PERFECT CURE 500 mg (S0786)

EXAMPLE PHARMACEUTICALS (PTY) LTD TABLETS

 PARACETAMOL 500 mg

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MODULE 1.1 COMPREHENSIVE TABLE OF CONTENTS

|  |
| --- |
| ZA Module 1 – Administrative Information |
|  | MBR1 | CTD MODULE & VOLUME |
| 1.0  | Letter of application/cover letter | See CTD | M1,V1 of 1 |
| 1.1  | Comprehensive table of contents | See CTD | M1,V1 of 1 |
| 1.2  | Application |  |  |
| 1.2.1  | Application form | See CTD | M1,V1 of 1 |
| 1.2.2  | Annexes | See CTD | M1,V1 of 1 |
| 1.2.2.1  | Proof of payment | See CTD | M1,V1 of 1 |
| 1.2.2.2  | Letter of authorisation for communication on behalf of the applicant/PHCR | - | Not included |
| 1.2.2.3  | Dossier product batch information | - | Not included |
| 1.2.2.4  | Electronic copy declaration | - | Not included |
| 1.2.2.5  | Curriculum vitae of the person responsible for pharmacovigilance | See CTD | M1,V1 of 1 |
| 1.2.2.6  | API change control | - | Not included |
| 1.2.2.7  | EMA certificate for a Vaccine Antigen Master File (VAMF) | - | Not included |
| 1.2.2.8  | EMA certificate for a Plasma Master File (PMF) | - | Not included |
| 1.3 South African labelling and packaging |
| 1.3.1  | South African Package Insert | See CTD | M1,V1 of 1 |
| 1.3.1.1  | Package insert | See CTD | M1,V1 of 1 |
| 1.3.1.2  | Standard References | - | Not included |
| 1.3.2  | Patient Information Leaflet  | See CTD | M1,V1 of 1 |
| 1.3.3  | Labels | See CTD | M1,V1 of 1 |
| 1.3.4  | Braille | - | Not included |
| 1.4 Information about the experts |
| 1.4.1  | Quality | - | Not included |
| 1.4.2  | Non-clinical | - | Not included |
| 1.4.3  | Clinical | - | Not included |
| 1.5 Specific requirements for different types of applications |
| 1.5.1  | Literature based submissions | - | Not included |
| 1.5.2  | Amendments/Variations [[1]](#footnote-2) | See CTD | M1,V1 of 1 |
| 1.5.2.1  | Tabulated schedule of amendments | See CTD | M1,V1 of 1 |
| 1.5.2.2  | Medicines Register Details | See CTD | M1,V1 of 1 |
| 1.5.2.3  | Affidavit by Responsible Pharmacist | See CTD | M1,V1 of 1 |
| 1.5.3  | Proprietary name applications and changes | - | Not included |
| 1.5.4  | Genetically modified organisms | - | Not included |
| 1.5.5  | Clinical Package Insert and Patient Information Leaflet amendments/updates | - | Not included |
| 1.6 Environmental risk assessment |
| 1.6.1  | Non-GMO (genetically modified organisms) | - | Not included |
| 1.6.2  | GMO  | - | Not included |
| 1.7 Good manufacturing practice |
| 1.7.1  | Date of last inspection of each site | See CTD | M1,V1 of 1 |
| 1.7.2  | Inspection reports or equivalent document | See CTD | M1,V1 of 1 |
| 1.7.3  | Latest GMP certificate or a copy of the appropriate licence | See CTD | M1,V1 of 1 |
| 1.7.4  | Release | See CTD | M1,V1 of 1 |
| 1.7.4.1  | API | - | Not included |
| 1.7.4.2  | IPIs | - | Not included |
| 1.7.4.3  | Finished Product Release Control (FPRC) tests | See CTD | M1,V1 of 1 |
| 1.7.4.4  | Finished Product Release Responsibility (FPRR) criteria | See CTD | M1,V1 of 1 |
| 1.7.5  | Confirmation of contract | See CTD | M1,V1 of 1 |
| 1.7.6  | CPP (WHO Certification scheme) | - | Not included |
| 1.7.7  | Proof of current registration of the Responsible Pharmacist by the SAPC | See CTD | M1,V1 of 1 |
| 1.7.8  | Proof of current registration by the SAPC of the pharmacist signing the dossier  | See CTD | M1,V1 of 1 |
| 1.7.9  | Proof of registration of the Applicant/PHCR as a pharmacy or a pharmacist  | See CTD | M1,V1 of 1 |
| 1.7.10  | Sample and Documents | - | Not included |
| 1.7.10.1  | Confirmation of submission of sample | - | Not included |
| 1.7.10.2  | Batch manufacturing record of the sample | - | Not included |
| 1.7.10.3  | CoA of the sample | - | Not included |
| 1.7.11  | Certified copy of a permit to manufacture specified Schedule 5, Schedules 6, 7 and 8 substances. | - | Not included |
| 1.7.12  | Inspection flow diagram | See CTD | M1,V1 of 1 |
| 1.7.13  | Organogram | See CTD | M1,V1 of 1 |
| 1.8 | Details of compliance with screening outcomes | - | Not included |
| 1.9 | Individual patient data - statement of availability | - | Not included |
| 1.10 | Foreign regulatory status | - | Not included |
| 1.10.1 | List of countries in which an application for the same product as being applied for has been submitted | - | Not included |
| 1.10.2 | Registration certificate or marketing authorisation | - | Not included |
| 1.10.3  | Foreign prescribing and patient information  | - | Not included |
| 1.10.4 | Data set similarities | - | Not included |
| 1.11 | Bioequivalence trial information | - | Not included |
| 1.11.1 | Study Title(s) (or brief description giving design, duration, dose and subject population of each study) | - | Not included |
| 1.11.2 | Protocol and study numbers | - | Not included |
| 1.11.3 | Investigational products (test and reference) details | - | Not included |
| 1.11.4 | Confirmation that the test product formulation and manufacturing process is that being applied for | - | Not included |
| 1.11.5  | Proof of procurement of the biostudy reference product  | - | Not included |
| 1.11.6  | Name and address of the Research Organisation(s) / Contract Research Organisation(s) where the bioequivalence studies were conducted  | - | Not included |
| 1.11.7 | Sponsor and responsible sponsor representative: name and address, contact details | - | Not included |
| 1.11.8 | Duration of Clinical phase: dates of dosing and last clinical procedure | - | Not included |
| 1.11.9 | Date of final report | - | Not included |
| 1.12 | Paediatric development programme | - | Not included |
| 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 | Annexure 14 | See MBR1 |
| 2.5 | Clinical Overview | Annexure 15 | See MBR1 |
| 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[[2]](#footnote-3) | Summary of Biopharmaceutic Studies and Associated Analytical Methods [[3]](#footnote-4) | - | - |
| 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 | - | - |
| 2.7.3.2 | 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 | Annexure 3 | See MBR1 |
| 3.2 | Body of data |  |  |
| 3.2.S | Active Pharmaceutical Ingredient ***(Paracetamol, ABCD Manufacturers)***  | Annexure 3 | See MBR1 |
| 3.2.S.1  | General information ***(Paracetamol, ABCD Manufacturers)*** | Annexure 3 | See MBR1 |
| 3.2.S.1.1 | Nomenclature ***(Paracetamol, ABCD Manufacturers)*** | Annexure 3 | See MBR1 |
| 3.2.S.1.2 | Structure *(****(Paracetamol, ABCD Manufacturers)*** | Annexure 3 | See MBR1 |
| 3.2.S.1.3 | General Properties ***(Paracetamol, ABCD Manufacturers)*** | Annexure 3 | See MBR1 |
| 3.2.S.2 | Manufacture ***(Paracetamol, ABCD Manufacturers)*** | Annexure 3 | See MBR1 |
| 3.2.S.2.1 | Manufacturer(s) ***(Paracetamol, ABCD Manufacturers)*** | Annexure 3 | See MBR1 |
| 3.2.S.2.2 | 3.2.S.2.2 Description of Manufacturing Process and Process Controls ***(Paracetamol, ABCD Manufacturers)*** | Annexure 3 | See MBR1 |
| 3.2.S.2.3) | Control of Materials (***(Paracetamol, ABCD Manufacturers)*** | Annexure 3 | See MBR1 |
| 3.2.S.2.4  | Controls of Critical Steps and Intermediates (name, manufacturer) | Annexure 3 | See MBR1 |
| 3.2.S.2.5 | Process Validation and/or Evaluation (name, manufacturer) | Annexure 3 | See MBR1 |
| 3.2.S.2.6 | Manufacturing Process Development *(name, manufacturer*) | Annexure 3 | See MBR1 |
| 3.2.S.3 | 3.2.S.3 Characterisation *(name, manufacturer)* | Annexure 3 | See MBR1 |
| 3.2.S.3.1 | Elucidation of Structure and other Characteristics *(name, manufacturer)* | Annexure 3 | See MBR1 |
| 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. [↑](#footnote-ref-3)
3. [↑](#footnote-ref-4)