|  |  |
| --- | --- |
| New application |  |
| Renewal  application |  |
| Re – Registration |  |



|  |  |
| --- | --- |
| Foreign | √ |
| Local |  |

# NATIONAL MEDICINES REGULATORY AUTHORITY SRI LANKA.

**120, Norris Canal Road, Colombo 10, Sri Lanka.**

**Telephone: +94 011 2698896/7 Fax: +94 011 2689704** [**email:info@nmra.gov.lk**](mailto:info@nmra.gov.lk)

**ASSESSMENT FORM OF REGISTRATION APPLICATION**

**BORDERLINE PRODUCTS**

1. 1.1 Application Number:

1.2 Letter from the market authorization holder/ local agent: Yes/No

1.3 Declaration form attached: Yes/No

1.4 Availability of samples: Yes/No

1. Name and address of the Applicant:
2. Date of submitting the application to the NMRA:
3. Date of Evaluation:
4. Classification Report Number:
5. Formulation Approval Number and date of issue (only for local manufacturers)
6. Sample Import Licence (Only for foreign manufactures):
7. Whole Sale Licence:
8. Valid authorization letter:
9. **Details of the Borderline Product**

|  |  |  |
| --- | --- | --- |
| Brand name |  | |
| Product name |  | |
| Is the Brand Name already registered with NMRA | Yes/ No (circle the correct response) | |
|  | Borderline Product |  |
| Medical Device |  |
| Medicine |  |
| Cosmetic |  |
| Other |  |
| Specify if other |  |
| Route of Administration (If applicable) |  | |
| Dosage Form (If applicable) |  | |
| Comments | | |

1. **Details of the Manufacturer**

|  |  |  |  |
| --- | --- | --- | --- |
| Type of Manufacturer | Local | Foreign | |
| Name |  | | |
| Site address |  | | |
| Official address | | Yes | No |
| Manufacturing site approval by NMRA |  |  |  |
| Valid GMP certificate from country of  origin |  |  |  |
| Status of Manufacturer | (a) Actual Manufacturer | (b) License  Holder | (c) Other |
| If (b) or (c) any other address of  manufacturing site |  | | |
| Comments | | | |

1. **Certificate of Pharmaceutical Product (COPP) / Free Sale Certificate (FSC) (**Insert “√ “ where necessary)

|  |  |  |  |
| --- | --- | --- | --- |
| Type of Manufacturer (Foreign) | | | |
| Issuing body of COPP/Free Sale Certificate | |  | |
|  | Yes | | No |
| Original (COPP/ Free Sale Certificate (FSC) present |  | |  |
| WHO Format ( If applicable) |  | |  |
| Product name is present |  | |  |
| Certificate Number |  | |  |
| Valid Period |  | |  |
| Date of Issue |  | |  |
| Valid at the point of submission |  | |  |
| Product is registered in the country of manufacture |  | |  |
| Product is marketed in the country of manufacture |  | |  |
| Address is tally with authorization letter |  | |  |
| Comments | | | |

1. **GMP details for manufacture (Foreign / Local )**

|  |  |  |
| --- | --- | --- |
|  | Yes | No |
| GMP certificate is available (if applicable) |  |  |
| Name & address of issuing body |  |  |
| ISO certificate (if applicable) |  |  |
| Valid at the point of submission |  |  |
| Manufacturer name & address are present |  |  |
| Manufacturer name and address tally with authorization letter |  |  |
| Manufacturer name and address tally with address in COPP/ Free Sale  Certificate |  |  |
| Product name is included in the approved product list (if applicable) |  |  |
| Comments: | | |

1. **Manufacturing License details (if applicable only)**

|  |  |  |
| --- | --- | --- |
|  | Yes | No |
| Manufacturing license is available |  |  |
| Name & address of the issuing body |  |  |
| Valid at the point of submission |  |  |
| Manufacturer name & address are present |  |  |
| Manufacturer name and address tally with authorization letter |  |  |
| List of products is attached |  |  |
| Comments: | | |

1. **Formulation details**

|  |  |  |
| --- | --- | --- |
|  | Yes | No |
| Brand name/Product name is available including dosage form |  |  |
| Master formula is given (per unit dose) |  |  |
| Batch Manufacturing formula is given |  |  |
| Description of manufacturing process |  |  |
| Specifications are given for API/ Active ingredients and all ingredients |  |  |
| Functions of all ingredients |  |  |
| Units of the active ingredients given as per the NMRA guideline |  |  |
| Are the units/values within authorized concentration or limits? |  |  |
| Comments: |  |  |

1. **Quality control data**

|  |  |  |  |
| --- | --- | --- | --- |
| **16.1 Active Pharmaceutical Ingredients (API)/ Active Ingredients** | | | |
| Specification is stated (BP/USP/IP/EP or In-House) | Yes | No | Accepted |
| Manufacture/s names mentioned in the certificates |  |  |  |
| Test results comply with the given specification |  |  |  |
| Conclusion is given |  |  |  |
| Valid GMP certificates with approved product list for all active ingredients |  |  |  |
| Specification is stated (BP/USP/IP/EP or In-House) |  |  |  |
| Comments: |  |  |  |
| **16.2 COA of Excipients (If applicable only)** | | |  |
| Specification is stated (BP/USP/IP/EP or In-House) |  |  |  |
| Manufacture/s names mentioned in the certificates |  |  |  |
| Test results comply with the given specification |  |  |  |
| Conclusion is given |  |  |  |
| Comments: |  |  |  |
| **16.3** **COA of Finished Products** | | | |
| Original COA is attached |  |  |  |
| Specification is stated (BP/USP/IP/EP or In-House) |  |  |  |
| Assay values present (APIs or Active ingredients) |  |  |  |
| Heavy metals test results available (If applicable) |  |  |  |
| Test results comply with the given specification |  |  |  |
| Conclusion is given |  |  |  |
| Endorsement of authorized officers present |  |  |  |
| Finish products test methods present |  |  |  |
| For In-House specification-analytical report attached (if applicable only) |  |  |  |
| Comments | | |  |

1. **Manufacturing Process Validation (If applicable only)**

|  |  |  |
| --- | --- | --- |
|  | Yes | No |
| Summery |  |  |
| Valid batch size (commercial batch size) used for validation |  |  |
| Three commercial/ consecutive batches used |  |  |
| Manufacturing Equipment |  |  |
| Critical Process step & Parameters  (Tablet/Capsule/ Cream/ Other) |  |  |
| Tabulation of the test result |  |  |
| Batch Analysis |  |  |
| Evaluation of data & where applicable, statistical process control analysis |  |  |
| Conclusion & Recommendation |  |  |
| Comments | | |

1. **Analytical validation report (If applicable only)**

|  |  |  |
| --- | --- | --- |
| Evaluation of analytical validation (Only for in house specification) | Yes | No |
| Chromatographic mode provided |  |  |
| Specificity |  |  |
| Linearity |  |  |
| Range |  |  |
| Accuracy |  |  |
| Precision |  |  |
| Robustness |  |  |
| Detection limit |  |  |
| Quantification Limit |  |  |
| System suitability |  |  |
| Date on reference standards |  |  |
| Comments |  |  |

1. **Original Stability data (if applicable only)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | | | Yes | No |
| Stability Protocol attached | | |  |  |
| Data for three commercial batches | | |  |  |
| Immediate Pack type & pack size | | |  |  |
| Discussion & Conclusion | | |  |  |
| Endorsement of authorized officers present | | |  |  |
| Stability Information details | | [ ]Physical test  [ ]Chemical Test  [ ]Microbiological Test | | |
| Claimed Shelf Life |  | Recommended Storage Condition |  | |
| Stability Data after reconstitution (If applicable) | | |  |  |
| Stability Data for diluent Solvent (If applicable) | | |  |  |
| Type of Study | | Real time | Accelerated | |
| Temperature & relative humidity | |  |  | |
| Intervals & periods of Testing | |  |  | |
| Comments | | | | |

1. **Container closure system & packaging**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | | | Yes | No |
| Details of the container | | |  |  |
| Description of outer packaging | | |  |  |
| Availability package insert | | |  |  |
| COA s of packages | | |  |  |
| Pack size | | |  |  |
| Pack type | Primary pack | |  |  |
| Secondary pack | |  |  |
| Inclusion | Dropper | Measuring Device | Solvent  Pack | Other |
| Availability of PIL |  | |  |  |
| Comments |  | |  |  |

1. **Product Information Leaflet**

|  |  |  |
| --- | --- | --- |
|  | Yes | No |
| Original PIL is attached to the dossier |  |  |
| Brand Name |  |  |
| Product name |  |  |
| API or Active ingredients included |  |  |
| Strength (if applicable) |  |  |
| Product description |  |  |
| Indication |  |  |
| Dose & direction |  |  |
| Special warnings/ precautions |  |  |
| Treatment for overdose |  |  |
| Treatment on pregnancy & Lactation |  |  |
| Treatment on special conditions |  |  |
| Contraindication |  |  |
| Adverse effects |  |  |
| Overdose treatment |  |  |
| Storage condition |  |  |
| Name & Address of manufacturer |  |  |
| Marketing Authorization holder |  |  |
| Date of revision of package Insert |  |  |
| Comments |  |  |

1. **Patient Information Leaflet (if applicable only)**

|  |  |  |
| --- | --- | --- |
|  | Yes | No |
| Original PIL is attached to the dossier |  |  |
| Provided in three language (English, Tamil, Sinhala) |  |  |
| Brand Name |  |  |
| Product name |  |  |
| API or Active ingredients included |  |  |
| Strength (if applicable) |  |  |
| Product description |  |  |
| Indication |  |  |
| Dose & direction |  |  |
| Special warnings/ precautions |  |  |
| Side effects |  |  |
| Storage condition |  |  |
| Name & Address of manufacturer |  |  |
| Marketing Authorization holder |  |  |
| Comments | | |

1. **Product registration in other countries**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| No | Country | Registered | | Marketed | | Classification |
| Yes | No | Yes | No |
| 1 | Australia |  |  |  |  |  |
| 2 | Canada |  |  |  |  |  |
| 3 | European Union(EU) |  |  |  |  |  |
| 4 | Japan |  |  |  |  |  |
| 5 | New Zealand |  |  |  |  |  |
| 6 | Singapore |  |  |  |  |  |
| 7 | UK |  |  |  |  |  |
| 8 | USA |  |  |  |  |  |
| 9 | Malaysia |  |  |  |  |  |
| 10 | Thailand |  |  |  |  |  |
| 11 | Any Other |  |  |  |  |  |
| Comments | | | | | | |

1. **Details of the Efficacy Data (If applicable only)**

|  |  |  |
| --- | --- | --- |
|  | Yes | No |
| Published reports |  |  |
| Detail Clinical trial report for the product |  |  |
| Comments | | |

1. **Labeling**

|  |  |  |
| --- | --- | --- |
|  | Yes | No |
| Brand name |  |  |
| Product name |  |  |
| Dosage Form |  |  |
| A list of APIs or active ingredients with amount per unit dose |  |  |
| Net Content/ Weight/ Volume |  |  |
| The Batch number |  |  |
| The Manufacturing date |  |  |
| The Expiry date |  |  |
| Storage Condition |  |  |
| Warning Statement/ Precaution (If applicable) |  |  |
| Direction for use (If applicable) |  |  |
| Claims if applicable |  |  |
| Name & Address of the Manufacturer |  |  |
| Name & Address of the Importer |  |  |
| Special labeling requirement |  |  |
| Comments | | |

1. **Promotional materials (if applicable only)**

|  |  |  |
| --- | --- | --- |
|  | Yes | No |
| Brand Name |  |  |
| Product name |  |  |
| API or Active ingredients included |  |  |
| Strength (if applicable) |  |  |
| Product description |  |  |
| Name & Address of manufacturer |  |  |
| Marketing Authorization holder |  |  |
| Indications/Claims |  |  |
| Comments | | |

**27. Other (if applicable only)**

|  |  |  |
| --- | --- | --- |
| Maximum retail price in LKR per unit dose | Yes | No |
| Post market sales volumes in country of origin |  |  |
| Post market sales volumes in Sri Lanka |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| Evaluation Comments: | | | |
| Recommendation |  | Schedule |  |
| Date: |  | Signature & P code |  |