

# Sultanate of Oman

Ministry of Health

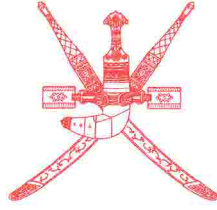
Directorate General of Pharmaceutical Affairs  
and Drug Control

MUSCAT

Circular No. 20 / 2012

04 -04-1433 H

26 -02-2012



سِلاطِنَة عُمان  
وَزارة الصِّحة  
الدَّيْرِية العامَّة للصِّدائِك  
والرِّقابة الدَّوائِيَّة  
مِسْقَط

**TO: ALL PRIVATE DRUG STORES**

After Compliments,

**Sub: Application Form-M**

**Requirements for marketing approval of Medical Device containing medicinal substances**

As you are aware that there are currently a large number of medical devices available in the market. In order to regulate those devices and to have a better control of such devices to ensure their safety and efficacy, we have decided to streamline the requirements for the approval of such devices to be marketed in the country.

As a first stage, we would start the formal registration of medical devices which are containing medicinal substances. In the future, please submit the requirements as per the enclosed Form (FORM-M) whenever you want to register such medical devices containing medicinal substances.

Thanking you and looking forward to your cooperation.

With best regards,

Ph. Mohammed Hāmdān Al Rubaie  
ACTG. DIRECTOR GENERAL

Encl: a/a

CC: Director, Office of H.E. The Undersecretary for Health Affairs  
DDC  
SH(Reg)



**MINISTRY OF HEALTH  
DIRECTORATE GENERAL OF PHARMACEUTICAL AFFAIRS  
AND DRUG CONTROL  
DIRECTORATE OF DRUG CONTROL**

**REQUIREMENTS FOR MARKETING APPROVAL OF MEDICAL DEVICES  
CONTAINING MEDICINAL SUBSTANCES  
FORM (M)**

-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

Type of application:

New

Re-registration

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

1. Name and Address of the Local Agent:

<b>Address</b>	<b>Administration Office</b>
P.O. Box: P.C.  Tel. No.  Fax No.  E-mail	

2. Copy of the drug store license:

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

4. Name of the Manufacturer:

5. Name of the Marketer to Oman:

6. Name of the batch releaser to Oman:

Name & Signature of the authorized Pharmacist  
in the Pharmacy

Stamp of the Pharmacy

**Part II (to be filled by the manufacturing company)**

**1. Information about the manufacturer**

- 1.1 Company information in details
- 1.2 Manufacturer License
- 1.3 Legalized GMP or ISO 13485 certificate or other equivalent certificate standard
- 1.4 If the marketing authorization holder is different from the manufacturer(s), a certificate showing the relation between the two companies (marketing authorization holder & manufacturers)

<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>

**2. Information about the product**

- 2.1 Trade Name of the device:
- 2.2 Description of the device:
- 2.3 Mechanism of action and Instructions for use:
- 2.4 Purpose of uses
- 2.5 Dosage Form:
- 2.6 Pack size:
- 2.7 Type of packaging material:
- 2.8 Shelf Life:
- 2.9 Storage Conditions in figures:
- 2.10 Potential side effects:
- 2.11 Warnings:
- 2.12 Contraindications:
- 2.13 Clarification whether the device contains animal or human materials:
- 2.14 The classification of device in the country of origin:

	Yes	No
3. Legalized CE Certificate or declaration of conformity issued from an accredited notified body certifying the conformity to the product standards	<input type="checkbox"/>	<input type="checkbox"/>
4. Composition or component of the device	<input type="checkbox"/>	<input type="checkbox"/>
5. Legalized pack insert (if available), the content of the pack insert should be as per attachment No. (1), 2 specimens of the pack insert are required.	<input type="checkbox"/>	<input type="checkbox"/>
6. Evidence of established procedures and systems for distribution records, complain handling, adverse incident reporting & recall	<input type="checkbox"/>	<input type="checkbox"/>
7. Summary of reported problems with the device	<input type="checkbox"/>	<input type="checkbox"/>
8. Safety and effectiveness data (risk assessment, pre-clinical and clinical studies, process validation studies)	<input type="checkbox"/>	<input type="checkbox"/>
9. Manufacturing process	<input type="checkbox"/>	<input type="checkbox"/>
10. List of countries in which the medical device is approved (Attached copies of approval certificates)	<input type="checkbox"/>	<input type="checkbox"/>
11. Ten samples when required with batch analysis certificate	<input type="checkbox"/>	<input type="checkbox"/>
12. Two specimens of inner, outer packs and labels	<input type="checkbox"/>	<input type="checkbox"/>
13. Quality Control Laboratory requirements as per attachment (2)	<input type="checkbox"/>	<input type="checkbox"/>

