**National Medicines Regulatory Authority, Sri Lanka**

Checklist for Accepting Registration Applications of Drug Products

Application No:

Product Name:

Brand Name:

Manufacturer:

Manufacturing Country:

Applicant:

Receipt attached: Yes/No

Date of submission:

Product Type: BTP/Vaccine/Blood Product/Other biological

Application Type: NME/NDF/NFDC/New/RR

Number of Volumes:

Page numbered both ways: Yes/No

\*\*\* All following documents are mandatory for accepting the application.

Part I – Administrative Documents

|  |  |  |
| --- | --- | --- |
| Document | Submitted | Remarks |
| 1.Comprehensive table of content (Index) | Yes/No |  |
| 2.Application form signed by authorized person ~~(~~Schedule I) | Yes/No |  |
| 3.Letter of Authorization from the manufacturer1 | Yes/No |  |
| 4.Copy of Company Profile approval letter/GMP certificate or report2 | Yes/No |  |
| 5.Copy of sample import license / copy of formulation approval3/ Copy of previous registration | Yes/No |  |
| 6.COPP (Original)  Addressed specifically to Sri Lanka.  Valid4  Product licensed in country of origin5  Explanatory notes  Signed by a designated person | Yes/No  Yes/No  Yes/No  Yes/No  Yes/No  Yes/No |  |
| 7. Price details | Yes/No |  |

Part II – Quality Documents

|  |  |  |
| --- | --- | --- |
| Document | Submitted | Remarks |
| 1. Original COA for finished Product. | Yes/No |  |
| 2. Copy of valid GMP certificate/s with the approved API list of the API manufacturer/s | Yes/No |  |
| 3.COA/s of API/s | Yes/No |  |
| 4.Master Formula | Yes/No |  |
| 5.Completed Real time stability data6 for minimum three batches | Yes/No |  |
| 6.BE study report/comparative dissolution report | Yes/No |  |
| 7.Specimen labels | Yes/No |  |
| 8. Specimen PIL | Yes/No |  |

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Signature & P code of the accepting pharmacist Date of acceptance

Explanatory Notes

1. Not applicable for local manufacturing products.
2. Company profile approval letter is mandatory for foreign manufacturing products and GMP certificate or report is mandatory for local manufacturing products.
3. Copy of sample import license is for foreign manufacturing products and formulation approval is for local manufacturing products.
4. Most countries do not specify a validity period. In such instances, date of issue should not be earlier than 2 years from the date of submission.
5. If not licensed in country of origin, dossier may be accepted for evaluation if a strong justification is provided.
6. Ongoing real time stability data for six months with accelerated stability data for six months shall be accepted for the local manufacturing products.