**FOR COMPLETENESS AND ACCEPTABILITY OF A DOSSIER**

APPLICATION NUMBER:

APPLICANT:

DRUG NAME:

DOSAGE FORM:

APPLICATION DATE:

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):

**BASIS FOR SUBMISSION**

GENERIC/TRADE NAME:

COMPANY NAME:

INNOVATOR PRODUCT NAME/COMPANY:

REGULATORY SCREENER: RECOMMENDATION:

DATE **FILE** **REFUSE TO RECEIVE**

**COMMENTS**

THERAPEUTIC CLASS:

THERAPEUTIC CODE:

**ADDITIONAL COMMENTS REGARDING THE APPLICATION**

**MODULE 1: ADMINISTRATIVE AND PRESCRIBING INFORMATION**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Instructions: If the specified document listed below is attached in the complete dossier, check “Yes”. If the document is missing, check “No”. If the document is not applicable for the purpose/types of product approval application, check “Not Applicable” and write your comments why the specific document is not required.** | **Yes** | **No** | **Not Applicable (NA)** | **COMMENT(S)** |
|  | Is the dossier correctly organized and each Module submitted in the appropriate color? |  |  |  |  |
| **1.0** | Is the letter of application attached? (both from local manufacturers/foreign applicant) |  |  |  |  |
| **1.1** | Is a comprehensive table of contents included? |  |  |  |  |
| **1.2** | 1.2.1 Is the signed, dated, and completed application form from PharmaDex (original signature) attached? |  |  |  |  |
| **1.2.2** | **Are the annexes to the application form listed below attached?**  **1.2.2.1**  Proof of payment  **1.2.2.2** Letter of authorisation for communication on behalf of the applicant  **1.2.2.3** Dossier product batch information  **1.2.2.4** Electronic copy declaration  **1.2.2.5** Curriculum vitae of the person responsible for pharmacovigilance  **1.2.2.6** API change control  **1.2.2.7** Certificate for a Vaccine Antigen Master File (VAMF) (if applicable)  **1.2.2.8** Certificate for a Plasma Master File (PMF) (if applicable) |  |  |  |  |
| **1.3** | **Is the Bangladesh labeling and packaging information attached?**  **1.3.1** Proposed Package Insert  **1.3.2** Proposed Patient Information Leaflet (PIL)  **1.3.3** Labels (outer and inner) |  |  |  |  |
| **1.4** | **Is the information about the Experts attached?**  **1.4.1** Particulars of quality Control Manager  **1.4.2** Name and qualification of Production Manager  **1.4.3** Name and Qualification of Clinical Manager |  |  |  |  |
| **1.5** | **Are specific requirements for amendment applications of registered products attached? (if applicable)**  **1.5.1** Literature based submissions  **1.5.2** Amendments / variations  **1.5.3** Proprietary name applications and changes  **1.5.4** Package insert and Patient Information Leaflet amendments / updates |  |  |  |  |
| **1.6** | Is the environmental risk assessment attached? |  |  |  |  |
| **1.7** | Is the manufacturer’s Good manufacturing practice (GMP) approved / inspected? |  |  |  |  |
| **1.7.1** | Is the date of last inspection of each site by Bangladesh regulatory authority or other authority of a country with which Bangladesh aligns itself included? |  |  |  |  |
| **1.7.2** | Are the inspection reports or equivalent document (not older than 2 years) from the local Regulatory Authority and/or WHO, FDA, MHRA, TGA, EU, Canada, PIC/S country attached? |  |  |  |  |
| **1.7.3** | Is the latest GMP certificate (not older than 2 years) for manufacturer/s and packer/s or a copy of the appropriate manufacturing licence attached? |  |  |  |  |
| **1.7.4** | **Are the Batch Release summary and details listed below included for each manufacturer included?**  **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, if applicable? |  |  |  |  |
| **1.7.5** | Is confirmation of contract between manufacturer/s and packer/s attached? |  |  |  |  |
| **1.7.6** | Is Certificate of a Pharmaceutical Product (CPP) in terms of the WHO certification scheme (Free Sales Certificate) and / or a copy of the registration or marketing authorisation certificate for the product if applicable attached? |  |  |  |  |
| **1.7.7** | Is the Bangladesh Pharmacist registration attached? |  |  |  |  |
| **1.7.8** | Is the document for registration of the company with Bangladesh stock exchange attached? |  |  |  |  |
| **1.7.9** | **Is the sample and documents listed below included?**  **1.7.9.1** Confirmation of submission of sample  **1.7.9.2** Batch manufacturing record of the sample  **1.7.9.3** Certificate of Analysis (CoA) of the sample |  |  |  |  |
| **1.7.10** | Is the Certified copy of permit to manufacture attached? |  |  |  |  |
| **1.7.11** | Is the inspection flow diagram attached? |  |  |  |  |
| **1.7.12** | Is the Organogram attached? |  |  |  |  |
| **1.8** | **Are the foreign regulatory status listed below included, if applicable?**  **1.8.1** List of countries in which an application for the same product as being applied for has been submitted  **1.8.2** Name, address, and signature of manufacturer’s authorized agent  **1.8.3** Number of manufacturer/importer already manufacturing/importing in Bangladesh  **1.8.4** Estimated market of this product/product group in Bangladesh  **1.8.5** Registration certificate or marketing authorisation in the country of origin or other country (free sale certificate, sale certificates from at least 2 other developing countries)  **1.8.6** Foreign prescribing and patient information  **1.8.7** Data set similarities |  |  |  |  |
| **1.9** | Is the pharmacovigilance plan attached? |  |  |  |  |
| **1.10** | Are details of compliance with screening outcomes included? |  |  |  |  |
| **1.11** | **Is the bioequivalence trial information below included?**  **1.11.1** Study Title(s) (or brief description giving design, duration, dose and subject population of each study)  **1.11.2** Protocol and study numbers |  |  |  |  |
| **1.11.3** | Are the investigational products (test and reference) details attached?, including  1.11.3.1 Active ingredient  1.11.3.2 Strength  1.11.3.3 Dosage form  1.11.3.4 Manufacturer of drug  1.11.3.5 Batch no.  1.11.3.6 Expiry or retest date  1.11.3.7 Country in which reference is procured |  |  |  |  |
| **1.11.4** | Is confirmation that the test product formulation and manufacturing process is that being applied for attached? |  |  |  |  |
| **1.11.5** | Is proof of procurement of the biostudy reference product attached? |  |  |  |  |
| **1.11.6** | Is the name and address of the Research Organisation(s) / Contract Research Organisation(s) where the bioequivalence studies were conducted attached? |  |  |  |  |
| **1.11.7** | Is the Sponsor and responsible sponsor representative names included? |  |  |  |  |
| **1.11.8** | Is the duration of Clinical phase: dates of dosing and last clinical procedure included? |  |  |  |  |
| **1.11.9** | Is the date of final report attached? |  |  |  |  |
| **1.12** | **Is the information on price**  **1.12.1** Proposed maximum retail price (MRP)/Indicative price  **1.12.2** Estimated price-per dose; per day treatment; cost of the recommended  course of treatment |  |  |  |  |
| **1.13** | **Paediatric development program (for future use)** |  |  |  |  |
| **1.14** | **Is the Risk Management plan attached?** |  |  |  |  |

**MODULE 2: QUALITY OVERALL SUMMARY (QOS)**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Submit in both PDF and MS Word** | **Yes** | **No** | **Not Applicable** | **COMMENT(S)** |
| **2.3** | **Is the Quality Overall Summary (QOS) included?** |  |  |  |  |
| **2.3.S** | **Did the applicant include the DRUG SUBSTANCE (Active Pharmaceutical Ingredients) details below?**  **2.3.S.1** General information  **2.3.S.2** Manufacture  **2.3.S.3** Characterization  **2.3.S.4** Control of drug substance  **2.3.S.5** Reference standards or materials  **2.3.S.6** Container closure system  **2.3.S.7** Stability |  |  |  |  |
| **2.3.P** | **Did the applicant include the DRUG PRODUCT details below?**  **2.3.P.1** Description and composition of the drug product  **2.3.P.2** Pharmaceutical development  **2.3.P.3** Manufacture  **2.3.P.4** Control of excipients  **2.3.P.5** Control of drug product  **2.3.P.6** Reference standards or materials  **2.3.P.7** Container closure system  **2.3.P.8** Stability |  |  |  |  |
| **2.3.A** | **Are there any APPENDICES attached?**  **2.3.A.1** Facilities and equipment  **2.3.A.2** Adventitious agents safety evaluation  **2.3.A.3** Novel excipients |  |  |  |  |
| **2.3.R** | **Is any Regional Information included?** |  |  |  |  |

**MODULE 3: QUALITY**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  | **Yes** | **No** | **Not Applicable** | **COMMENT(S)** |
| **3.2** | **Is the Body of Data included?** |  |  |  |  |
| **3.2.S** | **DRUG SUBSTANCE (Active Pharmaceutical Ingredients)** |  |  |  |  |
| **3.2.S.1** | **Did the applicant include the General Information?**  **3.2.S.1.1** Nomenclature  **3.2.S.1.2** Structure  **3.2.S.1.3** General Properties |  |  |  |  |
| **3.2.S.2** | **Are the manufacturing details below included?**  **3.2.S.2.1** Manufacturer(s)  **3.2.S.2.2** Description of manufacturing process and process controls  **3.2.S.2.3** Control of materials  **3.2.S.2.4** Controls of critical steps and intermediates  **3.2.S.2.5** Process validation and/or evaluation  **3.2.S.2.6** Manufacturing process development |  |  |  |  |
| **3.3.S.3** | **Is the drug substance characterization process included?**  **3.2.S.3.**1 Elucidation of structure and characteristics  **3.2.S.3.2** Impurities |  |  |  |  |
| **3.3.S.4** | **Is the control of active pharmaceutical ingredient attached?**  **3.2.S.4.1** Specifications  **3.2.S.4.2** Analytical procedures  **3.2.S.4.3** Validation of analytical procedures  **3.2.S.4.4** Batch analyses  **3.2.S.4.5** Justification of specification |  |  |  |  |
| **3.3.S.5** | Are the Reference standards and materials attached? |  |  |  |  |
| **3.3.S.6** | Is a description of the container closure system included? |  |  |  |  |
| **3.3.S.7** | **Are the Stability information included?**  **3.2.S.7.1** Stability summary and conclusion  **3.2.S.7.2** Post approval summary protocol and stability commitment  **3.2.S.7.3** Stability data |  |  |  |  |
| **3.2.P** | **DRUG PRODUCT (Finished Pharmaceutical Product)** | | | | |
| **3.2.P.1** | Is the Description and composition of the pharmaceutical product included? |  |  |  |  |
| **3.2.P.2** | Is the full description of Pharmaceutical development included? |  |  |  |  |
| **3.2.P.2.1** | **Are the Components of the pharmaceutical product included?**  **3.2.P.2.1.1** Active pharmaceutical substances(s)  **3.2.P.2.1.2** Excipients |  |  |  |  |
| **3.2.P.2.2** | **Is the Final pharmaceutical product included?**  **3.2.P.2.2.1** Formulation  **3.2.P.2.2.2** Overages  **3.2.P.2.2.3** Physiochemical and biological properties |  |  |  |  |
| **3.2.P.2.3** | Are the details of the Manufacturing process development attached? |  |  |  |  |
| **3.2.P.2.4** | Is a description of the container closure system included? |  |  |  |  |
| **3.2.P.2.5** | Are any Microbiology attributes included? If applicable? |  |  |  |  |
| **3.2.P.2.6** | Did the firm include any compatibility study? |  |  |  |  |
| **3.2.P.3** | **Are the details of Manufacture below included?**  **3.2.P.3.1** Manufacturers  **3.2.P.3.2** Batch formula  **3.2.P.3.3** Description of manufacturing process and process controls  **3.2.P.3.4** Controls of critical steps and intermediates  **3.2.P.3.5** Process validation and/or evaluation |  |  |  |  |
| **3.2.P.4** | **Is there description for the Control of inactive pharmaceutical ingredients?**  **3.2.P.4.1** Specifications  **3.2.P.4.2** Analytical procedures  **3.2.P.4.3** Validation of analytical procedures  **3.2.P.4.4** Justification of specifications  **3.2.P.4.5** Excipients of human or animal origin  **3.2.P.4.6** Novel excipients |  |  |  |  |
| **3.2.P.5** | **Is the control of pharmaceutical product list included?**  **3.2.P.5.1** Specifications  **3.2.P.5.2** Analytical procedures  **3.2.P.5.3** Validation of analytical procedures  **3.2.P.5.4** Batch analyses  **3.2.P.5.5** Characterization of impurities  **3.2.P.5.6** Justification of specifications |  |  |  |  |
| **3.2.P.6** | Are the reference standards or materials included, if applicable? |  |  |  |  |
| **3.2.P.7** | Is the container closure system information included? |  |  |  |  |
| **3.2.P.8** | **Is the stability information below included?**  **3.2.P.8.1** Stability summary and conclusion  **3.2.P.8.2** Post-approval stability protocol and stability commitment  **3.2.P.8.3** Stability data |  |  |  |  |
| **3.2.A** | **Are there any APPENDICES included?**  **3.2.A.1** Facilities and equipment  **3.2.A.2** Adventitious agents safety evaluation  **3.2.A.3** Novel excipients |  |  |  |  |
| **3.2.R** | Are there any REGIONAL INFORMATION included |  |  |  |  |
| **3.3** | LITERATURE REFERENCES |  |  |  |  |

**UPDATE FILING CHECKLIST LOG**

|  |  |
| --- | --- |
| **Month/Year** | **Version** |
| July - 2014 | Version 1 |