FORM (1)

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

DOCUMENTS REQUIRED AS PER CIRCULAR NO. _____

CHANGE OF PRIMARY PACKAGING MATERIAL
(DIRECT CONTACT WITH THE PRODUCT)

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

NAME OF THE COMPANY: _____ **REG. NO.** _____

ADDRESS OF COMPANY: _____

LOCAL AGENT: _____

REQUIREMENT OF DOCUMENTS	**YES**	**NO**
a) Current and proposed packaging material in table form.	☐	☐
b) Composition of the new packaging material in details with specifications.	☐	☐
c) Reasons warranting the change from the manufacturer.	☐	☐
d) Justifications from the Company.	☐	☐
e) 2 Specimens of the new packaging material.	☐	☐
f) 2 Samples of finished product in the new packaging material with Batch Analysis Certificate.	☐	☐
g) Stability studies as per Circular No. 56/2006.	☐	☐
h) Supported documents that the change approved in the country of origin.	☐	☐
i) Date of effectiveness of this change.	_____	

Pharmacist In-charge (Pharmacy)

Name: _____ Signature: _____

Date: _____ Stamp: _____

For Official use only:

DOCUMENTS: Complete ☐ Incomplete ☐

Signature: _____

Date: _____

FORM (2)

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

DOCUMENTS REQUIRED AS PER CIRCULAR NO. _____

CHANGE OF OUTER PACKS AND/OR INNER LABELS

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

NAME OF THE COMPANY: _____ **REG. NO.** _____

ADDRESS OF COMPANY: _____

LOCAL AGENT: _____

REQUIREMENT OF DOCUMENTS	**YES**	**NO**
a) Reasons warranting the change.	☐	☐
b) 1 Sample of finished product with Batch Analysis Certificate.	☐	☐
c) 2 Specimens of outer pack / inner label.	☐	☐
d) CD containing outer pack / inner label.	☐	☐
f) Date of effectiveness of this change.	_____	

Pharmacist In-charge (Pharmacy)

Name: _____ Signature: _____

Date: _____ Stamp: _____

For Official use only:

DOCUMENTS: Complete ☐ Incomplete ☐

Signature: _____

Date: _____

FORM (3)

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

DOCUMENTS REQUIRED AS PER CIRCULAR NO. _____

CHANGE OF PACK INSERT

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

NAME OF THE COMPANY: _____ **REG. NO.** _____

ADDRESS OF COMPANY: _____

LOCAL AGENT: _____

REQUIREMENT OF DOCUMENTS	**YES**	**NO**
a) The new pack insert stamped by Health Authorities in the Country of Origin confirming that it is the same in use there (Health Authority approval required for changes related to Indications, Dosages, Contra indications, Pregnancy & Lactation).	☐	☐
b) Comparison between the old and new pack insert in table form.	☐	☐
c) 2 Specimens of the new pack insert showing date of revision of pack insert & Code No.	☐	☐
d) 1 Sample along with Batch Analysis Certificate containing the new pack insert.	☐	☐
e) CD containing the new pack insert.	☐	☐
f) Date of effectiveness of this change	_____	

Pharmacist In-charge (Pharmacy)

Name: _____ Signature: _____

Date: _____ Stamp: _____

For Official use only:

DOCUMENTS: Complete ☐ Incomplete ☐

Signature: _____

Date: _____

FORM (4)

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

DOCUMENTS REQUIRED AS PER CIRCULAR NO. _____

CHANGE OF TRADE NAME

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

NAME OF THE COMPANY: _____ **REG. NO.** _____

ADDRESS OF COMPANY: _____

LOCAL AGENT: _____

REQUIREMENT OF DOCUMENTS	**YES**	**NO**
a) Fresh original legalized and attested C.P.P. issued by Health Authorities in the Country of Origin.	☐	☐
b) 1 Sample along with Batch Analysis Certificate.	☐	☐
c) 2 Specimens of inner & outer packs and pack insert.	☐	☐
d) CD containing the new inner &outer packs and pack insert.	☐	☐
e) Date of effectiveness of this change.	_____	

Pharmacist In-charge (Pharmacy)

Name: _____ Signature: _____

Date: _____ Stamp: _____

For Official use only:

DOCUMENTS: Complete☐ Incomplete☐

Signature: _____

Date: _____

FORM (5)

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

DOCUMENTS REQUIRED AS PER CIRCULAR NO. _____

CHANGE OF PACK SIZE / ADDITIONAL PACK SIZE

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

NAME OF THE COMPANY: _____ **REG. NO.** _____

ADDRESS OF COMPANY: _____

LOCAL AGENT: _____

REQUIREMENT OF DOCUMENTS	**YES**	**NO**
a) 2 Samples of the finished product with Batch Analysis Certificate.	☐	☐
b) 2 Specimens of inner & outer packs and pack insert.	☐	☐
c) CD containing the new inner & outer packs and pack insert.	☐	☐
d) Legalized Price Certificate.	☐	☐
e) Date of effectiveness of this change.	_____	

Pharmacist In-charge (Pharmacy)

Name: _____ Signature: _____

Date: _____ Stamp: _____

For Official use only:

DOCUMENTS: Complete☐ Incomplete☐

Signature: _____

Date: _____

FORM (6)

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

DOCUMENTS REQUIRED AS PER CIRCULAR NO. _____

CHANGE OF SHELF LIFE

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

NAME OF THE COMPANY: _____ **REG. NO.** _____

ADDRESS OF COMPANY: _____

LOCAL AGENT: _____

REQUIREMENT OF DOCUMENTS	**YES**	**NO**
a) Reasons warranting the change from Manufacturer.	☐	☐
b) Stability Studies as per Circular No. 56/2006.	☐	☐
c) 2 Samples of finished product with Batch Analysis Certificate.	☐	☐
d) Date of effectiveness of this change.	_____	

Pharmacist In-charge (Pharmacy)

Name: _____ Signature: _____

Date: _____ Stamp: _____

For Official use only:

DOCUMENTS: Complete☐ Incomplete☐

Signature: _____

Date: _____

FORM (7)

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

DOCUMENTS REQUIRED AS PER CIRCULAR NO. _____

CHANGE OF FORMULAS (EXCIPOENTS) INCLUDING: TABLET COATING, CAPSULE SHELL, COLOURING AGENT, FLAVORING AGENT – BY ADDITION, DELETION OR REPLACEMENT

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

NAME OF THE COMPANY: _____ **REG. NO.** _____

ADDRESS OF COMPANY: _____

LOCAL AGENT: _____

REQUIREMENT OF DOCUMENTS	**YES**	**NO**
a) Current and proposed composition formula in table form.	☐	☐
b) A fresh legalized and attested C.P.P. issued by Health Authorities mentioning the active and inactive ingredients and also stating that the product is marketed in the Country of Origin.	☐	☐
c) Stability study as per Circular No. 56/2006.	☐	☐
d) 2 Samples of the finished product with Batch Analysis Certificate.	☐	☐
e) Specification of the new material in the new composition formula.	☐	☐
f) Validation 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 In-charge (Pharmacy)

Name: _____ Signature: _____

Date: _____ Stamp: _____

For Official use only:

DOCUMENTS: Complete ☐ Incomplete ☐

Signature: _____

Date: _____

FORM (8)

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

DOCUMENTS REQUIRED AS PER CIRCULAR NO. _____

CHANGE IN SPECIFICATIONS AND/OR METHOD OF ANALYSIS OF THE FINISHED PRODUCT AND/OR THE RAW MATERIAL

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

NAME OF THE COMPANY: _____ **REG. NO.** _____

ADDRESS OF COMPANY: _____

LOCAL AGENT: _____

REQUIREMENT OF DOCUMENTS	**YES**	**NO**
a) Current and proposed specifications and/or method of analysis in table form.	☐	☐
b) Reasons warranting the change from manufacturer.	☐	☐
c) Stability studies if any as per Circular No. 56/2006 (if the specifications for stability parameters was modified).	☐	☐
d) Validation data to support the stability indicating nature in case of change to the method of analysis.	☐	☐
e) Batch Analysis Certificate for 1 batch according to the updated specification and/or method of analysis.	☐	☐
f) Supportive documents that the change approved in the country of origin.	☐	☐
g) Date of effectiveness of this change.	_____	

Pharmacist In-charge (Pharmacy)

Name: _____ Signature: _____

Date: _____ Stamp: _____

For Official use only:

DOCUMENTS: Complete☐ Incomplete☐

Signature: _____

Date: _____

FORM (10)

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

DOCUMENTS REQUIRED AS PER CIRCULAR NO. _____

CHANGE IN THE NAME OF PHARMACEUTICAL COMPANY
MERGER OR ALLIANCE BETWEEN TWO COMPANIES

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

NAME OF THE COMPANY: _____ **REG. NO.** _____

ADDRESS OF COMPANY: _____

LOCAL AGENT: _____

REQUIREMENT OF DOCUMENTS	**YES**	**NO**
a) Fresh legalized and attested Certificate issued by the Health Authorities in the Country of Origin stating:		
▪ Company's products are still marketed there (in the Country of Origin).	☐	☐
▪ Company still following the GMP guidelines as recommended by WHO or any other Health Authority.	☐	☐
▪ Company is still subject to periodical inspection by Health Authorities.	☐	☐
b) Summary of change in the product particulars (logo, pack design etc.) associated with the change in Company status. The Company status. The applicant is requested to refer to the requirements of the concerned document to update the product registration file.	☐	☐
c) Copy of the old Registration Certificate.	☐	☐
d) Letter from the manufacturer explaining the Production Lines.	☐	☐
e) Date of effectiveness of this change.	_____	

NB: In case of merger or alliance between two companied same set of documents to be submitted if both the firms are registered with MOH.

Pharmacist In-charge (Pharmacy)

Name: _____ Signature: _____

Date: _____ Stamp: _____

For Official use only:

DOCUMENTS: Complete ☐ Incomplete ☐

Signature: _____

Date: _____

FORM (9)

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

DOCUMENTS REQUIRED AS PER CIRCULAR NO. _____

CHANGE IN STORAGE CONTDITION

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

NAME OF THE COMPANY: _____ **REG. NO.** _____

ADDRESS OF COMPANY: _____

LOCAL AGENT: _____

REQUIREMENT OF DOCUMENTS	**YES**	**NO**
a) Reasons warranting the change from the manufacturer.	☐	☐
b) Stability studies as per Circular No. 56/2006.	☐	☐
c) 2 Samples of the finished product with Batch Analysis Certificate.	☐	☐
d) 2 Specimens of inner & outer packs and pack insert.	☐	☐
e) CD containing the new inner & outer packs and pack insert.	☐	☐
f) Date of implementation of this change.	_____	

Pharmacist In-charge (Pharmacy)

Name: _____ Signature: _____

Date: _____ Stamp: _____

For Official use only:

DOCUMENTS: Complete☐ Incomplete☐

Signature: _____

Date: _____

FORM (11)

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

DOCUMENTS REQUIRED AS PER CIRCULAR NO. _____

CHANGE IN THE MANUFACTURING SITE OF THE INTERMEDIATE AND/OR THE RAW MATERIAL

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

NAME OF THE COMPANY: _____ **REG. NO.** _____

ADDRESS OF COMPANY: _____

LOCAL AGENT: _____

REQUIREMENT OF DOCUMENTS	**YES**	**NO**
a) Current and proposed manufacturing sites.	☐	☐
b) Reasons warranting the change from Manufacturer.	☐	☐
c) Stability Studies as per our Circular No. 56/2006.	☐	☐
d) 2 Samples of finished product with Batch Analysis Certificate.	☐	☐
e) Date of effectiveness of this change.	_____	

Pharmacist In-charge (Pharmacy)

Name: _____ Signature: _____

Date: _____ Stamp: _____

For Official use only:

DOCUMENTS: Complete ☐ Incomplete ☐

Signature: _____

Date: _____

FORM (12)

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

DOCUMENTS REQUIRED AS PER CIRCULAR NO. _____

CHANGE IN THE MANUFACTURING PROCESS OF THE FINISHED PRODUCT AND/OR THE RAW MATERIAL

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

NAME OF THE COMPANY: _____ **REG. NO.** _____

ADDRESS OF COMPANY: _____

LOCAL AGENT: _____

REQUIREMENT OF DOCUMENTS	**YES**	**NO**
a) Current and proposed manufacturing process.	☐	☐
b) Reasons warranting the change from the manufacturer.	☐	☐
c) Full descrption and validation of the updated manufacturing process.	☐	☐
d) Legalized statement that there is no change in composition formula and specifications.	☐	☐
e) 2 Samples of finished product with batch analysis certificate.	☐	☐
f) Stability Studies as per our Circular No. 56/2006.	☐	☐
g) Date of effectiveness of this change.	_____	

Pharmacist In-charge (Pharmacy)

Name: _____ Signature: _____

Date: _____ Stamp: _____

For Official use only:

DOCUMENTS: Complete ☐ Incomplete ☐

Signature: _____

Date: _____

FORM (13)

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

DOCUMENTS REQUIRED AS PER CIRCULAR NO. _____

CHANGE IN BATCH SIZE OF THE FINISHED PRODUCT

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

NAME OF THE COMPANY: _____ **REG. NO.** _____

ADDRESS OF COMPANY: _____

LOCAL AGENT: _____

REQUIREMENT OF DOCUMENTS	**YES**	**NO**
a) Detailed letter from the manufacturer.	☐	☐
b) Comparative stability study between old & new batch sizes.	☐	☐
c) Batch analysis data (in tabulated format) on a minimum of one production batch manufactured, to both the current and proposed batch sizes.	☐	☐
d) Date of effectiveness of this change.	_____	

Pharmacist In-charge (Pharmacy)

Name: _____ Signature: _____

Date: _____ Stamp: _____

For Official use only:

DOCUMENTS: Complete ☐ Incomplete ☐

Signature: _____

Date: _____

FORM (14)

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

DOCUMENTS REQUIRED AS PER CIRCULAR NO. _____

CHANGE 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.** _____

NAME OF THE COMPANY: _____ **REG. NO.** _____

ADDRESS OF COMPANY: _____

LOCAL AGENT: _____

REQUIREMENT OF DOCUMENTS	**YES**	**NO**
a) Updated finished product specifications.	☐	☐
b) Composition of ink used, supported with safety profile documentation.	☐	☐
c) 2 samples of finished product with Batch Analysis Certificate.	☐	☐
d) Date of effectiveness of this change.	_____	

Pharmacist In-charge (Pharmacy)

Name: _____ Signature: _____

Date: _____ Stamp: _____

For Official use only:

DOCUMENTS: Complete ☐ Incomplete ☐

Signature: _____

Date: _____

FORM (15)

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

DOCUMENTS REQUIRED AS PER CIRCULAR NO. _____

CHANGE IN MARKETING AUTHORIZATION HOLDER

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

NAME OF THE COMPANY: _____ **REG. NO.** _____

ADDRESS OF COMPANY: _____

LOCAL AGENT: _____

REQUIREMENT OF DOCUMENTS	**YES**	**NO**
a) Reasons warranting the change from the manufacturer.	☐	☐
b) Fresh original legalized and attested C.P.P. issued by Health Authorities in the Country of Origin.		
c) 2 Specimens of outer pack, inner label & pack insert.	☐	☐
d) CD containing outer pack, inner label & pack insert.	☐	☐
e) 2 Samples of finished product with Batch Analysis Certificate.	☐	☐
f) Date of effectiveness of this change.	_____	

Pharmacist In-charge (Pharmacy)

Name: _____ Signature: _____

Date: _____ Stamp: _____

For Official use only:

DOCUMENTS: Complete ☐ Incomplete ☐

Signature: _____

FORM (16)

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

DOCUMENTS REQUIRED AS PER CIRCULAR NO. _____

CHANGE OF PRIMARY PACKAGING SITE

NAME OF THE PRODUCT: _____ REG. NO. _____

NAME OF THE COMPANY: _____ REG.NO. _____

ADDRESS OF COMPANY : _____

LOCAL AGENT: _____

REQUIREMENT OF DOCUMENTS	**YES**	**NO**
a) Clearly outline the "Approved" and "Proposed" primary packaging site.	☐	☐
b) A GMP Certificate showing that the proposed site is appropriately authorized for the pharmaceutical Form and the product concerned.	☐	☐
c) 2 samples of finished product + BAC.	☐	☐
d) Proof that the packaging material remains the same, and no change has been made.	☐	☐
e) Stability study of the product in the final packaging according to the GCC guidelines from the new site. **OR** Stability study from the old site supported by Batch analysis data of three production batches and comparative data on the last three batches from the previous site.	☐	☐

f). Date of effectiveness of this change _____

Pharmacist In-charge (Pharmacy)

Name: _____ Signature: _____

Date: _____ Stamp: _____

For Official use only:

DOCUMENTS: Complete ☐ Incomplete ☐

Signature: _____
Date: _____

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

APPLICATION FORM (R)
FOR RE-REGISTRATION OF PHARMACEUTICAL 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

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

1. Cash receipt for R.O. 75: Yes ( ) No ( )

-Receipt No. :
-Date :

2. Name and Address of the Local Agent:

Address	Administration Office
P.O. Box:	
P.C.	
Tel. No.	
Fax No.	
E-mail	

3. Full description of the product: (Trade Name, Strength & Pack size):

4. Name of the Manufacturer:

5. Registration No. & Date of the manufacturer 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):*

01. Information about the product

1.1 Trade Name of the Product:

1.2 International Non-proprietary Name (INN):

1.3 Dosage Form:

1.4 Strength:

1.5 Pack Size (by weight, volume or number of doses):

1.6 Type of Primary Packaging Material:

1.7 Shelf Life:

1.8 Storage Conditions in figures:

1.9 Manufacturer/Address:

1.10 Marketing Authorization Holder (MAH)/Address:

1.11 Packager/Address:

1.12 Batch Releaser to Oman/Address:

	Yes	No
02. Legalized Certificate of Pharmaceutical Product (C.P.P.) (WHO Certification Scheme or similar):	☐	☐
03. Two samples with Batch Analysis Certificate:	☐	☐
04. Two specimens of Outer pack, inner pack and pack insert along with soft copy (CD):	☐	☐
05. Photocopy of the registration certificate of the company:	☐	☐
06. In case, the manufacturer is different from the MAH, then an explanation from MAH is required to clarify the relationship between the two companies and to submit the legalized GMP certificate for the manufacturer in case it is not registered with MOH:	☐	☐
07. Declaration from the company confirming that no changes took place on product composition, storage condition, shelf life, packaging materials, method of analysis, or finished product specifications, otherwise the company should submit the required documents for that particular change:	☐	☐
08. Detailed Composition Formula:	☐	☐
09. Stability studies as per circular no. 69/2007 or at least for minimum of 12 months, along with commitment letter to submit long term stability study supporting the complete shelf life on periodic basis:	☐	☐
10. Source of Active Pharmaceutical Ingredients:	☐	☐

Name & Signature of the Authorized Person in the Company

Stamp of the Company

FOR OFFICIAL USE ONLY

Received ☐ **Not Received** ☐

Checked by (Reg.):

Signature:

Date :

Checked by(QCL):

Signature :

Date:

Record No:

Date: