**PERFECT CURE 500 mg (S0786)**

**EXAMPLE PHARMACEUTICALS (PTY) LTD TABLETS**

 **PARACETAMOL 500 mg**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |  |  |  |
| --- | --- | --- | --- |
| **Annexures/ PARTs / Modules** | **Comparison between Annexures / PARTs / Modules** | **Reason for amendment** | **Reviewer’s comment** |
|  | Existing | Amended |  |  |
| *Example 1 is* ***not acceptable*** *– it will take longer to evaluate as the changes have not been identified for easy reference. The format of example 2 is recommended as evaluation is facilitated by the identification of the specific items.* |
| **Example 1**10 (b) | Stability report: XXX  | Stability report YYY replaces report XXX | Includes stability data on 2 batches stored for 36 months  |  |
| **Example 2**10 (b) | Pages 10.0, 10.1, 10.3.1Stability data on two production batches stored for 24 months at 25 ºC/60 % RH and for 3 months at 40 ºC/75 % RH submitted. | Pages 10.0, 10.2.1, 10.2.2, 10.3.1, 10.3.2Stability data on the same two production batches stored for 36 months at 25 ºC/60 % RH included. | Extension of the shelf-life to 36 months applied for. |  |
|  | No index in 10 (b), attached data only referred to. | Detailed index included in 10 (b) | Administrative update to facilitate review. |  |
| 10 (c) | Shelf-life of 24 months approved. | A discussion of the results is included and a 36 months’ shelf-life is inferred. | Extension of the shelf-life to 36 months applied for. |  |
| **Example 3****MODULE****3.2.P.3.2** | ANNEXURE 11Page 11.0.1 Batch Size and FormulationBatch Size: 300 000 tablets | MODULE 3.2.P.3.2Batch FormulaBatch sizes: 300 000 & 900 000 | Change to CTD format**Type B, Category 7:** Additional batch size applied for to deal with increased product demand.* Process Validation Protocol-Module 3.2.P.3.5 page 10
* Stability (a) will be submitted as soon as 12 months data available
 |  |

**4 I declare that**

* **the amendments are in line with the relevant current guidelines and/or a motivation for any deviation has been submitted**
* **no amendments, other than those stated in the list of changes/amendments, have been made.**

**A Responsible**

Signature of HCR/applicant or delegate

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Name** | **Title** | **Qualification** | **Designation** | **e-mail** | **Tel number** |
| **A Responsible** | **Mr** | **B.Pharm** | **Responsible Pharmacist** | **respa@example.co.za** | **012 345 6789** |