Dossier

Common Technical Document

CTD Index

(Sample Document will provide on request)

Pragya Dossier-DMF Services
Plot No. 63, 76 & 77, Industrial Park (APIIC) Valasapalli, NH 42 Madanapalle -517 325, AP, India
For Quote - info@pdds.in & +91-96522-81814

#	Heading
	MODULE 1 Administrative Information and Prescribing Information
1.0	Cover Letter
1.1	Comprehensive table of contents
1.2	Application forms
1.3	Product information
1.3.1	Summary of Product Characteristics
1.3.2	Proposals for Samples/mockups of Packaging, Labeling, Package Leaflet/Insert
1.3.3	SPC's already approved in other countries medical
1.4	Information about experts
1.4.1	Quality
1.4.2	Non-Clinical
1.4.3	Clinical
1.5	Certificates and other information
	MODULE 2 Common Technical Document Summaries
2.1	Table of content
2.2	CTD Introduction
2.3	Quality Overall Summary
2.3.S	Drug Substance
2.3.S.1	General Information
2.3.S.2	Manufacture
2.3.S.3	Characterisation
2.3.S.4	Control of Drug Substance
2.3.S.5	Reference Standards or Materials
2.3.S.6	Container Closure System
2.3.S.7	Stability
2.3.P	Drug Product
2.3.P.1	Description and Composition of the Drug Product
2.3.P.2	Pharmaceutical Development
2.3.P.3	Manufacture

2.3.P.4	Control of Excipients
2.3.P.5	Control of Drug Product
2.3.P.6	Reference Standards or Materials
2.3.P.7	Container Closure System
2.3.P.8	Stability
2.4	Nonclinical Overview
2.5	Clinical Overview
2.6	Nonclinical Written and Tabulated Summaries
2.7	Clinical Summary
	MODULE 3 Quality
3.1	Table of Contents of Module 3
3.2	Body of Data
3.2.S	Drug Substance
3.2.S.1	General Information
3.2.S.1.1	Nomenclature
3.2.S.1.2	Structure
3.2.S.1.3	General Properties
3.2.S.2	Manufacture
3.2.S.2.1	Manufacturer (s)
3.2.S.2.2	Description of Manufacturing Process and Process Controls
3.2.S.2.3	Control of Materials
3.2.S.2.4	Controls of Critical Steps and Intermediates
3.2.S.2.5	Process Validation and/or Evaluation
3.2.S.2.6	Manufacturing Process Development
3.2.S.3	Characterisation
3.2.S.3.1	Elucidation of Structure and other Characteristics
3.2.S.3.2	Impurities
3.2.S.4	Control of Drug Substance
3.2.S.4.1	Specification
3.2.S.4.2	Analytical Procedures

3.2.S.4.3	Validation of Analytical Procedures
3.2.S.4.4	Batch Analyses
3.2.S.4.5	Justification of Specification
3.2.S.5	Reference Standards or Materials
3.2.S.6	Container Closure System
3.2.S.7	Stability
3.2.S.7.1	Stability Summary and Conclusions
3.2.S.7.2	Post-approval Stability Protocol and Stability Commitment
3.2.S.7.3	Stability Data
3.2.P	Drug Product
3.2.P.1	Description and Composition of the Drug Product
3.2.P.2	Pharmaceutical Development
3.2.P.3	Manufacture
3.2.P.3.1	Manufacturer(s)
3.2.P.3.2	Batch Formula
3.2.P.3.3	Description of Manufacturing Process and Process Controls
3.2.P.3.4	Controls of Critical Steps and Intermediates
3.2.P.3.5	Process Validation and/or Evaluation
3.2.P.4	Control of Excipients
3.2.P.4.1	Specifications
3.2.P.4.2	Analytical Procedures
3.2.P.4.3	Validation of Analytical Procedures
3.2.P.4.4	Justification of Specifications
3.2.P.4.5	Excipients of Human or Animal Origin
3.2.P.4.6	Novel Excipients
3.2.P.5	Control of Drug Product
3.2.P.5.1	Specification(s)
3.2.P.5.2	Analytical Procedures
3.2.P.5.3	Validation of Analytical Procedures
3.2.P.5.4	Batch Analyses

3.2.P.5.5	Characterisation of Impurities
3.2.P.5.6	Justification of Specification(s)
3.2.P.6	Reference Standards or Materials
3.2.P.7	Container Closure System
3.2.P.8	Stability
3.2.P.8.1	Stability Summary and Conclusion
3.2.P.8.2	Post-approval Stability Protocol and Stability Commitment
3.2.P.8.3	Stability Data
3.2.P.9	Product Interchangeability equivalence evidence
	MODULE 4 Non Clinical Study Reports
4.1	TABLE OF CONTENTS
4.2	STUDY REPORTS
4.2.1	Pharmacology
4.2.1.1	Primary Pharmacodynamics
4.2.1.2	Secondary Pharmcodynamics
4.2.1.3	Safety Pharmacology
4.2.1.4	Pharmacodynamic Drug Interactions
4.2.2	Pharmacokinetics
4.2.2.1	Method of Analysis
4.2.2.2	Absorption
4.2.2.3	Distribution
4.2.2.4	Metabolism
4.2.2.5	Excretion
4.2.2.6	Pharmacokinetic Drug Interactions (nonclinical)
4.2.2.7	Other Pharmacokinetic Studies
4.2.3	Toxicology
4.2.3.1	Single-Dose Toxicity
4.2.3.2	Repeat-Dose Toxicity
4.2.3.3	Genotoxicity
4.2.3.4	Carcinogenicity

4.2.3.5	Reproductive and Development Toxicity
4.2.3.6	Local Tolerance
4.2.3.7	Other Toxicity Studies
	MODULE 5 CLINICAL STUDY REPORTS
5.1	TABLE OF CONTENTS
5.2	Listing of All Clinical Studies
5.3	Clinical Study Reports
5.3.1	Biopharmaceutics Reports
5.3.1.1	Bioavailability Study Reports
5.3.1.2	Bioequivalence Study Reports
5.3.1.3	In-vivo/In-vitro Correlation Studies
5.3.1.4	Analytical Method Used in Bioavailability Study
5.3.2	Studies Pertinent to Pharmacokinetics using Human Biomaterials
5.3.3	Human Pharmacokinetics
5.3.4	Human Pharmacodynamics
5.3.5	Clinical Efficacy and Safety Studies