PRODUCT: REF:

*(Supporting documents should be appropriately numbered and referenced).*

1. **FINISHED PRODUCT**
   1. Description (physical characteristics):
   2. Composition (complete formula)
   3. Active ingredient

|  |  |  |  |
| --- | --- | --- | --- |
| Active ingredient: |  | Content |  |
|  |  |  |  |
|  |  |  |  |

1. Other ingredients (adjuncts, exicipents, preservative, colour, flavour, etc):

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Name of other ingredients |  | Content | |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

1. Packing or pack size (brief):
2. **MANUFACTURE OF PRODUCT**

*(Enclose the product in an envelope marked* ***‘CONFIDENTIAL’,*** *if desired.*

*If so indicate here, with appropriate reference).*

1. Complete batch manufacturing master formula:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Name of ingredients (active and otherwise) |  | Quantities used per batch | |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

1. Manufacturing process:

*(Provide a brief description and the principles of the process).*

1163

**3. QUALITY CONTROL**

1. State whether quality control is done in part or solely by the quality control department of the manufacturer or in an external laboratory.
2. If quality control tests are done by an external laboratory, indicate:
   1. The name and address of the laboratory;
   2. The tests done by the external laboratory;
   3. Why the tests are not done by the manufacturer.
3. Specifications for the active and other ingredients

|  |  |  |  |
| --- | --- | --- | --- |
|  |  | Source (state whether | Manufacturer and |
| Name of ingredient | Specifications | B.P or U.S.P or |
| country of origin |
|  |  | manufacturer’s) |
|  |  |  |
|  |  |  |  |
|  |  |  |  |

1. In- process quality control:

Tests performed during manufacturing process and sampling protocols:

|  |  |  |  |
| --- | --- | --- | --- |
| Tests | Stage at which test is | Frequency of | Quality of sample |
| done | sampling | taken each time |
|  |
|  |  |  |  |
|  |  |  |  |

1. Finished product quality control:

Tests and specification limits (check and release specifications):

|  |  |  |
| --- | --- | --- |
| Test | Acceptance limits | Release for test method and Limits (B.P. or |
| U.S. For manufacturers) |
|  |  |
|  |  |  |

The certificate of analysis to be certified by quality assurance manager.

Certificate of analysis of recent batch of product (minimum 1 batch) enclosed: [ ]

1. **STABILITY OF PRODUCT**:
   1. Storage condition must be included on the label.
   2. Proposed shelf life of product:

*(Where the extension of the shelf life for a clinical trial material is required, the manufacturer shall provide data to support the extension and data in the form of retest results shall be considered).*

1164

1. **STABILITY STUDIES**
2. Completed stability studies or accelerated stability studies.

*(provide a summary of the stability studies, characteristics and degradation products monitoring results and conclusions of completed stability studies)*. Results of studies of at least one batch are required.

1. On-going or proposed stability studies.

(Outline of on-going or proposed stability studies).

1. **CONTAINERS AND PACKAGING**
   1. Description of the immediate (primary) containers or packaging:
      1. Type
      2. Material
      3. Capacity, where applicable
      4. Closure and liner (type and material), where applicable.
2. Description of outer container or packaging
3. Dose-measuring device, applicators and administration set, if any:
   1. Description or type
   2. Material
   3. Capacity, where applicable
4. Packaging inclusions (such as desiccant and fillers) if any: Description and compositions
5. Is there any known interaction between the product and packaging material? (Yes or No); if yes, specify.
6. **LABELLING (Refer to Attachment 3).**

**Enclose samples or proposed drafts of the following:**

* 1. Label for immediate package or container of product
  2. Label for outer package or container of product
  3. Original package insert for comparator drug