Maldives Food and Drug Authority
Ministry of Health
Male`
Republic of Maldives

Form Number: MTG/RE-MF/Fo 0001/____-____

Application for Registration of Pharmaceutical Product

Serial #	REQUIREMENTS	Dossier Page No.	MFDA USE ONLY
A. Applicant information:			
	1) A letter of appointment from applicant /local agent bearing all the responsibilities of the manufacturer in regard to the product. (As per the format given in ANNEX 1)		
B. **Pharmaceutical Product Information sheet**:			
	The following information shall be provided : 1) Product name/Brand Name of the product		
	2) Generic name of the product		
	3) Active pharmaceutical ingredient(s)(use INN if any)		
	4) Non-active ingredients		
	5) Strength per unit dosage unit		
	6) Dosage form		
	7) Pack size: 7.1 Description of primary packing materials 7.2 Weight, volume and Dimension 7.3 Description of secondary packaging material 7.4 Number of units, weight , volume and dimensions 7.5 Number of secondary packs per standard pallet **Note: For drug product in plastic container, studies done on the plastic to demonstrate safety to use shall be provided.**		
	8) Route of administration		
	9) Therapeutic class		
	10) Proposed dispensing category		
	11) Shelf life		
	12) Storage condition		

C .Manufacturer of the product:			
	1) Company profile (for new companies and re- registration or changes for existing companies)		
	2) Manufacturer responsible for lot release of the finished dosage form. Provide full details of name, address, phone, fax, e-mail and contact details.		
	3) Manufacturer responsible for packaging of the finished dosage form, if different from the above. Provide full details of name, address, phone, fax, e-mail and contact details		
	4) Manufacturing license by the relevant Authority to perform the activities in (2) & (3)		
	5) Proof that the **product** is a WHO pre-qualified product if applicable		
	6) 6.1 Proof that the manufacturing site for the **product** is GMP compliant (Valid WHO type GMP certificate) (should have the validity of 06 months at the time of submission)		
	6.2 The agency approving the GMP of the site (WHO Compliant GMP Certificate)		
	7)The proof of validation of the manufacturing method for each standard batch size		
	8)Standard batch size quantities		
	9) Technical specifications of all raw material(s) and source (s), including steps taken to assure consistent quality of starting materials.		
	10) Brief profile of manufacturer(s), range of products manufactured and marketed in country of origin.		
	11) Brief description of 1) manufacturing plant lay-out and machinery employed. 2) Manufacturing and packaging process of the product.		
	12)List of personnel, their responsibilities and qualifications		
	13) Letter from the manufacturer for registering the product (Manufacturer to the Drug Regulatory Authority)		
	14)Any regulatory decisions taken on this product from any drug regulatory authorities (including recalls, bans alerts etc)		
D. Regulatory situation:			
	1) Evidence supporting the registration status of the product in the manufacturing		
	country and whether or not used in the country		
	2) Evidence supporting that product is registered for export.		
	3) Valid Certificate of Pharmaceutical Product (CPP), in accordance to the WHO Certification Scheme (should have the validity of 06 months at the time of submission)		
	4) List of countries where the product is registered and currently marketed.		
	5) Documentation supporting registration/ licensing status of the product in countries other than country of origin. (refer to" **reference county categorization for pharmaceutical product registration**" MFDA/MTG-RCPR/LS-13)		
	6) Free sale certificate of the product		
E. Finish product specification :			
	1) Specify the finish product specification with reference to pharmacopoeia indicating the edition		
	2) Copy of the finish product specification		
	3) Limit in % for the assay in active ingredients(s)		
	4) Additional specifications if any (eg dissolution etc)		
	5) Notarized of the Model certificate of analysis for batch release/Certificate of analysis of finished product		

F. Stability			
	1)Provide the stability testing data for the product		
	2)Specify the conditions for : 2.1 Satisfactory accelerated testing 2.1.1 Type of container 2.1.2 Conditions (temperature/relative humidity/Duration) 2.1.3 Number of Batches 2.1.4 Batch size 2.1.5 Date of study		
	2.2 Satisfactory real time testing 2.2.1 Type of container 2.2.2 Conditions (temperature/relative humidity/Duration) 2.2.3 Number of Batches 2.2.4 Batch size 2.2.5 Date of study		
	3) Is the stability testing done on the product of the same formula, manufactured on the same site and packed in the same packing material as the product that will be supplied?		
G. Therapeutic Equivalence			
	1)Demonstrated with evidence in either of the following way: 1.1 By In vivo bioequivalence studies with a reference product		
	1.2 By in vitro dissolution tests with a reference product		
H. Sample, Label and insert information			
	1)Shelf life		
	2) Storage conditions in detail (Eg Do not store above 30°c, protect from light etc)		
	3)Label Language(Attach a copy)		
	4) Copy of the packing insert		
	5) Samples of the packing with labels (3 nos)		
	6) Free non returnable Product samples: 6.1 Tablets/capsules :60 nos 6.2 syrups : 3 nos 6.3 Injectables : 3 nos		
I. Price			
	1)Cost price in USD		
	2) Proposing price for retailing it in Maldives market in USD		

Special Notes:

1. On Documents:

(a) Arrange the documents according to the checklist
(b) Table of contents and page number should indicate the location of documents inside the dossier
(c) Use identifying markers/separators in between sections
(d) All regulatory certificates must be notarised
(e) Incomplete documents and/or documents that do not comply with the above-stated notes will not be received.
(f) Documents must be submitted after setting up appointment. You may call +960-3014316, +960-33014317, Medicines and Therapeutic Goods Division, Maldives Food and Drug Authority to set up appointment
(g) The dossier submission fee is MRF 100 and if the product is successfully considered for registration a fee of MRF 300 is charged. The fee has to be paid to the finance section of the Maldives Food and Drug Authority after the dossier is received.

2. On Registration process

(a) Follow-up on the product application status will be through an official letter
(b) The final decision on registration of the products is by the Board for Pharmaceuticals
(c) The Board for Pharmaceuticals and the Maldives Food and Drug Authority registers medicines based on set criteria. All applicants will be informed of the results of the product evaluation process.
(d) Applicants who wish to know why their product has not passed registration may make a formal inquiry if they so desire so that reasons for disqualification may be informed.
(e) Applicants must name a designated person for correspondence including telephone and email address
(f) The address of the MFDA is :

Medicines and Therapeutic Goods Division
Maldives Food and Drug Authority
Phone: +960-3014316, +960-33014322
Email: mtg@health.gov.mv

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Statement by the Applicant (Local)

1) I have received and accepted the entire dossier from …… (Company name and address) for the product …… (Name of the product, Brand/ Generic/ Dosage Form/ Strength.

This dossier includes all data in support of the original Marketing Authorization as per the format of MFDA.

2) I hereby agree that I have sole responsibility for the mentioned product including obtaining approvals for any subsequent product variation and maintenance of the product registration.

3) I declare that information submitted in this application is correct and complete. I authorize the Maldives Food and Drug Authority to obtain information from any institution previously or currently associated with my company. If any information supplied by me is considered to be false, incomplete or misleading in any respect, Maldives Food and Drug Authority has the right to take action as it believes necessary including the disclosure of the information to any person or body the Maldives Food and Drug Authority considers has a legitimate interest in receiving it and I consent to such disclosure. I understand the Maldives Food and Drug Authority reserves the right to vary or revoke any decision made on the basis of untrue, incomplete or misleading information. Moreover I will co-operate with any person representing the Maldives Food and Drug Authority, by providing additional information or making the manufacturing premises available for inspection as required.

4) I also acknowledge the responsibility in the event of pharmacovigilance issues or quality defects associated with the product that may occur after the registration

Signed:
Full Name:
Identity Card Number:
Full Address:
Status of the signatory:
(To be signed by the managing director/president/CEO or an equivalent person who has overall responsibility for the company or organization)
Official company stamp:
Telephone Number:
Fax Number:
E mail contact details:
Date:

- *The applicant shall be responsible for the product and all information supplied in support of his application for registration of the product.*
- *Applicant shall be responsible for updating any information relevant to the product/application. MFDA should be informed in a timely manner any change in product information during the course of evaluation, and after product registration, especially if the information pertains to rejection/withdrawal, additional data on product efficacy and safety or current Good Manufacturing Practice (cGMP) compliance of the manufacturers (and repackers, if applicable).*

- *The applicant shall also supply relevant information in case where the manufacturing facility is sold, merged or changed to another.*

- *Any person who knowingly supplies any false or misleading information in connection with his application for registration commits an offence.*

- *The marketing authorization holder must assume responsibility for the quality, safety and efficacy of his products.*

Annex 3 of Medicines Regulations: General Criteria for Selecting Medicinal Products for the Maldives Market