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

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

****

***ASSESSMENT FORM OF REGISTRATION APPLICATION- BORDERLINE PRODUCTS***

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1. Application Number:
2. Name and address of the Applicant:
3. Date of submitting the application to the NMRA:
4. Date of Evaluation:
5. Classification Report Number:
6. Formulation Approval Number and date of issue (only for local manufacturers)
7. Sample Import Licence (Only for foreign manufactures):
8. Whole Sale Licence:
9. Authorization letter:
10. 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 |  |
| Food |  |
| Cosmetic |  |
| Other |  |
| Specify if other |  |
| Route of Administration (If applicable) |  |
| Dosage Form (If applicable) |  |
| Comments |

 |
|  11. 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 | 1. Physical Manufacturer
 | 1. License Holder
 | 1. Other
 |
| If (b) or (c) any other address of manufacturing site |  |
| Comments |

12. Details of the manufacturer (Insert “√ “ where necessary)

|  |  |
| --- | --- |
| Type of Manufacturer | Foreign |
| Certificate of Pharmaceutical Product (COPP) / Free Sale Certificate |
| Issuing body of COPP/Free Sale Certificate |  |
|  | Yes | No |
| Original (COPP/ Free Sale Certificate) 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 |

13. GMP details for foreign 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: |

14. 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: |

15. 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 |  |  |
| 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: |

16. Quality control data (If applicable)

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes | No | Accepted |
|  COA /s of all active ingredients  |  |  |  |
| 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 |  |  |  |
| Valid GMP certificates with approved product list for all active ingredients |  |  |  |
| Comments: |  |  |  |
| COA of Excipients  |  |
| 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: |  |  |  |
|  COA of Finished Products  | Yes | No |  |
| 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 |  |  |  |
| For In-House specification-analytical report attached (if applicable only) |  |  |  |
| Comments |  |

17. Manufacturing Process Validation (If applicable)

|  |  |  |
| --- | --- | --- |
|  | 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 |

18. 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  |

19.Original Stability data (if applicable)

|  |  |  |
| --- | --- | --- |
|  | 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 |

20. 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 |  |  |  |

21. Product Information Leaflet (if applicable only)

|  |  |  |
| --- | --- | --- |
|  | 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 |

22. Patient Information Leaflet

|  |  |  |
| --- | --- | --- |
|  | 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 |

23.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 |

24. Details of the Efficacy Data (If applicable)

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

25. 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 |

26. Promotional materials

|  |  |  |
| --- | --- | --- |
|  | 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

|  |  |  |
| --- | --- | --- |
| 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 |  |  |
| PA |  |  |

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

 |
|  |