/ Action taken with IP	Severity	CTCAE Grade [3]/ Relationship to IP	Action taken to treat AE/ Withdraw due to AE?
XX-XXX	1	XXXXXXXX / XXXXXXXX / (XXXXXXXX)	Yes / DDMMMYYYY(XX) – DDMMMYYYY(XX)	Yes: Hospitalization	XXXXXXXX/ XXXXXXXX	Mild	-/ XXXXXXXX	XXXXXXXX / No
	2	XXXXXXXX / XXXXXXXX / (Diarrhea)	No / DDMMMYYYY(XX) – DDMMMYYYY(XX)	No	XXXXXXXX/ XXXXXXXX	XXXXXXXX	Grade 2/ XXXXXXXX	XXXXXXXX / No
XX-XXX	1	XXXXXXXX / XXXXXXXX / (XXXXXXXX)	XXX / DDMMMYYYY(XX) – DDMMMYYYY(XX)	No	XXXXXXXX/ XXXXXXXX	XXXXXXXX	-/ XXXXXXXX	XXXXXXXX / Yes

[1] A treatment-emergent AE (TEAE) is defined as an AE with a start date on or after the first application to trial medication.
[2] Study day is calculated relative to the date of first study drug administration (Day 1).
[3] Assessed for Lymphocytopenia or Diarrhea ONLY

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XX

Listing 16.2.8.1: Urine Pregnancy Test
All Randomized Female Subjects with Childbearing Potential
[PPC-06 400 mg QD][PPC-06 400 mg BID][PPC-06 600 mg BID][Placebo]

Subject Number	Childbearing Potential	Visit	Date of Test (Day)[1]	Result
XX-XXX	Abstinence	Baseline	DDMMMYYYY(XX)	Negative
		Week 4	DDMMMYYYY(XX)	Negative
		Week 8	DDMMMYYYY(XX)	Negative
		Etc.		
XX-XXX	XXXXXXX	Baseline	DDMMMYYYY(XX)	Negative
		Week 4	DDMMMYYYY(XX)	Negative
		Week 8	DDMMMYYYY(XX)	Negative
		Etc.		

[1] Study day is calculated relative to the date of first study drug administration (Day 1).

Generated on XX/XX/XX:XXXX by XXXX / Uses: XX

Dr Reddy's Laboratories, SA
Protocol Number: PPC-06-CD-004

Listing 16.2.8.2.X: Clinical Laboratory Test
[Chemistry] [Hematology] [Urinalysis] [Lymphocyte]
All Randomized Subjects
[PPC-06 400 mg QD][PPC-06 400 mg BID][PPC-06 600 mg BID][Placebo]

Subject Number	Analysis Visit	Date (Day) [1]	Parameter (Unit)	Reference Range	Results	CFBL	Abnormality
XX-XXX	Baseline	DDMMMYYYY (XX)	XXXX	XXXX,XXXX	XX.XX	XX	
			XXXX	XXXX,XXXX	XX.XX	XX	High
			XXXX	XXXX,XXXX	XX.XX	XXX	Low
	Week 4	DDMMMYYYY (XX)	XXXX	XXXX,XXXX	XX.XX	XXX	
	Week 8	DDMMMYYYY (XX)	XXXX	XXXX,XXXX	XX.XX	XXX	
	Etc.						

CFBL = Change from Baseline
[1] Study day is calculated relative to the date of first study drug administration (Day 1).

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XX

[Programming Note: for lymphocyte listing, drop the parameter (unit) column]

Dr Reddy's Laboratories, SA
Protocol Number: PPC-06-CD-004

Listing 16.2.8.3: Laboratory Values Outside of Normal Range
All Randomized Subjects
[PPC-06 400 mg QD][PPC-06 400 mg BID][PPC-06 600 mg BID][Placebo]

Subject Number	Analysis Visit	Date (Day) [1]	Category	Parameter (Unit)	Reference Range	Result	Abnormality
XX-XXX	Baseline	DDMMMYYYY (XX)	Chemistry	XXXX	XXXX,XXXX	XX.XX	Low
			Hematology	XXXX	XXXX,XXXX	XX.XX	Low
			Urinalysis	XXXX	XXXX,XXXX	XX.XX	Low
	Week 4	DDMMMYYYY (XX)	XXX	XXXX	XXXX,XXXX	XX.XX	High
	Week 8	DDMMMYYYY (XX)	XXX	XXXX	XXXX,XXXX	XX.XX	XXX
	Week 24	DDMMMYYYY (XX)	XXX	XXXX	XXXX,XXXX	XX.XX	XXX
	Etc.						

[1] Study day is calculated relative to the date of first study drug administration (Day 1).

Generated on XX/XX/XX:XXXX by XXXX/ Uses: XXXX

Listing 16.2.8.4: Vital Signs
All Randomized Subjects
[PPC-06 400 mg QD][PPC-06 400 mg BID][PPC-06 600 mg BID][Placebo]

Subject Number	Analysis Visit	Visit Date (Day) [1]	Weight (kg)	SBP (mmHg)		DBP (mmHg)		Pulse Rate (bpm)	
				Value	CFBL	Value	CFBL	Value	CFBL
XX-XXX	Baseline	DDMMYYYY (XX)	XX.X	XX.X	--	XX.X	--	XX.X	--
	Week 4	DDMMYYYY (XX)	XX.X	XX.X [H]	XX.X *	XX.X	XX.X	XX.X	XX.X
	Week 8	DDMMYYYY (XX)	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
XX-XXX	Baseline	DDMMYYYY (XX)	XX.X	XX.X	--	XX.X	--	XX.X	--
	Week 4	DDMMYYYY (XX)	XX.X	XX.X	XX.X	XX.X [L]	XX.X**	XX.X	XX.X
	Week 8	DDMMYYYY (XX)	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X

Note: SBP=Systolic blood pressure; DBP=Diastolic blood pressure; CFBL= change from baseline; *=abnormal change from baseline; **=markedly abnormal change from baseline.
[1] Study day is calculated relative to the date of first study drug administration (Day 1).

Generated on XX/XX/XX:XXXX by XXXX / Uses: XXXX

*[Programming Note: put abnormality flag (L, H) in bracket next to the observed abnormal values. Include * or ** for abnormal CFBL values]*

Listing 16.2.8.5: Abnormal Physical Examination Results
Randomized Subjects with Abnormal Results
[PPC-06 400 mg QD][PPC-06 400 mg BID][PPC-06 600 mg BID][Placebo]

Subject Number	Analysis Visit	Visit Date (Day) [1]	Findings
XX-XXX	Baseline	DDMMMYYYY (XX)	Abnormal Not Clinically Significant
XX-XXX	XXXX	DDMMMYYYY (XX)	Abnormal Clinically Significant

[1] Study day is calculated relative to the date of first study drug administration (Day 1).

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XXXX

Listing 16.2.8.6.1: 12-Lead ECG Results
All Randomized Subjects
[PPC-06 400 mg QD][PPC-06 400 mg BID][PPC-06 600 mg BID][Placebo]

			HR (beats/min)		PR (msec)		QRS (msec)		QTcB (msec)		QTcF (msec)		RR (msec)		QT (msec)	
Subject Number	**Analysis Visit**	**Date and Time (Day) [1]**	**Value**	**CFBL**	**Value**	**CFBL**	**Value**	**CFBL**	**Value**	**CFBL**	**Value**	**CFBL**	**Value**	**CFBL**	**Value**	**CFBL**
XX-XXX	Baseline	DDMMYYYY T HH:MM (XX)	XX.X	--	XX.X	--	XX.X	--	XX.X	--	XX.X	--	XX.X	--	XX.X	--
	Week 4	DDMMYYYY T HH:MM (XX)	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	Week 8	DDMMYYYY T HH:MM (XX)	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
XX-XXX	Baseline	DDMMYYYY T HH:MM (XX)	XX.X	--	XX.X	--	XX.X	--	XX.X	--	XX.X	--	XX.X	--	XX.X	--
	Week 4	DDMMYYYY T HH:MM (XX)	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	Week 8	DDMMYYYY T HH:MM (XX)	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X

Note: HR = heart rate, CFBL= change from baseline
[1] Study day is calculated relative to the date of first study drug administration (Day 1).

Generated on XX/XX/XX:XXXX by XXXX / Uses: XXXX

Dr Reddy's Laboratories, SA
Protocol Number: PPC-06-CD-004

Listing 16.2.8.6.2: 12-Lead ECG Findings
All Randomized Subjects
[PPC-06 400 mg QD][PPC-06 400 mg BID][PPC-06 600 mg BID][Placebo]

Subject Number	Analysis Visit	Date and Time (Day) [1]	Interpretations		Findings	Comments
			Vendor	Investigator		
XX-XXX	Baseline	DDMMYYYY T HH:MM (XX)	Normal	Normal	Conduction evaluation: Right bundle branch block Axis evaluation: Left axis deviation	Rhythm evaluation: normal sinus rhythm Physician comment: artifact
	Week 4	DDMMYYYY T HH:MM (XX)	XXX	XXX	XXXX	XXXXX
	<Etc.>					

[1] Study day is calculated relative to the date of first study drug administration (Day 1).

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XXXX

Dr Reddy's Laboratories, SA
Protocol Number: PPC-06-CD-004

Listing 16.2.8.7: Stool Consistency
All Randomized Subjects
[PPC-06 400 mg QD][PPC-06 400 mg BID][PPC-06 600 mg BID][Placebo]

Subject Number	Analysis Visit	Visit Date (Day) [1]	Number of bowel movements per day [2]	Bristol Chart Stool Type
XX-XXX	Baseline	DDMMMYYYY (XX)	2	Type 3
	Week 4	DDMMMYYYY (XX)	3	XXXXX
	<Etc.>			

[1] Study day is calculated relative to the date of first study drug administration (Day 1).
[2] Average per day over the past 2 weeks.

Generated on XX/XX/XX:XXXX by XXXXX / Uses: XXXX