PERFECT CURE 500 mg (S0786)

EXAMPLE PHARMACEUTICALS (PTY) LTD TABLETS

PARACETAMOL 500 mg

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| 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)* | | | | |  |  | |  | | |  | | |
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| 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)* | | | | |  |  | |  | | |  | | |
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| 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 | |  |  | | | |  | | | | | | |
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| 4.2.1 | Pharmacology | | |  | | |  |  | | |  | | | | |
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| 4.2.2.7 | Other pharmacokinetic studies | | |  | | |  |  | | |  | | | | |
| 4.2.3 | Toxicology | | |  | | |  |  | | |  | | | | |
| 4.2.3.1 | Single-dose toxicity (in order by species, by route) | | |  | | |  |  | | |  | | | | |
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| 4.2.3.3 | Genotoxicity | | |  | | |  |  | | |  | | | | |
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| 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) | | |  | | |  |  | | |  | | | | |
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| 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 | | |  | | |  |  | | |  | | | | |
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| 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 | | |  | | |  |  | | |  | | | | |
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1. Amendments guideline [↑](#footnote-ref-2)
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