Company Registration Form 2:
Manufacturing Facility Details

United Arab Emirates
Ministry of Health
www.moh.gov.ae

Date:		Application Type:	

Type of Company:	

1. Applicant: Name and details of the Company that is submitting the application for registration of the site:

Company Name:					
Address:		City:			
State/Province:		Country:		E-Mail:	
Phone:		Fax:		Web Site:	

Have you previously held any registration certificate recorded by Drug Control Department? ◯ **yes** ◯ **no**
(If YES please attach evidence)

2. Manufacturing Site Details:

Site Name:					
Company Name:					
Address:		City:			
State/Province:		Country:		E-Mail:	
Phone:		Fax:		Web Site:	

3. Type of medicinal products manufactured at this site:

Medicines for Human use: ◯ **yes** ◯ **no** Medicines for use of Animals: ◯ **yes** ◯ **no**

4. Manufacturing License Details:

Competent Authority that Issued the License:					
License Number:		Issued On:		Valid Till:	

5. cGMP Certification Details:

GMP Certificate Issued By:					
GMP Cert. Number:		Issued On:		Valid Till:	

6. Mention the authorities and country (other than C.O.O) where the site is approved for the product registration*

Country	Type of Evidence**	Certificate Number	Issued On:

**All information mentioned above should be supplemented with relevant attached documents.*

*** Evidence could be cGMP certificate or registration certificate of the site or registration certificate of product including the site name and address.*

7. Specify the operations carried out in the manufacturing site:

Manufacture	◯ yes ◯ no	Storage & Handling	◯ yes ◯ no	Batch Releaser	◯ yes ◯ no
Assembly & Labeling	◯ yes ◯ no	Analytical Testing	◯ yes ◯ no		

8. Activities at the site:

Please tick MA (Manufacture and Assembly) or MO (Manufacture only) as appropriate for each category of production.

Activities	MO	MA
Sterile Products		
Sterile Liquid Dosage Forms		
Large Volume Parenteral (100ml or more)	☐	☐
Irrigation Solutions (100ml or more)	☐	☐
Small Volume Parenteral (Below 100ml)	☐	☐
Small Volume (Eye drops)	☐	☐
Aseptically prepared	☐	☐
Terminally sterilized products	☐	☐
Other Sterile Liquid Dosage Forms please specify:	☐	☐
Sterile Semi-Solid Dosage Forms		
Creams	☐	☐
Ointments	☐	☐
Aseptically prepared	☐	☐
Terminally sterilized products	☐	☐
Other Sterile Semi-Solid Forms please specify:	☐	☐
Sterile Solid Dosage Forms		
Solid fill (including powders for reconstitution)	☐	☐
Freeze-dried (lyophilized)	☐	☐
Sutures and licensable wound management devices	☐	☐
Other Sterile Solid Forms please specify:	☐	☐
Non Sterile Products	MO	MA
Solid, Semi-solid and other liquid non-sterile dosage forms (Unit and Multi-dose non-sterile liquids)		
Aerosols (pressurized)	☐	☐
Sprays	☐	☐
Solutions	☐	☐
Lotions	☐	☐
Liquids	☐	☐
Suspension	☐	☐
Tablets: Film Coated	☐	☐
Tablets: Enteric Coated	☐	☐
Tablets: Effervescent	☐	☐
Other Tablets, please specify:	☐	☐
Capsules, hard gelatin	☐	☐
Capsules, soft gelatin	☐	☐
Suppositories	☐	☐
Pessaries	☐	☐

Non Sterile Products (Continued)	MO	MA
Powders	☐	☐
Granules	☐	☐
Effervescent Granules	☐	☐
Creams	☐	☐
Ointments	☐	☐
Paste	☐	☐
Gel	☐	☐
Intra mammary preparation for veterinary use	☐	☐
Medical Gases	☐	☐
Other Non-Sterile dosage forms, please specify:	☐	☐
Active Ingredients (BIOLOGICAL) Produced or Handled at the Site	MO	MA
Vaccines	☐	☐
Sera and other Immunologicals	☐	☐
Blood and other blood products	☐	☐
Other biologicals, please specify:	☐	☐
Other Active Ingredients Produced or Handled at the Site (POTENTIALLY HAZARDOUS)	MO	MA
Penicillins	☐	☐
Cephalosporins	☐	☐
Hormones	☐	☐
Cytostatics	☐	☐
Cytotoxics	☐	☐
Other Active Ingredients Produced or Handled at the Site (MISCELLANEOUS)	MO	MA
Radioactive Pharmaceuticals	☐	☐
Veterinary Ectoparasiticides	☐	☐
Veterinary Feed additives & Premixes	☐	☐
Medical Devices, please specify:	☐	☐
Herbal Medicines	MO	MA
Solid Dosage Forms	☐	☐
Liquid Dosage Forms	☐	☐
Homeotherapeutics	MO	MA
Solid Dosage Forms	☐	☐
Liquid Dosage Forms	☐	☐
ASSEMBLY ONLY **NOTE: Filling of sterile products is classified as manufacture, not as assembly. Please Tick the appropriate.		
PRIMARY PACKAGING		
Filling of Primary Container	☐	
Liquid dosage forms	☐	
Semi-solid dosage forms (including creams and ointments)	☐	
Solid dosage forms (including tablets and powders)	☐	
Blister and/or strip packaging	☐	
Medical gases	☐	
SECONDARY PACKAGING		
Secondary packaging of primary containers	☐	
Labeling of primary containers	☐	

Sterilizations processes used in the site for products or components (if available)	Yes	No
Steam or steam/air	☐	☐
Biocidal gas/chemical	☐	☐
Dry heat	☐	☐
Irradiation/electron beam	☐	☐
By ethylene oxide	☐	☐

DECLARATION

We hereby declare that all the information given above are true and correct, and assume full responsibility for this declaration with all consequences which might arise from false or erroneous information

Full name of the Manufacturing Facility:			
Contact Person's Name:		Designation:	

Address:		City:			
State/Province:		Country:		E-Mail:	
Phone:		Fax:		Web Site:	

Signature of Authorized Signatory

Company Seal/Stamp

Name of the Signatory:

Designation/Title:

To be signed by the Managing Director/ of the manufacturing site or an equivalent person who has overall responsibility for the Manufacturing the finished product.

Please Note: All information should be completely filled by the company. Incomplete application form will be rejected by the Drug Control Department, MOH, United Arab Emirates.

LIST OF REQUIRED DOCUMENTS TO BE SUBMITTED ALONG WITH THIS FORM

1. The application form duly filled, signed and stamped by the responsible person in the company
2. A legalized letter issued by the company on its original letterhead, signed and stamped by the responsible person in the company, authorizing a person or a local establishment to submit the registration files on its behalf, to the Drug Control Department. (This person / the local establishment will be responsible to receive the registration certificate from the Drug Control Department)
3. Legalized current GMP certificate issued by the competent authority in country of origin. (Attested true by the UAE Embassy)
4. Legalized valid Manufacturing License issued by the competent authority in country of origin. (Attested true by the UAE Embassy)
5. List of the products manufactured and/or assembly by the site.
6. Site Master file
7. Notarized copies of registration certificates or evidence of GMP certification from other countries where the manufacture site is registered.

Print Form