Common Technical Document
Dossier Index

COMMON TECHNICAL DOCUMENT (CTD) DOSSIER COMPRISES THE FOLLOWING MODULES:

MODULE 1 -ADMINISTRATIVE AND PRESCRIBING INFORMATION

MODULE 2 -COMMON TECHNICAL DOCUMENT SUMMARIES

MODULE 3 –QUALITY

MODULE 4 –NON CLINICAL STUDY REPROTS

MODULE 5 –CLINICAL STUDY REPORTS

Note: Module 1 is country specific and not considered as a main part of Common Technical Document. Module 4 is generally not applicable for generic product and module 5 is applicable for Bioequivalence Study.

Module 1: ADMINISTRATIVE AND PRESCRIBING INFORMATION: Only applicable for Tunisia

1.0. Letter of Request

1.1. Table of Contents

1.2. Application Form

1.3. Information on Manufacture

1.3.1. Manufacturing License

1.3.2. Certificates of Good Manufacturing Practice

1.3.3. Subcontracting if any

1.4. Product Information

1.4.1. Summary of product characteristics, Labelling and Notice

1.4.2. Model: Notice and Labelling

1.4.3. Samples

1.4.4. Imported Drug: Not Applicable

1.4.5. Drug manufactured under license: Not Applicable

1.5. Price Information

1.5.1. Price Proposal

1.5.2. Daily treatment costs and / or cost per cure

1.5.3. Price Certification

1.5.4. Price list in other countries: Not applicable

1.5.5 Status and corresponding rate of reimbursement

1.6. Information on Pharmacovigilance

1.7. Receipt of payment for registration

Module 2- COMMON TECHNICAL DOCUMENT SUMMARIES

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2.3.S.2 Manufacture

2.3.S.3 Characterization

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 NONCLNICAL OVERVIEW

2.5 CLINICAL OVERVIEW

2.6 NONCLINICAL SUMMARY

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2.6.2 Pharmacology written Summary

2.6.3 Pharmacology Tabulated Summary

2.6.4 Pharmacokinetics Written Summary

2.6.5 Pharmacokinetics Tabulated Summary

2.6.6 Toxicology Written Summary

2.6.7 Toxicology Tabulated Summary

2.7 CLINICAL SUMMARY

2.7.1 Summary of Biopharmaceutics and Associated Analytical Methods

2.7.2 Summary of Clinical Pharmacology Studies

2.7.3 Summary of Clinical Efficacy

2.7.4 Summary of Safety

2.7.5 References

2.7.6 Synopses of Individual Studies

Module 3- QUALITY

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 of 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.2.1 Components of the Drug Product

3.2.P.2.1.1 Drug Substance

3.2.P.2.1.2 Excipients

3.2.P.2.2 Drug Product

3.2.P.2.2.1 Formulation Development

3.2.P.2.2.2 Overages

3.2.P.2.2.3 Physicochemical and Biological Properties

3.2.P.2.3 Manufacturing Process Development

3.2.P.2.4 Container Closure System

3.2.P.2.5 Microbiological Attributes

3.2.P.2.6 Compatibility

3.2.P.3 Manufacture

3.2.P.3.1 Manufacturer

3.2.P.3.2 Batch Formula

3.2.P.3.3 Description of Manufacturing Process and Process Controls

3.2.P.3.4 Control of Critical Steps and Intermediates

3.2.P.3.5 Process Validation / 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

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3.2.P.5.3 Validation of Analytical Procedures

3.2.P.5.4 Batch Analyses

3.2.P.5.5 Characterization of Impurities

3.2.P.5.6 Justification of Specifications

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 Conclusions

3.2.P.8.2 Post-approval Stability Protocol and Stability Commitment

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4.2.1.2 Secondary Pharmacodynamics

4.2.1.3 Safety Pharmacology

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4.2.2.1 Analytical Methods and Validation Reports

4.2.2.2 Absorption

4.2.2.3 Distribution

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4.2.2.5 Excretion

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4.2.3.4.3 Other studies

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4.2.3.5.1 Fertility and early embryonic development

4.2.3.5.2 Embryo-fetal development

4.2.3.5.3 Prenatal and postnatal development including maternal function

4.2.3.5.4 Studies in which the offspring are dosed and /or further evaluated

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5.3.1.2 Comparative bioavailability and bioequivalence study reports

5.3.1.3 In vitro-In vivo correlation Study Reports

5.3.1.4 Reports of Bioanalytical and Analytical Methods for Human Studies

5.3.2 Report of pharmacokinetic studies using Human Biomaterials

5.3.2.1 Plasma Protein Binding Study Reports

5.3.2.2 Reports of Hepatic Metabolism and Drug Interaction Studies

5.3.2.3 Reports of studies using other Human Biomaterials

5.3.3 Reports of Human Pharmacokinetic (PK) Studies

5.3.3.1 Healthy subject PK and Initial tolerability study reports

5.3.3.2 Patient PK and Initial tolerability study reports

5.3.3.3 Intrinsic Factor PK Study reports

5.3.3.4 Extrinsic factory PK study reports

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5.3.4.1 Healthy subject PD and PK/PD study reports

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