POPULATION PHARMACOKINETICS REPORT

Report Number:	
Report Title:	Population Pharmacokinetic Report
Study Drug:	Drug A
Indication(s):	Nothing
Study Number(s):	12345
Sponsor:	
Prepared By:	MMJ
Reviewed By:	MMJ
Approved By:	MMJ
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Report Status:	DRAFT

Contents

Figures in-text

Tables in-text

1.

2. EXECUTIVE SUMMARY

The executive summary provides a brief overview of the analysis, highlighting the purpose, key findings affecting usage, labeling, and any additional recommendations based on the population PK analysis. It should be concise, typically consisting of 2-3 short paragraphs, and prepared with the understanding that it may be copied and pasted into a regulatory document.

SYNOBSIS

3. INTRODUCTION

4. METHODS

5. RESULTS

For each analysis (e.g. PopPK, PK/PD analysis, exposure-response analysis and simulations), an own sub-section should be included.

5.1. Exploratory Data Analysis

Exploratory analysis performed prior to modeling, e.g. concentration-time curves or descriptive analyses of PD measures.

5.2. Model Development

5.2.1. Base Model

Structural models considered, and model chosen. Diagnostic Plots for the assessment of structural models attempted. Discussion of alternative residual error and between subject variability models attempted, including alternative forms of variance covariance matrices as well as interoccasion variability. Statistical model chosen.

Goodness of fit graphs for the assessment of random effects structures employed.

5.2.2. Covariate Model

Method for identifying candidate covariates, description of covariate entered/excluded at each step and final covariate model selected.

5.2.3. Final Model

It is advisable to include a diagram or table depicting the various modeling steps, with the corresponding objective function values.

It is essential to include a table with all final model parameter estimates. The table should include parameter estimates and their associated uncertainty, with variability reported as CV% and precisión reported as the percent relative standard error (RSE%) or the 95 percent confidence Interval.

Add calculation methods below the table. It is advisable to include a comparison of parameter estimates from the base to the final model. If a previous model exists, a comparison of parameter estimates from the previous and current model may be added. The reliability of the analysis results can be checked by careful examination of diagnostic plots, including predicted versus observed concentration, predicted concentration superimposed on the data, and posterior estimates of parameter versus covariate values. Checking the parameter estimates, standard errors, case deletion diagnostics, and sensitivity analysis may also be appropriate.

5.3. Model Evaluation

External and/or internal validation including visual predictive checks. Potential application of bootstrap to obtain confidence intervals

5.4. Model Application

Model based simulations to evaluate the effect of covariates and other factors might impact PK (or PD).

6. DISCUSSION

7. CONCLUSION

Summary of major findings. Contextualize the PK model based simulations with regard to therapeutic window ?

8. REFERENCES

A. SI-01