

Check-list CTD Type dossier

Module 1: Administrative Information and Prescribing Information

1.1 - Comprehensive Table of Contents (Module 1-5)

1.2 - Application Form

- Annex 6.01 - Proof of payment
- Annex 6.03 - Proof of establishment
- Annex 6.04 - Letter of authorization for communication
- Annex 6.05 - CV of the QP
- Annex 6.06 - Manufacturing authorization
- Annex 6.08 - Manufacturing and release flow chart
- Annex 6.09 - GMP inspections
- Annex 6.12 - TSE Statement - Feb2005
- Annex 6.14 - Scientific advice given by CHMP
- Annex 6.17 - List of Mock-ups or samples
- Annex 6.18 - Others

1.3 - Summary of Product Characteristics, Labeling and Package Leaflet

1.3.1 - 1.3.3 Summary of Product Characteristics, Labeling, Package Leaflet

- A. Labeling
- B. Package Leaflet

1.3.4 - Mock-ups and specimens

English version:

Blister strip foil

1.3.5 - SPCs already approved in the Member States

1.4 - Information about the Experts

1.4.1 - Information about the Expert - Quality

Signature Page:

Curriculum Vitae:

1.4.2 - Information about the Expert - Nonclinical

Signature Page:

Curriculum Vitae:

1.4.3 - Information about the Expert - Clinical

Signature Page:

Curriculum Vitae:

1.5 - Specific requirements for different types of applications

1.6 - Annex – Environmental risk assessment

Signature Page:

Curriculum Vitae:

Module 2: Common Technical Document Summaries

2.1 - Common Technical Document Table of Contents (Module 2 - 5)

2.2 - Introduction

2.3 - Quality Overall Summary

2.3 - Introduction

2.3.S - Drug Substance

2.3.P - Drug Product

2.3.A - Appendices

2.3.R - Regional Information

2.4 - Nonclinical Overview

Expert Statement

2.5 - Clinical Overview

2.6 - Nonclinical Summary

2.6.1 - Introduction

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 Biopharmaceutical Studies and Associated Analytical Methods

Appendix 1

2.7.2 - Summary of Clinical Pharmacology Studies

2.7.3 - Summary of Clinical Efficacy

2.7.4. Summary of Clinical Safety

2.7.5. Literature References

2.7.6. Synopses of Individual Studies

Module 3: Quality

3.1 -Table of Contents

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.2.2 - Description of Manufacturing

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 - Characterization

3.2.S.3.1 - Elucidation of Structure and other Characteristics

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

3.2.3.7.1 - 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 - Manufacturers)
- 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
- 3.2.P.5.2 - Analytical Procedures
- 3.2.P.5.3 - Validation of Analytical Procedures
- 3.2.P.5.4 - Batch Analysis
- 3.2.P.5.5 - Characterization of Impurities
- 3.2.P.5.6 - Justification of Specification

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
- 3.2.P.8.3 - Stability Data

3.2.A - Appendices

- 3.2.A.1 - Facilities and Equipment
- 3.2.A.2 - Adventitious Agents Safety Evaluation
- 3.2.A.3 - Excipients

3.2.R - Regional Information

Materials of animal and/or human origin

3.3 - Literature References

Module 4: Nonclinical 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 Pharmacodynamics**
- 4.2.1.2 - Pharmacodynamics Drug Interactions**

4.2.2 - Pharmacokinetics

- 4.2.2.1 - Analytical Methods and Validation Reports (if separate reports are available)**
- 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**
- 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

4.2.3.3.1 - In vitro

4.2.3.3.2 - In vivo (including supportive toxicokinetics evaluations)

4.2.3.4 - Carcinogenicity (including supportive toxicokinetics evaluations)

4.2.3.4.1 - Long-Term Studies (in order by species; including range-finding studies that cannot appropriately be included under repeat-dose toxicity or pharmacokinetics)

4.2.3.4.2 - Short- or Medium-Term Studies (in order by species; including range-finding studies that cannot appropriately be included under repeat-dose toxicity or pharmacokinetics)

4.2.3.4.3 - Other Studies

4.2.3.5 - Reproductive and Development Toxicity (including range-finding studies and supportive toxicokinetics evaluations)

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 (juvenile animals) Are Dosed and/or Further Evaluated

4.2.3.6 - Local Tolerance

4.2.3.7 - Other Toxicity Studies

4.2.3.7.1 - Antigenicity

4.2.3.7.2 - Immunotoxicity

4.2.3.7.3 - Dependence

4.2.3.7.4 - Metabolites

4.2.3.7.5 - Impurities

4.2.3.7.6 - Other

4.3 - Literature References

Module 5: Clinical Study Reports

5.1 - Table of Contents for Clinical Study Reports

5.2 - Tabular Listing of All Clinical Studies

5.3 - Clinical Study Reports

5.3.1 - Reports of Biopharmaceutical Studies

5.3.1.1 - Bioavailability (BA) Study Reports

5.3.1.2 - Comparative BA and Bioequivalence (BE) 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 - Reports of Studies Pertinent to Pharmacokinetics using Human Biomaterials

5.3.2.1 - Plasma Protein Binding Study Reports

5.3.2.3 - Reports of Studies Using Other Human Biomaterials

5.3.3 - Reports of Human Pharmacokinetics (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

5.3.3.2 - Reports of Hepatic Metabolism and interaction Studies

5.3.3.3 - Intrinsic Factor PK Study Reports

5.3.3.4 - Extrinsic Factor PK Study Reports

5.3.3.5 - Population PK Study Reports

5.3.4 - Reports of Human Pharmacodynamic (PD) Studies

5.3.4.1 - Healthy Subject PD and PK/PD Study Reports

5.3.4.2 - Patient PD and PK/PD Study Reports

5.3.5 - Reports of Efficacy and Safety Studies

5.3.5.1 - Study Reports of Controlled Clinical Studies Pertinent to the Claimed Indication

5.3.5.2 - Study Reports of Uncontrolled Clinical Studies

5.3.5.3 - Reports of Analyses of Data From More Than One Study, Including any Formal Integrated Analyses, Meta-analyses, and Bridging Analyses

5.3.5.4 - Other Clinical Study Reports

5.3.6 - Reports of Post-Marketing Experience

5.3.7 - Case Report Forms and Individual Patient Listings

5.4 - Literature References and Signature Pages

5.4.1 - Literature References

5.4.2 - Report Signature Pages

Additional to CTD or NTA dossier - set of the documents to be available from CUSTOMER

1. Power of attorney for PERFORMER in fixed template issued by CUSTOMER. Original certified by the Apostille.
2. Marketing Authorisation Holder (MAH) data in Country of service. Original on CUSTOMER letterhead.
3. Certificates & supportive documents that applicable to product status in country of origin: CPP, FDA, Free Sale (with reference on all manufacturing sites to be applied in Country). Original or notarized copy.
4. Manufacturing license for all (main & alternative) finished product supplying sites. Copy.
5. GMP certificate for all finished product supplying sites to be approved in Country. Original certified by the Apostille.
6. GMP inspection report self-statement for all finished product supplying sites. Copy certified by CUSTOMER.
7. Site Master File of all manufacturing production sites to be approved. Copy certified by CUSTOMER.
8. Manufacturing license for the active substance (-s) (main & alternative) manufacturers. Copy.
9. TM protection Certificate issued by International or Country Domestic IP Authorities (upon wish of MAH to have protected Product Trade Name in Country). Copy certified by CUSTOMER.
10. List of countries, in which the product has been already approved with dates and numbers. Original on CUSTOMER letterhead.

1. All mentioned data is mandatory. Other legal, scientific, technical data with regard to applied product could be required in process of evaluation in accordance with expert opinion;

2. Samples & materials intended for registration in Ukraine to be imported with special permission from Health Authorities.

Attach all necessary documents to your letter and email to **info@alenpharm.com**

See also:

Medical supplies

http://www.alenpharm.com/docs/medical_supplies.pdf

Cosmetics

<http://www.alenpharm.com/docs/cosmetics.pdf>

BAA

<http://www.alenpharm.com/docs/baa.pdf>