(Made under Regulation 5(1) (b) and 16(1))

MODULE 1: ADMINISTRATIVE INFORMATION	
1.0 PARTICULARS OF THE PRODUCT	
1.1	Type of the medicinal product application New Generic Extension application Duplicate license Renewal* * If variation has been made, information supporting the changes should be submitted. See variation guidelines for registered medicinal products.
1.2	Proprietary Name
1.3	International Non-proprietary Name (INN) of the Active Pharmaceutical Ingredient (API)
1.4	Strength of Active Pharmaceutical Ingredient (API) per unit dosage form:
1.5	Name and address (physical and postal) of Applicant
(Company) Name: Address: Country: Telephone: Telefax: E-Mail:	
1.6	Name and address (physical and postal) of Local Technical Representative
(Company) Name: Address: Country: Telephone: Telefax: E-Mail:	
1.7	Pharmaceutical Dosage form* and route of administration* * List of standard terms for dosage forms and routes of administration is available in the guidelines on submission of documentation for registration of human medicinal products
1.7.1	Dosage form:
1.7.2	Route(s) of administration (use current list of standard terms)
1.8	Packing/pack size:
1.9	Visual description (Add as many rows as necessary)
1.10	Proposed shelf life (in months):
1.10.1	Proposed shelf life (after reconstitution or dilution):
1.10.2	Proposed shelf life (after first opening container):
1.10.3	Proposed storage conditions:

1.10.4	Proposed storage conditions after first opening:
1.11	Other sister medicinal products registered or applied for registration
1.11.1	Do you hold Marketing Authorization (s) of other medicinal product (s) containing the same active substance (s) in other countries? If yes state; ▪ Product name (s), strength (s), pharmaceutical form (s): ▪ Partner States where product is authorized: ▪ Marketing authorization number(s): ▪ Indication(s):
1.11.2	Have you applied for Marketing Authorization medicinal product (s) containing the same active substance (s) in other countries? ▪ Product name (s), strength (s), pharmaceutical form (s): ▪ Indication(s):
1.12	Pharmacotherapeutic group and ATC Code
1.12.1	Pharmacotherapeutic group:
1.12.2	ATC Code: (Please use current ATC code)
1.12.3	If no ATC code has been assigned, please indicate if an application for ATC code has been made: ☐
1.13	Distribution category: Controlled Drug ☐ POM ☐ Pharmacy Only ☐ OTC ☐ General sale ☐ (Applicants are invited to indicate which categories they are requesting, however, TMDA reserves the right to change and/or apply only those categories provided for in their national legislation)
1.14	Country of origin:
1.15	Product Marketing Authorization in the country of origin (Attach Certificate of Pharmaceutical Product from National Medicines Regulatory Authority). If not registered, state reasons

☐Authorized Country: Date of authorization (dd-mm-yyyy): Proprietary name: Authorization number: ☐ Refused Country: Date of refusal (dd-mm-yyyy): Reason for Refusal:	☐ Withdrawn (by applicant after authorization) Country: Date of withdrawal (dd-mm-yyyy): Proprietary name: Reason for withdrawal: ☐ Suspended/revoked (by competent authority) Country: date of suspension/revocation (dd-mm-yyyy): Reason for suspension/revocation: Proprietary name:

1.16	List ICH and Observers where the product is approved.
1.17	Name(s) and complete physical address(es) of the manufacturer(s)
1.17.1	Name(s) and physical address (es) of the manufacturing site of the finished pharmaceutical product (FPP), including the final product release if different from the manufacturer. Alternative sites should be also declared here. All manufacturing sites involved in the manufacturing process of each step of the finished product, stating the role of each including quality control / in-process testing

	sites should be listed. (Add as many rows as necessary
Name: Company name: Address: Country: Telephone: Telefax: E-Mail:	
1.17.2	Name(s) and physical address(es) of the manufacturer(s) of the active pharmaceutical ingredient(s) (API) (Add as many rows as necessary) All manufacturing sites involved in the manufacturing process of each source of active substance, including quality control / in-process testing sites should be listed.
Name: Company name: Address: Country: Telephone: Telefax: E-Mail:	
1.18	Name and address (physical and postal) of the Brokers and Suppliers (if applicable)
Name: Company name: Address: Country: Telephone: Telefax: E-Mail:	
1.19	Name and address (physical and postal) of the person or company responsible for Pharmacovigilance
Name: Company name: Address: Country: Telephone: Telefax: E-Mail:	
1.20	State the reference/monograph standard such as British Pharmacopeia, United States Pharmacopeia, Ph. Eur, Japanese Pharmacopeia, In-house monograph e.t.c. used for Finished Medicinal Product.
1.21	Qualitative and Quantitative composition of the active substance(s) and excipient(s) A note should be given as to which quantity the composition refers (e.g. 1 capsule).

Name of active ingredient(s)*	Quantity / dosage unit	Unit of measure	Reference/ monograph standard	
1.				
2.				
3.				
e.t.c				
Name Excipient(s)				
1.				
2.				
3				
e.t.c				

Note: * Only one name for each substance should be given in the following order of priority: INN**, Pharmacopoeia, common name, scientific name
** The active substance should be declared by its recommended INN, accompanied by its salt or hydrate form if relevant.
Details of averages should not be included in the formulation columns but should be stated below:
- Active substance(s):
- Excipient(s):

1.22	Name and address (physical and postal) of the Contract Research Organisation(s) where the clinical studies of the product were conducted or name and address of laboratory where comparative dissolution studies in support of bio-waiver were conducted. (If applicable)

Name:
Company name:
Address:
Country:
Telephone:
Telefax:
E-Mail:

2.0 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 Tanzania Medicines and Medical Devices Authority.

I further agree that I am obliged to follow the requirements of the Legislations and Regulations

which are applicable to medicinal products.

I also consent to the processing of information provided by TMDA.

It is hereby confirmed that fees will be paid/have been paid according to the fees and charges regulations

Name: ……..…….
Position in the company:……
Signature: ……..……
Date:……..
Official stamp:……..

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