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