APPLICATION NUMBER:

APPLICATION DATE:

TRADE NAME:

APPROVED GENERIC NAME(S) (INN if any):

STRENGTH(S) PER DOSAGE UNIT:

DOSAGE FORM:

RECEIVED DATE:

FIRST GENERIC (New Product in Bangladesh)

GENERIC (Existing Product in Bangladesh)

AMENDMENT TO LICENCE #

LOCAL MANUFACTURER

IMPORTER

PAPER SUBMISSION: TYPE II DMF # (if any):

APPLICANT NAME:

APPLICANT ADDRESS:

APPLICANT POINT OF CONTACT/POSITION:

APPLICANT TELEPHONE/FAX NUMBER:

APPLICANT EMAIL ADDRESS:

ADMINISTRATIVE PART REVIEWER: OVERALL ADMINISTRATIVE PART RESULT:

DATE: **SATISFACTORY** **UNSATISFACTORY**

**MODULE 1 ADMINISTRATIVE AND PRESCRIBING INFORMATION EXECUTIVE SUMMARY**

**Write a brief summary of the result and outcome.**

**SUMMARY OF PRODUCT INFORMATION**

|  |  |  |  |
| --- | --- | --- | --- |
| **Generic name of the pharmaceutical product** |  | | |
| **Trade name of the pharmaceutical product** |  | | |
| **International non-proprietary name(s) of the active pharmaceutical ingredient(s) (API(s)), including form (salt, hydrate, polymorph), if available** |  | | |
| **For domestic site, has the applicant provided a copy of a current and satisfactory site license issued by DGDA? Or from WHO, USFDA, MHRA, TGA, EU, Canada, PIC/s country** |  | | |
| **Applicant name and address** |  | | |
| **Dosage form** |  | | |
| **Reference Number(s)** |  |  |  |
| **Strength(s)** |  |  |  |
| **Route of administration** |  | | |
| **Proposed indication(s)** |  | | |
| **Contact information** | Name:  Phone:  Fax:  Email: | | |

**Reviewer’s Comments:**

**ADMINISTRATIVE INFORMATION**

1. **GMP Certification**

Volume & Page(s):

**Has the applicant provided the copy of latest (not older than three years) GMP certificate for manufacturer/s, packer/s and FPRCs or a copy of appropriate license?**

**Has the applicant provided inspection reports or equivalent document (not older than three years) from the Health Authorities of either DGDA, USFDA, MHRA, TGA, EU, Canada, PIC/S country, at each site as well as the date of last inspection of each site?**

**Detailed Applicant Response:**

**Reviewer’s Response:**

Is the information in this section of the application satisfactory? Yes No

If ‘No’ please write reasons:

Other Comments:

**Has the applicant provided the GMP documents required by the inspectorate? Including;**

**1.7.4 Batch release procedures**

**1.7.4.1 Active pharmaceutical ingredients**

**1.7.4.2 Inactive pharmaceutical ingredients**

**1.7.4.3 Finished Product Release Control (FPRC) tests**

**1.7.4.4 Finished Product Release Responsibility (FPRR) criteria**

**1.7.5 Confirmation of contract**

**1.7.6 Certificate of a Pharmaceutical Product (CPP); WHO certification scheme if**

**applicable**

**1.7.7 Proof of current registration of the Responsible Pharmacist**

**1.7.8 Sample and Documents**

**1.7.8.1 Confirmation of submission of the sample**

**1.7.8.2 Batch manufacturing record of the sample**

**1.7.8.3 Certificate of Analysis (CoA) of the sample**

**1.7.9 Certified copy of permit to manufacture**

**1.7.10 Inspection flow diagram (self-inspection)**

**1.7.11 Organogram**

* **Has the applicant provided Certificate of Pharmaceutical Product (CPP) issued by competent Authorities in the exporting country? Is the CPP valid and authenticated by the Bangladesh Embassy?**

**Detailed Applicant Response:**

**Reviewer’s Response:**

Is the information in this section of the application satisfactory? Yes No

If ‘No’ please write reasons:

Other Comments:

1. **Foreign Regulatory Status**

Volume & Page(s):

**List the countries in which this product has been granted a marketing authorization, together with any restrictions on sales or distribution.**

**Has the applicant provided copies of the product marketing authorization certificates (Free Sales Certificate, Sales Certificates from at least 2 other developing countries) in other countries where the product is available?**

**List any countries in which the product has been withdrawn from the market, or where an application for marketing has been rejected, deferred or withdrawn, and the reason:**

**Detailed Applicant Response:**

**Reviewer’s Response:**

Is the information in this section of the application satisfactory? Yes No

If ‘No’ please write reasons:

Other Comments:

**Has the applicant provided the proof or information of agency agreement including name, address, and signature of manufacturer’s authorized agent in Bangladesh?**

**Has the applicant provided the estimated market of the product/product group in Bangladesh including proposed prices for the product in Bangladesh?**

**Detailed Applicant Response:**

**Reviewer’s Response:**

Is the information in this section of the application satisfactory? Yes No

If ‘No’ please write reasons:

Other Comments:

**Has the applicant provided the foreign prescribing and patient information if the marketing authorization has been granted by other Health Authorities?**

**Has the applicant provided explanation on the similarities/differences in the data packages submitted in other countries?**

**Detailed Applicant Response:**

**Reviewer’s Response:**

Is the information in this section of the application satisfactory? Yes No

If ‘No’ please write reasons:

Other Comments:

1. **Pharmacovigilance Plan**

Volume & Page(s):

**Has the applicant provided full details of the information on pharmacovigilance? Including;**

* **Proof that the applicant has the services of a qualified person responsible for pharmacovigilance**
* **Proof that the applicant has the necessary means for the notification of any adverse reaction occurring either in the Community or in a third country**
* **Is the description of the applicant’s pharmacovigilance system follow the requirements and format as DGDA’s adverse drug events guidelines available on the website?**

**Detailed Applicant Response:**

**Reviewer’s Response:**

Is the information in this section of the application satisfactory? Yes No

If ‘No’ please write reasons:

Other Comments:

1. **Interchangeability**

Volume & Page(s):

**Has the applicant provided satisfactory information or arguments regarding the interchangeability of the product with existing brands in relation to quality, stability, therapeutic equivalence, product information and labelling?**

**If the applicant has submitted bioequivalence studies, were these conducted in a reliable facility and using the appropriate comparator product?**

**Has the applicant discussed the sensitizing potential of any new excipients in the new formulation?**

**Summarize the applicant’s conclusions and indicate whether you agree.**

**Detailed Applicant Response:**

**Reviewer’s Response:**

Is the information in this section of the application satisfactory? Yes No

If ‘No’ please write reasons:

Other Comments:

**Price Information**

Volume & Page(s):

**Has the applicant provided data how they calculated proposed maximum retail price (MRP)/Indicative price? Including the estimated price / dose / day treatment and cost of the recommended course of treatment for the medicine should be provided by the manufacturer.**

**Detailed Applicant Response:**

**Reviewer’s Response:**

Is the information in this section of the application satisfactory? Yes No

If ‘No’ please write reasons:

Other Comments:

**PRESCRIBING INFORMATION**

1. **Package Insert**

Volume & Page(s):

**Has the applicant provided copy of the package insert and/or information that are intended for distribution with the product to the patient and/or prescribers?**

**Does the package insert have the following information?**

1. Product name
2. Name and strength of Active Ingredient(s)
3. Product description
4. Pharmacokinetics / pharmacodynamics
5. Indication
6. Recommended dose
7. Mode of administration
8. Contraindication
9. Warnings and Precautions
10. Interactions with other Medications
11. Pregnancy and lactation
12. Undesirable effects
13. Overdose and treatment
14. Storage condition
15. Dosage forms and packaging available
16. Name and address of Manufacturer / Marketing Authorization Holder
17. Date of Revision of Package Insert

**If the copy of package insert has been provided, are there consistent with the current DGDA Guideline for Product Information on Packaging Materials?**

**Detailed Applicant Response:**

**Reviewer’s Response:**

Is the information in this section of the application satisfactory? Yes No

If ‘No’ please write reasons:

Other Comments:

1. **Patient Information Leaflet (PIL)**

Volume & Page(s):

**Has the applicant provided copy of the Patient Information Leaflet (PIL) and/or information that are intended for distribution with the product to the patient?**

**Does the package insert have the following information?**

1. Name of product
2. Description of product
3. What is the medicine
4. Strength of the medicine
5. What is the medicine used for?
6. How much and how often should you use this medicine?
7. When should you not take this medicine?
8. Undesirable effects
9. What other medicine or food should be avoided whilst taking this medicine?
10. What should you do if you miss a dose?
11. How should you keep this medicine?
12. Signs and symptoms of over dosage
13. What to do when you have taken more than the recommended dosage?
14. Name / logo of manufacturer / importer / Marketing Authorisation Holder
15. Care that should be taken when taking the medicine?
16. When should you consult your doctor?
17. Date of Revision of PIL

**If the copy of the Patient Information Leaflet has been provided, are there consistent with the current DGDA Guideline for Product Information on Packaging Materials?**

**Detailed Applicant Response:**

**Reviewer’s Response:**

Is the information in this section of the application satisfactory? Yes No

If ‘No’ please write reasons:

Other Comments:

1. **Labels (outer and inner)**

Volume & Page(s):

**Has the applicant provided a specimen or mock-up of the labelling for Unit Carton and Inner Label?**

**Does the Labelling for Unit Carton and Inner Label have the following information?**

1. Product name

2. Dosage form

3. Name of Active Ingredient(s)

4. Strength of Active Ingredient(s)

5. Batch number

6. Manufacturing date

7. Expiration date

8. Route of administration

9. Storage condition

10. Registration number

11. Name and address of Marketing Authorization Holder / or Product Owner

12. Name and address of manufacturer

13. Special Labeling (if applicable) eg. Sterile, external use, cytotoxic, alcohol content

14. Warning (if applicable)

15. Pack sizes (Unit/volume)

**Does the Labelling for Blister/Strips have the following information?**

1. Product name
2. Name of Active Ingredient
3. Strength of Active Ingredient
4. Batch Number
5. Expiration date
6. Name / Logo of manufacturer / Product owner / Marketing Authorisation Holder
7. Country’s registration number

**Detailed Applicant Response:**

**Reviewer’s Response:**

Is the information in this section of the application satisfactory? Yes No

If ‘No’ please write reasons:

Other Comments: