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: _____

MINISTRY OF HEALTH
DTE. GENERAL OF PHARMACEUTICAL AFFAIRS & DRUG CONTROL

DOCUMENTS REQUIRED AS PER CIRCULAR NO. _____

(1) CHANGE IN TRADE NAME

NAME OF THE PRODUCT: ..... REG NO: .....

MANUFACTURER:..... LOCAL AGENT: .....

REQUIRED DOCUMENTS

	YES	NO
a) Letter from the manufacturer stating the changes	☐	☐
b) Legalised Free Sale Certificate	☐	☐
c) 2 specimens of outer / inner labels and pack insert in Arabic and/or English (if any)	☐	☐
d) 2 samples of finished product + BAC	☐	☐

Pharmacist Incharge (Pharmacy)

Name:..... Signature:.....

Date:..... Stamp:.....

For Official use only:

DOCUMENTS Complete ☐ Incomplete ☐

Signature: .....

MINISTRY OF HEALTH
DTE. GENERAL OF PHARMACEUTICAL AFFAIRS & DRUG CONTROL

DOCUMENTS REQUIRED AS PER CIRCULAR NO._____

(2) CHANGE OF EXCIPIENT

(including: Tab coating, capsule shell, colouring agents or flavouring agent, by addition, deletion or replacement)

NAME OF THE PRODUCT: ..... REG NO: .....

MANUFACTURER:..... LOCAL AGENT: .....

REQUIRED DOCUMENTS

	YES	NO
a) A letter stating the changes from manufacturer	☐	☐
b) Current and proposed composition formula in table form	☐	☐
c) Legalised Free Sale Certificate	☐	☐
d) Reasons warranting the change from the manufacturer	☐	☐
e) 2 samples of finished product + BAC	☐	☐
f) Method of analysis and updated finished product specifications in its new formula if it is different from the old one.	☐	☐
g) Date of effectiveness of this change	☐	☐

Pharmacist Incharge (Pharmacy)

Name:..... Signature:.....

Date:..... Stamp:.....

For Official use only:

DOCUMENTS Complete ☐ Incomplete ☐

Signature: .....

Date:.....

MINISTRY OF HEALTH
DTE. GENERAL OF PHARMACEUTICAL AFFAIRS & DRUG CONTROL

DOCUMENTS REQUIRED AS PER CIRCULAR NO. _____

(3) CHANGES OR ADDITION OF IMPRINTS, BOSSING OR OTHER MARKINGS (EXCEPT SCORING / BREAKLINES) ON TABLETS OR PRINTING ON CAPSULES, INCLUDING REPLACEMENT OR ADDITION OF INKS

NAME OF THE PRODUCT: ..... REG NO: .....

MANUFACTURER:..... LOCAL AGENT: .....

REQUIRED DOCUMENTS

	YES	NO
a) Updated finished product specifications	☐	☐
b) Authority approval in Country of origin	☐	☐
c) Composition of ink used, supported with safety profile documentation	☐	☐
d) 2 samples of finished product + BAC	☐	☐
e) Date of effectiveness of this change	.....	

Pharmacist Incharge (Pharmacy)

Name:..... Signature:.....

Date:..... Stamp:.....

For Official use only:

DOCUMENTS Complete ☐ Incomplete ☐

Signature: .....

Date:.....

MINISTRY OF HEALTH
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DOCUMENTS REQUIRED AS PER CIRCULAR NO. _____

(4) CHANGES IN METHOD OF MANUFACTURE

NAME OF THE PRODUCT: ..... REG NO: .....

MANUFACTURER:..... LOCAL AGENT: .....

REQUIRED DOCUMENTS

		YES	NO
a)	Letter from manufacturer stating the change	☐	☐
b)	Current and proposed manufacturing process	☐	☐
c)	Reasons warranting the change from the manufacturer	☐	☐
d)	Approval of concerned authorities in country of origin	☐	☐
e)	Legalized statement that there is no change in composition formula and specifications	☐	☐
f)	2 samples of finished product + BAC	☐	☐
g)	Date of effectiveness of this change	.....	

Pharmacist Incharge (Pharmacy)

Name:..... Signature:.....

Date:..... Stamp:.....

For Official use only:

DOCUMENTS Complete ☐ Incomplete ☐

Signature: .....

Date:.....

MINISTRY OF HEALTH
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DOCUMENTS REQUIRED AS PER CIRCULAR NO. _____

(5) CHANGES IN FINISHED PRODUCT SPECIFICATION AND/OR METHOD OF ANALYSIS

NAME OF THE PRODUCT: ..... REG NO: .....

MANUFACTURER:..... LOCAL AGENT: .....

REQUIRED DOCUMENTS

	YES	NO
a) A letter stating the changes from manufacturer	☐	☐
b) Current and proposed specifications and / or method of analysis in table form	☐	☐
c) Reasons warranting the change from manufacturer.	☐	☐
d) Validation data to support the stability indicating nature in case of change to the method of analysis	☐	☐
e) 2 samples of finished product + BAC	☐	☐
f) Date of effectiveness of this change	.....	

Pharmacist Incharge (Pharmacy)

Name:..... Signature:.....

Date:..... Stamp:.....

For Official use only:

DOCUMENTS Complete ☐ Incomplete ☐

Signature: .....

Date:.....

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DOCUMENTS REQUIRED AS PER CIRCULAR NO._____

(6) CHANGE IN SHELF LIFE AND/OR STORAGE CONDITIONS

NAME OF THE PRODUCT: ..... REG NO: .....

MANUFACTURER:..... LOCAL AGENT: .....

REQUIRED DOCUMENTS

	YES	NO
a) A letter stating the changes from manufacturer	☐	☐
b) Current and proposed storage conditions / shelf life in table form	☐	☐
c) Reasons warranting the change from the manufacturer	☐	☐
d) Certificate from concerned authorities in country of origin stating the shelf life and storage conditions.	☐	☐
b) 2 samples of finished product + BAC	☐	☐
c) Stability study (not required in case of reduction in shelf life)	☐	☐
g) Date of effectiveness of this change	.....	

Pharmacist Incharge (Pharmacy)

Name:..... Signature:.....

Date:..... Stamp:.....

For Official use only:

DOCUMENTS Complete ☐ Incomplete ☐

Signature: .....

Date:.....

MINISTRY OF HEALTH
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DOCUMENTS REQUIRED AS PER CIRCULAR NO._____

(7) CHANGE IN PACKAGING MATERIAL

NAME OF THE PRODUCT: ..... REG NO: .....

MANUFACTURER:..... LOCAL AGENT: .....

REQUIRED DOCUMENTS

	YES	NO
a) A letter stating the changes from manufacturer	☐	☐
b) Current and proposed Packaging material in table form	☐	☐
c) Composition of the new packaging material in detail with specifications	☐	☐
d) Reason warranting the change from the manufacturer	☐	☐
e) 2 Samples of finished product + BAC	☐	☐
f) Stability study as per Cir. No. 64/05	☐	☐
g) Supported documents that the change approved in the country of origin.		
h) Date of effectiveness of this change	.....	

Pharmacist Incharge (Pharmacy)

Name:..... Signature:.....

Date:..... Stamp:.....

For Official use only:

DOCUMENTS Complete ☐ Incomplete ☐

Signature: .....

Date:.....

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DOCUMENTS REQUIRED AS PER CIRCULAR NO. _____

(8) CHANGE OF OUTER/INNER LABEL:

(DESIGN, DIMENSIONS, SHAPE, COLOUR, LOGO, ARRANGEMENT AND DISTRIBUTION OF INFORMATION IN THE LABEL)

NAME OF THE PRODUCT: ..... REG NO: .....

MANUFACTURER:..... LOCAL AGENT: .....

REQUIRED DOCUMENTS

	YES	NO
a) A letter stating the changes from manufacturer	☐	☐
b) Approval of concerned authorities in country of origin	☐	☐
c) 2 samples of finished product + BAC	☐	☐
d) 2 specimens of outer and inner label	☐	☐

Pharmacist Incharge (Pharmacy)

Name:..... Signature:.....

Date:..... Stamp:.....

For Official use only:

DOCUMENTS Complete ☐ Incomplete ☐

Signature: .....

Date:.....

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DOCUMENTS REQUIRED AS PER CIRCULAR NO.

(9) CHANGE OF PACK SIZE / ADDITIONAL PACK SIZE

NAME OF THE PRODUCT: ..... REG NO: .....

MANUFACTURER:..... LOCAL AGENT: .....

REQUIRED DOCUMENTS

	YES	NO
a) A letter stating the changes from manufacturer	☐	☐
b) 2 samples of finished product + BAC	☐	☐
c) 2 specimens of outer, inner labels and pack insert	☐	☐

Pharmacist Incharge (Pharmacy)

Name:..... Signature:.....

Date:..... Stamp:.....

For Official use only:

DOCUMENTS Complete ☐ Incomplete ☐

Signature: .....

Date:.....

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DOCUMENTS REQUIRED AS PER CIRCULAR NO.

(10) CHANGE OF PACK INSERT

NAME OF THE PRODUCT: ..... REG NO: .....

MANUFACTURER:..... LOCAL AGENT: .....

REQUIRED DOCUMENTS

	YES	NO
a) A letter stating the changes from manufacturer	☐	☐
b) Legalised pack insert by concerned authorities in country of origin	☐	☐
c) Comparison table between the old and new pack insert	☐	☐
d) 2 specimens of the new pack insert	☐	☐
e) 2 samples of finished product + BAC	☐	☐

Pharmacist Incharge (Pharmacy)

Name:..... Signature:.....

Date:..... Stamp:.....

For Official use only:

DOCUMENTS Complete ☐ Incomplete ☐

Signature: .....

Date:.....

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DOCUMENTS REQUIRED AS PER CIRCULAR NO. _____

(11) CHANGE IN THE NAME OF MARKETING AUTHORIZATION COMPANY / MANUFACTURER

NAME OF THE PRODUCT: ..... REG NO: .....

MANUFACTURER:..... LOCAL AGENT: .....

REQUIRED DOCUMENTS

	YES	NO
a) A letter stating the changes from manufacturer	☐	☐
b) Legalised Free Sale Certificate issued by concerned authorities in country of origin and attested by Oman Embassy indicating the name and address of the new marketing authorization company / manufacturer.	☐	☐
c) 2 samples of finished product + BAC	☐	☐
d) 2 specimens of the outer pack, inner label and pack insert.	☐	☐

Pharmacist Incharge (Pharmacy)

Name:..... Signature:.....

Date:..... Stamp:.....

For Official use only:

DOCUMENTS Complete ☐ Incomplete ☐

Signature: .....

Date:.....

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DOCUMENTS REQUIRED AS PER CIRCULAR NO._____

(12) RESOURCING OF THE MANUFACTURING SITE TO ANOTHER SITE IN THE SAME COUNTRY

NAME OF THE PRODUCT: ..... REG NO: .....

MANUFACTURER:..... LOCAL AGENT: .....

REQUIRED DOCUMENTS

	YES	NO
a) A letter stating the changes from manufacturer	☐	☐
b) Legalised Free Sale Certificate for each product stating the new site.	☐	☐
c) Legalized cGMP for the new site.	☐	☐
d) 2 samples of finished product + BAC	☐	☐

NB: In case there is a change in the cauntry of origin for manufacturing company, a new application is required for the company and the product.

Pharmacist Incharge (Pharmacy)

Name:..... Signature:.....

Date:..... Stamp:.....

For Official use only:

DOCUMENTS Complete ☐ Incomplete ☐

Signature: .....

Date:.....

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DOCUMENTS REQUIRED AS PER CIRCULAR NO.

NAME OF THE PRODUCT: ..... REG NO: .....

MANUFACTURER:..... LOCAL AGENT: .....

A declaration from the Company confirming that no other changes took place in the product particulars, otherwise applicant should submit documents for that particular change as directed in the concerned requirement.

Pharmacist Incharge (Pharmacy)

Name:..... Signature:.....

Date:..... Stamp:.....

For Official use only:

DOCUMENTS Complete ☐ Incomplete ☐

Signature: .....

Date:.....