Dossier sections

Module 1: Administrative information and prescribing information

1.1 Cover letter

1.2 Table of contents

1.3 Application form

1.4 Letter of authorization/ Agency agreement

1.5 GMP certificate and manufacturing license

1.6 Certificate of Pharmaceutical Product (CPP)

1.7 Registration status in other countries

1.8 European Certificate of Suitability (CEP)

1.9 Labeling

1.10 Prescribing information

1.10.1 Summary of Product Characteristics (SmPC)

Annex IV Medicines Registration Guideline

1.10.2 Patient information leaflet

1.11 Samples

Module 2: Quality Overall Summary – Product Dossier (QOS-PD)

2.1 Product Dossier (PD) Table of contents (Module 2-5)

2.2 Product Dossier Introduction

2.3 Quality Overall Summary

Annex III Medicines Registration Guideline

Module 3: Quality

3.1 Table of contents of module 3

3.2 Body of Data

3.2.S Active Pharmaceutical Ingredient (API) / Drug Substance (name, manufacturer)

3.2.S.1 General information

3.2.S.1.1 Nomenclature (name, manufacturer)

3.2.S.1.2 Structure (name, manufacturer)

3.2.S.1.3 General properties (name, manufacturer)

3.2.S.2 Manufacture (name, manufacturer)

3.2.S.2.1 Manufacturer(s) (name, manufacturer)

3.2.S.2.2 Description of manufacturing process and process controls (name, manufacturer)

ICH Q7, WHO Technical Report Series No. 957 Annex 2, ICH M4Q

3.2.S.2.3 Control of materials (name, manufacturer)

ICH Q6A

3.2.S.2.4 Controls of critical steps and intermediates (name, manufacturer)

3.2.S.2.5 Process validation and/or evaluation (name, manufacturer)

3.2.S.2.6 Manufacturing process development (name, manufacturer)

3.2.S.3 Characterization (name, manufacturer)

3.2.S.3.1 Elucidation of structure and other characteristics (name, manufacturer)

ICH Q6A, ICH Q6A Decision tree 4(1) & 4(2)

3.2.S.3.2 Impurities (name, manufacturer)

ICH Q3A, ICH Q3B, ICH Q3C, ICH Q6A, WHO Technical Report Series No. 970, 2012

3.2.S.4 Control of the API (name, manufacturer)

3.2.S.4.1 Specification (name, manufacturer)

ICH Q3A, ICH Q3C, ICH Q6A, WHO Technical Report Series No. 970, 2012

3.2.S.4.2 Analytical procedures (name, manufacturer)

ICH Q2, WHO Technical Report Series No. 943, Annex 3

3.2.S.4.3 Validation of analytical procedures (name, manufacturer)

ICH Q2

3.2.S.4.4 Batch analyses (name, manufacturer)

ICH Q3A, ICH Q3C, ICH Q6A

3.2.S.4.5 Justification of specification (name, manufacturer)

ICH Q3A, ICH Q3C, ICH Q6A, officially recognized pharmacopoeia

3.2.S.5 Reference standards and materials (name, manufacturer)

ICH Q6A, WHO Technical Report Series No. 943, Annex 3

3.2.S.6 Container closure system (name, manufacturer)

WHO Technical Report Series No. 902, Annex 9, 2002, officially recognized pharmacopoeia

3.2.S.7 Stability (name, manufacturer)

3.2.S.7.1 Stability summary and conclusion (name, manufacturer)

ICH Q1A, ICH Q1B, ICH Q1D, ICH Q1E, WHO Technical Report Series No. 953, Annex 2

3.2.S.7.2 Post-approval stability protocol and stability commitment (name, manufacturer)

ICH Q1A, ICH Q1B, ICH Q1D, ICH Q1E, WHO Technical Report Series No. 953, Annex 2

3.2.S.7.3 Stability data (name, manufacturer)

ICH Q1A, ICH Q1B, ICH Q1D, ICH Q1E, ICH Q2, WHO Technical Report Series No. 953, Annex 2

3.2.P Drug Product (Finished Pharmaceutical Product [FPP])

3.2.P.1 Description and composition of the FPP (name, dosage form)

ICH Q6A

3.2.P.2 Pharmaceutical development (name, dosage form)

ICH Q6A, ICH Q8, ICH Q9, ICH Q10