**National Medicines Regulatory Authority, Sri Lanka**

**Checklist for Accepting Registration Applications of Drug Products**

Fill by the regulatory officer of the applicant before the issuing of payment

Generic Name of the Product:

Brand Name:

Name and address of the Manufacturer:

Name and address of the Applicant:

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. At the accepting point only check the availability of such documents.**

Part I – Administrative Documents

| Document | Page number | Availability | Remarks |
|---|---|---|---|
| 1. Comprehensive table of content (Index) | | | |
| 2. Application form signed by authorized person (Schedule I) | | | |
| 3. Letter of Authorization from the manufacturer[1] | | | |
| 4. Copy of Company Profile approval letter / GMP certificate or report[2] | | | |
| 5. Copy of sample import license / copy of formulation approval[3] / Copy of previous registration | | | |
| 6. COPP (Original) | | | |
| 7. Price details | | | |

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.

Part II – Quality Documents

| Document | Page Number | Availability | Remarks |
|---|---|---|---|
| 1. Original COA for finished Product. | | | |
| 2. Copy of valid GMP certificate/s and the approved API list of the API manufacturer/s with Drug Master File (DMF) of API/s | | | |
| 3.COA/s of API/s | | | |
| 4.Master Formula | | | |
| 5.Completed Real time stability data[1] for minimum three batches | | | |
| 6.BE study report / comparative dissolution report | | | |
| 7.Specimen labels | | | |
| 8. Specimen PIL | | | |

1. Ongoing real time stability data for six months with accelerated stability data for six months shall be accepted for the local manufacturing products.
2. Which are in priority list published in website. For other locally manufactured products accelerated stability data for six months may be considered on request by the local manufacturer individual basis.

 Page numbers column of the above tables should be filled by regulatory officer of the applicant. 

Availability column of the above tables should be ticked by the accepting officer of the NMRA.

Payment receipt number:…… Date:……

…….

Signature,

Name

Designation of the applicant

Date:

Application number:

Date of submission:

……..

Signature,

Name

Designation of the accepting officer.

Date: