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

APPLICATION FORM (A)
FOR REGISTRATION OF PHARMACEUTICAL MANUFACTURER/SUBSIDIARY

-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*)

	Yes	No
1. Cash Receipt for R.O. 100/-: - Receipt No. _____ - Date: _____	☐	☐
2. Name and Address of the Local Agent in Oman		
3. A letter from the Pharmaceutical company confirming that the applicant is the Local Agent in the Sultanate	☐	☐
4. Photocopy of Ministry of Commerce & Industry - Oman certificate indicating that the applicant is the Sole Agent of the Pharmaceutical Company in the Sultanate.	☐	☐

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

Name & Signature of
the authorized person
Local Agent

Stamp of the
Local Agent

_____

Part II: (*To be filled by the company*)

1.Type of the company:

Parent		**Subsidiary**	

2. Name and Address Details: -

2.1 Name of the manufacturer: _____
2.2 Date of establishment: _____

2.3 Address of the Company in the country of origin:

Address	**Manufacturing Plant**	**Administration Office**
Street		
City		
P.O.Box		
P. C.		
Country		
Tel. No.		
Fax No.		
E-Mail		

	Yes	**No**
3. Legalized Certificate of Registration of the Company as a manufacturer of pharmaceutical products in the country of origin. - Manufacturer License No. _____ - Date of first Licensing _____	☐	☐
4. Legalized Certificate issued by the Health Authorities stating that the manufacturer fulfills the requirements of current Good Manufacturing Practice (cGMP) and the manufacturing plant is subjected to periodic inspection:	☐	☐
5. An undertaking letter from the manufacturer that the finished products exported to the Sultanate will have the same composition & specifications as those marketed in the country of origin	☐	☐
6. Statement of Capital Assets (Pharmaceutical Division)	☐	☐

7. No. of employees & their qualifications in the following departments:-

Department		Qualifications					
		Ph.D.	M.Sc	B.Sc.	Tech	Others	Total
1	Research						
2	Production						
3	Quality Control						
4	Packaging						
5	Others						
					Grand Total		

	Yes	No
8. List of manufacturing equipment / instruments :	☐	☐
9. Statement of Affiliated Branches & their activities:	☐	☐
10. Statement of full responsibility of the parent company towards its affiliated branch (applied for its registration).	☐	☐
11. List of the products manufactured by the company indicating trade names, generic names and countries where these products are registered and marketed and when:	☐	☐
12. Status of registration in other countries:		
12.1: Legalized list of countries where the company is registered	☐	☐
12.2: Photocopies of legalized registration certificate of the company/its products(CPP) in at least three countries with advanced drug control system	☐	☐
12.3: Photocopies of registration certificates of the company and the range of products registered in Gulf Countries if available :	☐	☐
13. Research & Development Department:		
13.1: List of the company patented products within the last 10 years indicating the following:- Trade, Generic, Chemical Names, Dosage Forms, Strength, Therapeutic Category, Patent number, date and country where the patent granted.	☐	☐

	Yes	No
13.2: Photocopy of patent certificates for any of the products/molecules.	☐	☐
13.3: Development made by the company	☐	☐

Name & Signature of
The authorized person
in the Company

_____

Stamp of the Company

FOR OFFICIAL USE ONLY

Received ☐ Not received ☐

Checked by: _____

Signature: _____

Dated: _____

Record No: _____
Date: _____