MINISTRY OF HEALTH
Directorate General of Pharmaceutical Affairs and Drug Control
Department of Drug Control

APPLICATION FORM FOR HEALTH PRODUCT

- This application form to be filled by the applicant by typing ONLY (original & one photocopy).
- All the documents submitted with this application should either be in English or Arabic.
- Arrangement of the documents in the folder should follow the same sequence followed in this form.
- The documents required, as per Attachment II & III referring to requirements 8 & 9 respectively should be submitted in a separate folder.

Type of application: New ☐ Re-registration ☐

PART I: (*To be filled by local agent*)

1. Name & address of the Local Agent:

Address	**Administration Office**
P.O.Box	
P. C.	
Tel. No.	
Fax No.	
E-Mail	

2. Full description of the product:(Trade name, Strength & Pack size)

3. Name of the manufacturer :

4. Name of marketing authorization holder

5. Regn No. & date, if the manufacturer is registered with MOH Oman:

Name & Signature of the authorized pharmacist in the pharmacy

Stamp of the pharmacy

PART II (*To be filled by the manufacturing company*)

REQUIREMENT OF DOCUMENTS

		YES	*NO*
1	**MANUFACTURER**		
1.1	Legalized cGMP Certificate of the manufacturer	☐	☐
1.2	List of affiliated branches & related manufacturers with address	☐	☐
1.3	List of countries in which the company is registered	☐	☐
1.4	List of the products manufactured by the Company	☐	☐
1.5	If the marketing authorization holder is different from the manufacturer(s),		
	(A) Legalized cGMP Certificate of the marketing authorization holder	☐	☐
	(B) A certificate showing the relation between the two companies (marketing authorization holder & manufacturers)	☐	☐

2. INFORMATION ABOUT THE PRODUCT

2.1 Trade Name of the product: _____

2.2 International Non proprietary name (INN): _____

2.3 Dosage Form: _____

2.4 Strength: _____

2.5 Pack size (By weight, volume or number of doses): _____

2.6 Type of packaging material: _____

2.7 Shelf Life: _____

2.8 Storage Conditions in figures: _____

	Yes	No
3. Legalized Certificate of Pharmaceutical Product (C.P.P) (WHO Certification Scheme or similar) or Free Sale Certificate	☐	☐
4. Scientific report containing: - Composition formula (Active & Inactive ingredients) - Pharmacological effects / mode of action - Therapeutic category - Indications - Dosage regimen & route of administration. - Precautions, warnings & contra-indications - Adverse Effects - Drug interactions - Incompatibilities - Use time period (shelf life after opening) - when applicable - Over dosage (briefly state symptoms, non-drug treatment, supportive therapy & specific anti-dote - if available). - Advantage claimed over similar other product if any. - Legal category in the country of origin. - List of References & Publications.	☐	☐
5. Pack insert (if available) legalized by the health authorities in the country of origin and 2 specimens of the pack insert are required.	☐	☐
6. Certificate issued from Company and legalized by authorities in country of origin showing that the products do not contain hormones, heavy metals, antibiotics, steroidal products, pork derivatives or any other natural or chemical materials which affect the behaviour and bio-functions of human (and if the product contains ingredients of animal origin, type of animal to be stated and the part from which material is taken and alcohol percentage should be stated with reasons for its use. alcohol content should be in following ranges: - 0.5% for children below 6 years - 5% children between 6 and 12 years - 10% above 12 years	☐	☐

	Yes	No
7. Stability studies (if requested).	☐	☐
8. Ten samples & analysis requirements as per Annexure 10 of Circular No. 64/05	☐	☐
9. Two specimens of inner, outer packs &labels The outer packs and/or inner labels should contain the Following: - Composition of the product - Warnings and precautions - Storage conditions in degree centigrade	☐	☐
10. List of countries where the product is registered & marketed supported by photocopies of registration certificates… if available	☐	☐

Name & Signature of
the authorized pharmacist
in the company

Stamp of the
company

FOR OFFICIAL USE ONLY

Received ☐ Not received ☐

Checked by (Reg.): _____ Checked by(QCL): _____

Signature: _____ Signature: _____

Date: _____ Date: _____

Record No: _____ Date: _____