|  |
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| ZA Module 1 – Administrative Information |
|  |  |
| 1.0  | Letter of application |  |
| 1.1  | Comprehensive table of contents |  |
| 1.2  | Application |  |
| 1.2.1  | Application form |  |
| 1.2.2  | Annexes |  |
| 1.2.2.1  | Proof of payment |  |
| 1.2.2.2  | Letter of authorisation for communication on behalf of the applicant/PHCR |  |
| 1.2.2.3  | Dossier product batch information |  |
| 1.2.2.4  | Electronic copy declaration |  |
| 1.2.2.5  | Curriculum vitae of the person responsible for pharmacovigilance |  |
| 1.2.2.6  | API change control |  |
| 1.2.2.7  | EMA certificate for a Vaccine Antigen Master File (VAMF) |  |
| 1.2.2.8  | EMA certificate for a Plasma Master File (PMF) |  |
| 1.3  | South African labelling and packaging |  |
| 1.3.1  | South African Package Insert |  |
| 1.3.1.1  | Package insert |  |
| 1.3.1.2  | Standard References |  |
| 1.3.2  | Patient Information Leaflet  |  |
| 1.3.3  | Labels |  |
| 1.3.4  | Braille |  |
| 1.4  | Information about the experts |  |
| 1.4.1  | Quality |  |
| 1.4.2  | Non-clinical |  |
| 1.4.3  | Clinical |  |
| 1.5  | Specific requirements for different types of applications |  |
| 1.5.1  | Literature based submissions |  |
| 1.5.2  | Amendments/Variations [[1]](#footnote-2) |  |
| 1.5.2.1  | Tabulated schedule of amendments |  |
| 1.5.2.2  | Medicines Register Details |  |
| 1.5.2.3  | Affidavit by Responsible Pharmacist |  |
| 1.5.3  | Proprietary name applications and changes |  |
| 1.5.4  | Genetically modified organisms |  |
| 1.5.5  | Clinical Package Insert and Patient Information Leaflet amendments/updates |  |
| 1.6  | Environmental risk assessment |  |
| 1.6.1  | Non-GMO (genetically modified organisms) |  |
| 1.6.2  | GMO  |  |
| 1.7  | Good manufacturing practice |  |
| 1.7.1  | Date of last inspection of each site |  |
| 1.7.2  | Inspection reports or equivalent document |  |
| 1.7.3  | Latest GMP certificate or a copy of the appropriate licence |  |
| 1.7.4  | Release |  |
| 1.7.4.1  | API |  |
| 1.7.4.2  | IPIs |  |
| 1.7.4.3  | Finished Product Release Control (FPRC) tests |  |
| 1.7.4.4  | Finished Product Release Responsibility (FPRR) criteria |  |
| 1.7.5  | Confirmation of contract |  |
| 1.7.6  | CPP (WHO Certification scheme) |  |
| 1.7.7  | Proof of current registration of the Responsible Pharmacist by the SAPC |  |
| 1.7.8  | Proof of current registration by the SAPC of the pharmacist signing the dossier  |  |
| 1.7.9  | Proof of registration of the Applicant/PHCR as a pharmacy or a pharmacist  |  |
| 1.7.10  | Sample and Documents |  |
| 1.7.10.1  | Confirmation of submission of sample |  |
| 1.7.10.2  | Batch manufacturing record of the sample |  |
| 1.7.10.3  | CoA of the sample |  |
| 1.7.11  | Certified copy of a permit to manufacture specified Schedule 5, Schedules 6, 7 and 8 substances. |  |
| 1.7.12  | Inspection flow diagram |  |
| 1.7.13  | Organogram |  |
|  |  |  |
| ZA Module 1 – Administrative Information |
| 1.0  | Letter of application |  |
| 1.1  | Comprehensive table of contents |  |
| 1.2  | Application |  |
| 1.2.1  | Application form |  |
| 1.2.2  | Annexes |  |
| 1.2.2.1  | Proof of payment |  |
| 1.2.2.2  | Letter of authorisation for communication on behalf of the applicant/PHCR |  |
| 1.2.2.3  | Dossier product batch information |  |
| 1.2.2.4  | Electronic copy declaration |  |
| 1.2.2.5  | 1.2.2.5 Curriculum vitae of the person responsible for pharmacovigilance |  |
| 1.2.2.6  | API change control |  |
| 1.2.2.7  | EMA certificate for a Vaccine Antigen Master File (VAMF) |  |
| 1.2.2.8  | EMA certificate for a Plasma Master File (PMF) |  |
| 1.3  | South African labelling and packaging |  |
| 1.3.1  | South African Package Insert |  |
| 1.3.1.1  | Package insert |  |
| 1.3.1.2  | Standard References |  |
| 1.3.2  | Patient Information Leaflet  |  |
| 1.3.3  | Labels |  |
| 1.3.4  | Braille |  |
| 1.4  | Information about the experts |  |
| 1.4.1  | Quality |  |
| 1.4.2  | Non-clinical |  |
| 1.4.3  | Clinical |  |
| 1.5  | Specific requirements for different types of applications |  |
| 1.5.1  | Literature based submissions |  |
| 1.5.2 [[2]](#footnote-3) | Amendments/Variations [[3]](#footnote-4) |  |
| 1.5.2.1  | Tabulated schedule of amendments |  |
| 1.5.2.2  | Medicines Register Details |  |
| 1.5.2.3  | Affidavit by Responsible Pharmacist |  |
| 1.5.3  | Proprietary name applications and changes |  |
| 1.5.4  | Genetically modified organisms |  |
| 1.5.5  | Clinical Package Insert and Patient Information Leaflet amendments/updates |  |
| 1.6  | Environmental risk assessment |  |
| 1.6.1  | Non-GMO (genetically modified organisms) |  |
| 1.6.2  | GMO  |  |
| 1.7 | Good manufacturing practice |  |
| 1.7.1 | Date of last inspection of each site |  |
| 1.7.2 | Inspection reports or equivalent document |  |
| 1.7.3 | Latest GMP certificate or a copy of the appropriate licence |  |
| 1.7.4 | Release |  |
| 1.7.4.1 | API |  |
| 1.7.4.2 | IPIs |  |
| 1.7.4.3 | Finished Product Release Control (FPRC) tests |  |
| 1.7.4.4 | Finished Product Release Responsibility (FPRR) criteria |  |
| 1.7.5 | Confirmation of contract |  |
| 1.7.6 | CPP (WHO Certification scheme) |  |
| 1.7.7  | Proof of current registration of the Responsible Pharmacist by the SAPC |  |
| 1.7.8  | Proof of current registration by the SAPC of the pharmacist signing the dossier  |  |
| 1.7.9  | Proof of registration of the Applicant/PHCR as a pharmacy or a pharmacist  |  |
| 1.7.10 | Sample and Documents |  |
| 1.7.10.1 | Confirmation of submission of sample |  |
| 1.7.10.2 | Batch manufacturing record of the sample |  |
| 1.7.10.3 | CoA of the sample |  |
| 1.7.11 | Certified copy of a permit to manufacture specified Schedule 5, Schedules 6, 7 and 8 substances. |  |
| 1.7.12 | Inspection flow diagram |  |
| 1.7.13 | Organogram |  |
| 1.8 | Details of compliance with screening outcomes |  |
| 1.9 | Individual patient data - statement of availability |  |
| 1.10 | Foreign regulatory status |  |
| 1.10.1 | List of countries in which an application for the same product as being applied for has been submitted |  |
| 1.10.2 | Registration certificate or marketing authorisation |  |
| 1.10.3  | Foreign prescribing and patient information  |  |
| 1.10.4 | Data set similarities |  |
| 1.11 | Bioequivalence trial information |  |
| 1.11.1 | Study Title(s) (or brief description giving design, duration, dose and subject population of each study) |  |
| 1.11.2 | Protocol and study numbers |  |
| 1.11.3 | Investigational products (test and reference) details |  |
| 1.11.4 | Confirmation that the test product formulation and manufacturing process is that being applied for |  |
| 1.11.5  | Proof of procurement of the biostudy reference product  |  |
| 1.11.6  | Name and address of the Research Organisation(s) / Contract Research Organisation(s) where the bioequivalence studies were conducted  |  |
| 1.11.7 | Sponsor and responsible sponsor representative: name and address, contact details |  |
| 1.11.8 | Duration of Clinical phase: dates of dosing and last clinical procedure |  |
| 1.11.9 | Date of final report |  |
| 1.12 | Paediatric development programme |  |
| 1.13 | Risk management plan |  |
| Module 2 - CTD Summaries |
| 2.1  | CTD Table of Contents (modules 2 to 5) |  |
| 2.2 | Introduction |  |
| 2.3 | QualityOverall Summary - Introduction |  |
| 2.3.S | Quality Overall Summary - Active Pharmaceutical Ingredient *(name, manufacturer)* |  |
| 2.3.S.1 | General Information *(name, manufacturer)* |  |
| 2.3.S.2 | Manufacture *(name, manufacturer)* |  |
| 2.3.S.3 | Characterisation *(name, manufacturer)* |  |
| 2.3.S.4 | Control of Active Pharmaceutical Ingredient *(name, manufacturer)* |  |
| 2.3.S.5 | Reference Standards or Materials *(name, manufacturer)* |  |
| 2.3.S.6 | Container Closure System *(name, manufacturer)* |  |
| 2.3.S.7 | Stability *(name, manufacturer)* |  |
| 2.3.P | Quality Overall Summary - Finished Pharmaceutical Product *(name, dosage form)* |  |
| 2.3.P.1 | Description and Composition of the Pharmaceutical Product *(name, dosage form)* |  |
| 2.3.P.2 | Pharmaceutical Development *(name, dosage form)* |  |
| 2.3.P.3 | Manufacture *(name, dosage form)* |  |
| 2.3.P.4 | Control of Excipients *(name, dosage form)* |  |
| 2.3.P.5 | Control of Pharmaceutical Product *(name, dosage form)* |  |
| 2.3.P.6 | Reference Standards or Materials *(name, dosage form)* |  |
| 2.3.P.7 | Container Closure System *(name, dosage form)* |  |
| 2.3.P.8 | Stability *(name, dosage form)* |  |
| 2.3.A | Quality Overall Summary - Appendices |  |
| 2.3.A.1 | Facilities and equipment *(name, manufacturer)* |  |
| 2.3.A.2 | Adventitious agents safety evaluation *(name, dosage form, manufacturer)* |  |
| 2.3.A.3 | Excipients |  |
| 2.4 | Non-clinical Overview |  |
| 2.5 | Clinical Overview |  |
| 2.5.1 | Product Development Rationale |  |
| 2.5.2 | Overview of Biopharmaceutics |  |
| 2.5.3 | Overview of Clinical Pharmacology |  |
| 2.5.4 | Overview of Efficacy |  |
| 2.5.5 | Overview of Safety |  |
| 2.5.6 | Benefits and Risks Conclusions |  |
| 2.5.7 | Literature References |  |
| 2.6 | Non-clinical Written and Tabulated Summaries |  |
| 2.6.1 | Introduction |  |
| 2.6.2 | Pharmacology Written Summary  |  |
| 2.6.2.1 | Brief Summary |  |
| 2.6.2.2 | Primary Pharmacodynamics |  |
| 2.6.2.3 | Secondary Pharmacodynamics |  |
| 2.6.2.4 | Safety Pharmacology |  |
| 2.6.2.5 | Pharmacodynamic Medicine Interactions |  |
| 2.6.2.6 | Discussion and Conclusions |  |
| 2.6.2.7 | Tables and Figures (See Appendix A) |  |
| 2.6.3  | Pharmacology Tabulated Summary (See Appendix B)  |  |
| 2.6.4 | Pharmacokinetics Written Summary 2 |  |
| 2.6.4.1 | Brief Summary |  |
| 2.6.4.2 | Methods of Analysis |  |
| 2.6.4.3 | Absorption |  |
| 2.6.4.4 | Distribution |  |
| 2.6.4.5 | Metabolism (interspecies comparison) |  |
| 2.6.4.6 | Excretion |  |
| 2.6.4.7 | Pharmacokinetic Medicine Interactions |  |
| 2.6.4.8 | Other Pharmacokinetic Studies |  |
| 2.6.4.9 | Discussion and Conclusions |  |
| 2.6.4.10 | Tables and Figures (See Appendix A) |  |
| 2.6.5 | Pharmacokinetics Tabulated Summary (See Appendix B) |  |
| 2.6.6 | Toxicology Written Summary 2 |  |
| 2.6.6.1 | Brief Summary |  |
| 2.6.6.2 | Single-Dose Toxicity |  |
| 2.6.6.3 | Repeat-Dose Toxicity (including supportive toxicokinetics evaluations) |  |
| 2.6.6.4 | Genotoxicity |  |
| 2.6.6.5 | Carcinogenicity (including supportive toxicokinetics evaluations) |  |
| 2.6.6.6 | Reproductive and Developmental Toxicity (including range-finding studies and supportive toxicokinetics evaluations) |  |
| 2.6.6.7 | Local Tolerance |  |
| 2.6.6.8 | Other Toxicity Studies (if available) |  |
| 2.6.6.9 | Discussion and Conclusions |  |
| 2.6.6.10 | Tables and Figures (See Appendix A) |  |
| 2.6.7 | Toxicology Tabulated Summary (See Appendix B) |  |
| 2.7 | Clinical Summary |  |
| 2.7.1[[4]](#footnote-5) | Summary of Biopharmaceutic Studies and Associated Analytical Methods [[5]](#footnote-6) |  |
| 2.7.1.1 | Background and Overview |  |
| 2.7.1.2 | Summary of Results of Individual Studies |  |
| 2.7.1.3 | Comparison and Analyses of Results Across Studies |  |
| 2.7.1.4 | Appendix |  |
| 2.7.2 | Summary of Clinical Pharmacology Studies 3 |  |
| 2.7.2.1 | Background and Overview |  |
| 2.7.2.2 | Summary of Results of Individual Studies |  |
| 2.7.2.3 | Comparison and Analyses of Results Across Studies |  |
| 2.7.2.4 | Special Studies |  |
| 2.7.2.5 | Appendix |  |
| 2.7.3 | Summary of Clinical Efficacy – *Indication* 3 |  |
| 2.7.3.1 Background and Overview of Clinical Efficacy | 2.7.3.1 Background and Overview of Clinical Efficacy |  |
| 2.7.3.2 | Summary of Results of Individual Studies |  |
| 2.7.3.3 | Comparison and Analyses of Results Across Studies |  |
| 2.7.3.3.1 | Study Populations |  |
| 2.7.3.3.2 | Comparison of Efficacy Results of All Studies |  |
| 2.7.3.3.3 | Comparison of Results in Sub-populations |  |
| 2.7.3.4 | Analysis of Clinical Information Relevant to Dosing Recommendations |  |
| 2.7.3.5 | Persistence of Efficacy and/or Tolerance Effects |  |
| 2.7.3.6 | Appendix |  |
| 2.7.4 | Summary of Clinical Safety 3 |  |
| 2.7.4.1 | Exposure to the Medicine |  |
| 2 7.4.1.1 | Overall Safety Evaluation Plan and Narratives of Safety Studies |  |
| 2 7.4.1.2 | Overall Extent of Exposure |  |
| 2 7.4.1.3 | Demographic and Other Characteristics of Study Population |  |
| 2.7.4.2 | Adverse Events |  |
| 2.7.4.2.1 | Analysis of Adverse Events |  |
| 2.7.4.2.1.1 | Common Adverse Events |  |
| 2.7.4.2.1.2 | Deaths |  |
| 2.7.4.2.1.3 | Other Serious Adverse Events |  |
| 2.7.4.2.1.4 | Other Significant Adverse Events |  |
| 2.7.4.2.1.5 | Analysis of Adverse Events by Organ System or Syndrome |  |
| 2.7.4.2.2 | Narratives |  |
| 2.7.4.3 | Clinical Laboratory Evaluations |  |
| 2.7.4.4 | Vital Signs, Physical Findings and Other Observations related to Safety |  |
| 2.7.4.5 | Safety in Special Groups and Situations |  |
| 2.7.4.5.1 | Intrinsic Factors |  |
| 2.7.4.5.2 | Extrinsic Factors |  |
| 2.7.4.5.3 | Medicine Interactions |  |
| 2.7.4.5.4 | Use in Pregnancy and Lactation |  |
| 2.7.4.5.5 | Overdose |  |
| 2.7.4.5.6 | Medicine Abuse |  |
| 2.7.4.5.7 | Withdrawal and Rebound |  |
| 2.7.4.5.8  | Effects on Ability to Drive of Operate Machinery or Impairment of Mental Ability |  |
| 2.7.4.6 | Post-marketing Data |  |
| 2.7.4.7 | Appendix |  |
| 2.7.5 | Literature References |  |
| 2.7.6 | Synopses of Individual Studies |  |
| Module 3 - Quality |
| 3.1 | Table of contents of module 3 |  |
| 3.2 | Body of data |  |
| 3.2.S | Active Pharmaceutical Ingredient *(name, manufacturer)*  |  |
| 3.2.S.1  | General information (name, manufacturer) |  |
| 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 | 3.2.S.2.2 Description of Manufacturing Process and Process Controls *(name, manufacturer)* |  |
| 3.2.S.2.3) | Control of Materials (name, manufacturer) |  |
| 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 | 3.2.S.3 Characterisation *(name, manufacturer)* |  |
| 3.2.S.3.1 | Elucidation of Structure and other Characteristics *(name, manufacturer)* |  |
| 3.2.S.3.2 | Impurities *(name, manufacturer)* |  |
| 3.2.S.4 | Control of active pharmaceutical ingredient *(name, manufacturer)* |  |
| 3.2.S.4.1 | Specifications *(name, manufacturer)* |  |
| 3.2.S.4.2*manufacturer)* | Analytical Procedures *(name, manufacturer)* |  |
| 3.2.S.4.3 | Validation of Analytical Procedures *(name, manufacturer)* |  |
| 3.2.S.4.4 | Batch Analyses *(name, manufacturer)* |  |
| 3.2.S.4.5 | Justification of Specification *(name, manufacturer)* |  |
| 3.2.S.5 | Reference Standards or Materials *(name, manufacturer)* |  |
| 3.2.S.6 | Container Closure System *(name, manufacturer)* |  |
| 3.2.S.7 | Stability *(name, manufacturer)* |  |
| 3.2.S.7.1 | Stability summary and conclusions *(name, manufacturer)* |  |
| 3.2.S.7.2 | Post approval stability protocol and stability commitment *(name, manufacturer)* |  |
| 3.2.S.7.3 | Stability Data *(name, manufacturer)* |  |
| 3.2.P | Pharmaceutical Product *(name, dosage form)* |  |
| 3.2.P.1 | Description and Composition of the pharmaceutical product *(name, dosage form)* |  |
| 3.2.P.2 | Pharmaceutical Development *(name, dosage form)* |  |
| 3.2.P.2.1 | Components of the Pharmaceutical Product *(name, dosage form)* |  |
| 3.2.P.2.1.1 | Active Pharmaceutical Ingredient(s) *(name, dosage form)* |  |
| 3.2.P.2.1.2 | Excipients *(name, dosage form)* |  |
| 3.2.P.2.2 | Final pharmaceutical product *(name, dosage form)* |  |
| 3.2.P.2.2.1 | Formulation development *(name, dosage form)* |  |
| 3.2.P.2.2.2 | Overages *(name, dosage form)* |  |
| 3.2.P.2.2.3 | Physicochemical and biological properties *(name, dosage form)* |  |
| 3.2.P.2.3 | Manufacturing process development *(name, dosage form)* |  |
| 3.2.P.2.4 | Container closure system *(name, dosage form)* |  |
| 3.2.P.2.5 | Microbiological attributes *(name, dosage form)* |  |
| 3.2.P.2.6 | Compatibility *(name, dosage form)* |  |
| 3.2.P.3 | Manufacture *(name, dosage form)* |  |
| 3.2.P.3.1 | Manufacturer(s) *(name, dosage form)* |  |
| 3.2.P.3.2 | Batch formula *(name, dosage form)* |  |
| 3.2.P.3.3 | Description of manufacturing process and process controls *(name, dosage form)* |  |
| 3.2.P.3.4 | Controls of critical steps and intermediates *(name, dosage form)* |  |
| 3.2.P.3.5 | Process validation and/or evaluation *(name, dosage form)* |  |
| 3.2.P.4 | Control of Inactive Pharmaceutical Ingredients *(name, dosage form)* |  |
| 3.2.P.4.1 | Specifications *(name, dosage form)* |  |
| 3.2.P.4.2 | Analytical procedures *(name, dosage form)* |  |
| 3.2.P.4.3 | Validation of analytical procedures *(name, dosage form)* |  |
| 3.2.P.4.4 | Justification of specifications *(name, dosage form)* |  |
| 3.2.P.4.5 | Excipients of human or animal origin *(name, dosage form)* |  |
| 3.2.P.4.6 | Novel excipients *(name, dosage form)* |  |
| 3.2.P.5 | Control of pharmaceutical product *(name, dosage form)* |  |
| 3.2.P.5.1 | Specification(s) *(name, dosage form)* |  |
| 3.2.P.5.2 | Analytical procedures *(name, dosage form)* |  |
| 3.2.P.5.3 | Validation of analytical procedures *(name, dosage form)* |  |
| 3.2.P.5.4 | Batch analyses *(name, dosage form)* |  |
| 3.2.P.5.5 | Characterisation of impurities *(name, dosage form)* |  |
| 3.2.P.5.6 | Justification of specifications *(name, dosage form)* |  |
| 3.2.P.6 | Reference standards or materials *(name, dosage form)* |  |
| 3.2.P.7 | Container closure system *(name, dosage form)* |  |
| 3.2.P.8  | Stability *(name, dosage form)* |  |
| 3.2.P.8.1 | Stability summary and conclusion *(name, dosage form)* |  |
| 3.2.P.8.2 | Post-approval stability protocol and stability commitment *(name, dosage form)* |  |
| 3.2.P.8.3 | Stability data *(name, dosage form)* |  |
| 3.2.A | Appendices |  |
| 3.2.A.1 | Facilities and equipment *(name, manufacturer)* |  |
| 3.2.A.2 | Adventitious agents safety evaluation *(name, dosage form, manufacturer)* |  |
| 3.2.A.3 | Excipients |  |
| 3.2.R | Regional Information |  |
| 3.2.R.1  | Pharmaceutical and Biological availability |  |
| 3.2.R.1.1 | Overview |  |
| 3.2.R.1.1.1 | Country where developed, company developed by, test product synonyms. |  |
| 3.2.R.1.1.2 | The type of study(ies) submitted in support of efficacy |  |
| 3.2.R.1.1.3 | The purpose of the study or studies |  |
| 3.2.R.1.1.4 | The status of the reference product |  |
| 3.2.R.1.1.5 | A description of the type of study(ies) |  |
| 3.2.R.1.1.6 | Confirmation that the data submitted have been obtained with the formulation and manufacturing process being applied for |  |
| 3.2.R.1.1.7 | Confirmation that the test product (all strengths) was manufactured by the same manufacturer and site applied for |  |
| 3.2.R.1.1.8  | Confirmation that the test product was manufactured with API(s) manufactured by the same manufacturer(s) as being applied for |  |
| 3.2.R.1.1.9 | A statement whether *in vivo-in vitro* correlation from the data was obtained by the method/s used, if applicable |  |
| 3.2.R.1.1.10 | Motivation for the use of the particular reference product |  |
| 3.2.R.1.1.11 | Motivation for the use of a pharmaceutical alternative or lower strength |  |
| 3.2.R.1.1.12 | Tabular summary of the information pertaining to the study products |  |
| 3.2.R.1.1.13 | The formulation of each of the dosage strengths of the test product(s) in tabular form in the case of a biowaiver of proportionally similar dosage strengths |  |
| 3.2.R.1.1.14 | A discussion and conclusion of the outcomes of each of the studies and other relevant information to support and justify acceptance of product efficacy |  |
| 3.2.R.1.1.15 | An overall conclusion |  |
| 3.2.R.1.1.16 | References |  |
| 3.2.R.1.2. | Reference product/s (local and foreign) |  |
| 3.2.R.1.3 | Certificates of Analysis |  |
| 3.2.R.1.4 | Pharmaceutical availability studies |  |
| 3.2.R.1.4.1 | Dissolution studies, data and reports |  |
| 3.2.R.1.4.2 | Other |  |
| 3.2.R.2 | Parent API manufacturer with various sites |  |
| 3.2.R.3 | Certificate(s) of suitability with respect to the Ph.Eur. (CEPs) |  |
| 3.2.R.4 | Multiple API manufacturers |  |
| 3.2.R.4.1 | Comparative API manufacturers study report |  |
| 3.2.R.4.2. | Comparative results |  |
| 3.2.R.4.3 | Confirmation of compliance with guidelines |  |
| 3.2.R.4.4 | Certificates of analysis |  |
| 3.2.R.5 | Medical device |  |
| 3.2.R.6 | Materials of animal and/or human origin |  |
| 3.2.R.7  | Batch records of samples  |  |
| 3.2.R.8 | Other |  |
| 3.3 | Literature references |  |
| Module 4 - Non-clinical study reports |
| 4.1 | Table of contents of Module 4 |  |
| 4.2 | Study reports |  |
| 4.2.1 | Pharmacology |  |
| 4.2.1.1 | Primary pharmacodynamics |  |
| 4.2.1.2 | Secondary pharmacodynamics |  |
| 4.2.1.3 | Safety pharmacology |  |
| 4.2.1.4 | Pharmacodynamic medicine interactions |  |
| 4.2.2 | Pharmacokinetics |  |
| 4.2.2.1 | Analytical methods and validation reports |  |
| 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 medicine interactions (non clinical) |  |
| 4.2.2.7 | Other pharmacokinetic studies |  |
| 4.2.3 | Toxicology |  |
| 4.2.3.1 | Single-dose toxicity (in order by species, by route) |  |
| 4.2.3.2) | Repeat dose toxicity (in order by species, by route, by duration; including supportive toxicokinetics evaluations) |  |
| 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 be appropriately included under repeat-dose toxicity or pharmacokinetics) |  |
| 4.2.3.4.2  | Short or medium term studies (including range finding studies that cannot be appropriately included under repeat-dose) |  |
| 4.2.3.4.3 | Other studies |  |
| 4.2.3.5 | Reproductive and developmental toxicity (including range-finding studies and supportive toxicokinetics evaluations) (If modified study designs are used, the following subheadings should be modified accordingly) |  |
| 4.2.3.5.1  | Fertility and early embryonic development  |  |
| 4.2.3.5.2  | Embryo-foetal 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 (if available) |  |
| 4.2.3.7.1 | Antigenicity |  |
| 4.2.3.7.2 | Immunotoxicity |  |
| 4.2.3.7.3 | Mechanistic studies (if not included elsewhere) |  |
| 4.2.3.7.4 | Dependence |  |
| 4.2.3.7.5 | Metabolites |  |
| 4.2.3.7.6 | Impurities |  |
| 4.2.3.7.7 | Other |  |
| 4.3 | Literature references |  |
| Module 5 - Clinical Study Reports |
| 5.1 | Table of contents of Module 5 |  |
| 5.2 | Tabular listing of all clinical studies |  |
| 5.3 | Clinical study reports |  |
| 5.3.1 | Reports of biopharmaceutic 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 |  |
| 5.3.2.2 | Reports of Hepatic Metabolism and Medicine 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 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 |  |
| 5.3.5.4 | Other Study Reports |  |
| 5.3.6 | Reports of Post-marketing experience |  |
| 5.3.7 | Case report forms and individual patient listings |  |
| 5.4 | Literature references |  |

1. Amendments guideline [↑](#footnote-ref-2)
2. Amendments guideline [↑](#footnote-ref-3)
3. Amendments guideline [↑](#footnote-ref-4)
4. [↑](#footnote-ref-5)
5. [↑](#footnote-ref-6)