**National Medicines Regulatory Authority, Sri Lanka**

Checklist for Accepting Classification Applications of Borderline Products

Application No :

Product Name :

Brand Name :

Manufacturer :

Manufacturing country :

Applicant :

Receipt attached : Yes / No

Date of submission :

Page numbered both ways : Yes/No

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

|  |  |  |
| --- | --- | --- |
| **Document** | **Submitted** | **Remarks** |
| 1.Comprehensive table of content (Index) | Yes/No |  |
| 2.Two copies of Acknowledgment |  |  |
| 3.Request letter from the applicant | Yes/No |  |
| 4.Letter of Authorization from the manufacturer1 | Yes/No |  |
| 5.Product Master Formula | Yes/No |  |
| 6.Free sale certificate / COPP  Valid2  Freely sold in country of origin  Issued by Health/Drug or Food Authority3  If submit the COPP4 | Yes/No |  |
| 7.COA for finished product | Yes/No |  |
| 8.Legible Label / Promotional materials | Yes/No |  |
| 9.PIL / PtIL | Yes/No |  |

\*\*\*Only files with cover page will be accepted.

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Signature & P code of the accepting pharmacist Date of acceptance

Explanatory Notes

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