PERFECT CURE 500 mg (S0786)

EXAMPLE PHARMACEUTICALS (PTY) LTD TABLETS

 PARACETAMOL 500 mg

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| 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)