**ANNEX 1: APPLICATION FORM FOR RENEWAL OF REGISTRATION OF HUMAN AND VETERINARY PHARMACEUTICAL PRODUCTS**

**General Instructions:**

Please read all the instructions carefully prior to completing this Application form.

Provide as much details, accurate and complete information as possible. Note that all areas are to be filled out by the applicant EXCEPT where indicated by GREY COLOURS which are for TMDA Official Use Only.

Please state the exact location (Annex number) of any appended documents in the relevant sections of the form.

Before submitting the completed form, please countercheck to confirm whether you have provided all requested information.

This application form should be accompanied by a Batch Manufacturing Record (BMR) of all commercial batches manufactured within the last six months from the date of submission of this application.

Should you have any questions regarding this form, please contact the Tanzania Medicines and Medical Devices Authority (TMDA).

A properly filled out and signed original copy of the form with all its annexes (including a hard copy and an electronic copy in MS Word on a CD-ROM) must be submitted together with the pharmaceutical quality part of the dossier. The entire dossier should be submitted both in hard-copy and on a CD-ROM. A complete application should be sent to the following address:

Director General

Tanzania Medicines and Medical Devices Authority

P.O. Box 77150 EPI Mabibo

Off Mandela Road Dar-es-Salaam Tanzania

# For official use only

|  |  |
| --- | --- |
| 1.1 Application Number |  |
| 1.2 Date of submission of the dossier |  |
| 1.3 Evaluator | Name | Signature |
| 1.4 Auditor | Name | Signature |
| 1.5 Date of evaluation |  |
| 1.6 Date of auditing |  |
| 1.7 Number of files |  |
| * 1. Conclusion of the assessment

*If the dossier is* **RECOMMENDED***specify:** + - *Primary packaging and shelf-life of product,*
		- *Storage condition of product and special precautions.*
		- *Distribution category*
 | **RECOMMENDED (no outstanding issues) QUERY RAISED****REJECTED****(*Please delete which does not apply*)** |
| **2. To be filled in by the applicant** |
| Type of the pharmaceutical product HumanVeterinary |
| 2.1Registration number |  |

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| --- | --- |
| 2.2Date of expiry of current registration |  |
| 2.3Proprietary Name of the Product |  |
| 2.4International Non-proprietary Name (INN) of the Active Pharmaceutical Ingredient (API), strength, |  |
| 2.5 Pharmaceutical Dosage form |  |
| 2.6 Route of administration |  |
| 2.7 Anatomic Therapeutic Classification (ATC) Code |  |
| 2.8Name and address (physical and postal) of Applicant |  |
| 2.9 Name and address(es) of the manufacturer(s) of the active pharmaceutical ingredient(s).*(Add as many rows as necessary)* |  |
| 2.10 site/location of manufacture of API (s) |  |
| 2.11 Name(s) and complete address (es) of the manufacturer(s) of the finished product(s), including the final product release if different from the manufacturer.*(Add as many rows as necessary)* |  |
| 2.12. Site/location of manufacture FPP |  |
| 2.13 Name and complete address of the Local Responsible Person ( who must beresident in Tanzania and in case of company be incorporated in Tanzania) |  |
| 2.14 Visual physical description of the FPP |  |
| 2.15 Packing/pack size |  |
| 2.16 Proposed shelf life (in months) |  |
| 2.17 Proposed shelf life (after reconstitution or dilution) |  |
| 2.18 Proposed shelf life (after first opening container) |  |

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| 2.19 Proposed storage conditions |  |
| 2.20 Proposed storage conditions after first opening |  |
| 2.21 Distribution category: eg Controlled Drug POM Pharmacy Only OTC General sale(Applicants are invited to indicate which categories they are requesting, however, the NMRAs reserve the right to change and/orapply only those categories provided for in their national legislation) |  |
| 2.22 Country of origin |  |
| 2.23 Current registration status in other countries including East African community (EAC) and the SouthernAfrican Development Community (SADC) countries |  |

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|  | **3. FINISHED PHARMACEUTICAL PRODUCT(s) [FPP(s)]** |  |
|  | **3.1 Manufacturing and Marketing authorization** |  |
|  |  |  |
|  | **3.3 Formulation** |  |
|  |  |  |
|  | Strength (label claim) |  |  |
| Master Production Document Reference Number and/or Version |  |
| Batch Size (number of dosage units) |  |
| Ingredients (APIs and excipients) starting with APIs | Quality standard | Specifi- cation | Dosage per unit compositi on | Batch quantities |
|  |  | m g | % | kg | % |

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| Film coating/Hard capsule |
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| Composition of all *components that are mixtures* (e.g., colourants, coatings, capsule shells, imprinting inks):Description of accompanying reconstitution diluent(s), if applicable: |
|  | **3.4 Control of the FPP** |  |
|  | 4.9.1 Specifications for the FPP |  |
|  |  |  |
|  | Standard Claimed (e.g., In-house, BP, PhEur, PhInt, USP) |  |  |
| Specification Reference Number and/or Version |  |
| Test | Analytical Procedure(Type/Source/Version) | Acceptance Criteria |
| Batch release | Shelf life |
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|  | **3.5 Container/closure system(s) and other packaging** |  |
|  | 1. Description of the container closure systems, including unit count or fill size, container size or volume:
2. Materials of construction of each primary packaging component:
3. Summary of specifications of each primary and functional secondary (e.g., foil pouches) packaging components:
 |  |
|  | **3.6 Completed Real time stability testing:**Applicable only if registration was based on accelerated and partial real time stability data |  |
|  | Stability protocol for continuing (i.e., ongoing) batches: |  |
|  | Protocol Parameter | Description |  |
| Storage conditions (including tolerances) |  |
| Testing frequency |  |
| Number of batches per strength and batch sizes |  |
| Container closure system(s) |  |
| Stability-indicating quality parameters |  |
| Photostability testing |  |
| Tests and acceptance criteria |  |
| Other |  |
|  |  |
|  | FPPs packaged in impermeable containers |  |
|  |  |  |
|  | FPPs packaged in semi-permeable containers |  |
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|  | **Evaluation** |  |
|  | (a) Summary of stress testing and results (e.g., photostability studies, cyclic studies for |  |

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|  | semi-solids, freeze-thaw studies):1. Summary of real time testing (e.g., studies conducted, protocols used, results obtained):
	1. Description of stability study details:

Storage CompletedConditions Batch Number Batch Size Container (and Proposed)Closure System Test Intervals(C, % RH) (in months)* 1. Summary and discussion of stability study results:
1. Proposed storage conditions and shelf life (and in-use storage conditions and in-use period, if applicable):
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|  | Extrapolation of data |  |
|  |  |  |
|  | Core storage statements |  |
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|  | **3.7. Container labelling** |  |
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|  | 3.7.1 Packaging or, where there is no outer packaging, on the immediate packaging |  |
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|  | 3.7.2 Blisters and strips |  |
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|  | **3.8 Current package insert and if available patient information leaflet** |  |
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| **4.0 DECLARATION BY AN APPLICANT** |
| I, the undersigned certify that all the information in this form and accompanying documentation is correct, complete and true to the best of my knowledge.I further confirm that the information referred to in my application dossier is available for verification during GMP inspection.I also agree that I shall carry out pharmacovigilance to monitor the safety of the product in the market and provide safety update reports to the National Medicines Regulatory Authority of the EAC Partners States.I further agree that I am obliged to follow the requirements of the Partner States Legislations and Regulations, which are applicable to medicinal products.I also consent to the processing of information provided by the EAC Partner States.It is hereby confirmed that fees will be paid/have been paid according to the National/Community rules\*Name: …………………………………………………………………..……………………….Position in the company …………………………………………………………………… |

Signature: …………………………………………………………………………….…………

Date:………………………………………..

Official stamp:……………………………..

\* Note: If fees have been paid, attach proof of payment