**National Medicines Regulatory Authority, Sri Lanka**

Checklist for Accepting Registration Applications of Borderline Products

Application No :

Product Name :

Brand Name :

Manufacturer :

Manufacturing country :

Applicant :

Receipt attached : Yes / No

Date of submission :

Classification file No :

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.Two copies of acknowledgment | Yes/No |  |
| 3.Request letter from the applicant | Yes/No |  |
| 4.Preliminary Evaluation Report | Yes/No |  |
| 5.Sample Import License / Formulation approval1 | Yes/No |  |
| 4.Letter of Authorization from the manufacturer2 | Yes/No |  |
| 6.Free sale certificate / COPP  Valid3  Freely sold in country of origin  Issued by Health/Drug or Food Authority4  If submit the COPP5 | Yes/No |  |

Part II – Quality Documents

|  |  |  |
| --- | --- | --- |
| **Document** | **Submitted** | **Remarks** |
| 1.Original COA for finished product | Yes/No |  |
| 2.Copy of valid GMP certificate | Yes/No |  |
| 3.Copy of valid Manufacturing license | Yes/No |  |
| 4.Product master formula | Yes/No |  |
| 5.COA/s of API/s | Yes/No |  |
| 4.Copy of valid GMP certificate/s with the approved API list of the API manufacturer/s | Yes/No |  |
| 6.Completed original Real time and Accelerated Stability data for three batches | Yes/No |  |
| 7.Specimen labels | Yes/No |  |
| 8.Specimen PIL/PtIL | Yes/No |  |

\*\*\*Only files with cover page and covered with red tape will be accepted.

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Signature & P code of the accepting pharmacist Date of acceptance

Explanatory Notes

1. Sample Import License for imported products and Formulation approval for locally manufactured products
2. Not applicable for local manufacturing products
3. 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.
4. If FSC is issued by Ministry of Commerce or Industry, GMP certificate and Manufacturing License need to be submitted.
5. Valid, addressed specifically to Sri Lanka, product licensed in country of origin, explanatory notes, signed by a designated person are mandatory requirements.