PERFECT CURE 500 mg (S0786)

EXAMPLE PHARMACEUTICALS (PTY) LTD TABLETS

PARACETAMOL 500 mg

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| 1.11.2 | Protocol and study numbers | | | - | Not included |
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| 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)