



**DRUG REGULATORY AUTHORITY OF PAKISTAN  
FORM-1**

[see rule 4(2), 5(1), and 6(2)]

**APPLICATION FORM FOR GRANT OR RENEWAL OF AN  
ESTABLISHMENT LICENCE TO MANUFACTURE MEDICAL DEVICES**

I/WE .....  
 (1)..... (2)..... (attach list of partners) Holder (s) of  
 CNIC No. .... Owner of M/S  
 ..... hereby apply for Establishment Licence of my firm/company established  
 under company /partnership Act ..... Having NTN ..... located at the premises as  
 under .....

Sr. No.	Description	Particular		
<b>1.</b>	<b>Purpose of application, whether;</b>	<b>Please select appropriate column</b>		
(i)	Fresh/New Application			
(ii)	For renewal of establishment licence to manufacture medical devices			
	(i) Licence number and date:			
	(ii) Validity date:			
	(iii) Last renewal date and its validity:			
	(iv) Attach certificate of licence and last renewal:			
(iii)	Proposed change of any particular of a licensed establishment (in case of any proposed change, please mention details of change)			
<b>2.</b>	<b>Establishment details</b>	<b>Please provide detail against each where applicable</b>		
(i)	Establishment name and address:			
(ii)	Type of ownership i.e. partnership, proprietorship, public limited, private limited etc:			
(iii)	Business registration as issued by the Registrar of Companies or any other authorized body:			
(iv)	Names of partners/proprietors/directors:			
(v)	addresses of partners/proprietors/directors:			
(vi)	Date of establishment:			
(vii)	Details of premises (please provide triplicate detail layout plan with dimension ):			
(viii)	Details of section wise equipments and machinery for manufacturing and instruments for quality control :			
Sr.No.	Name of Equipment	Make	Model	Capacity
(1)	(2)	(3)	(4)	(5)
<b>3.</b>	<b>Detail Of Qualified technical Person</b>			

	<b>(Attached copies of CNIC, Photographs, Degrees , Experience Certificate and Certificate of Concerned council)</b>	
(a)	Names of production incharge for supervising manufacturing processes	
	Qualifications of production incharge	
(b)	Names and qualifications of quality control incharge for supervising quality control department	
	Qualifications of quality control incharge for supervising quality control department	
(c)	Other technical staff working in these departments:	
4.	<b>Proof of fee deposited:</b>	
5.	<b>Details of medical devices intended to be manufactured:</b>	
6.	Any other relevant information that may be required by the MDB.	

**DECLARATION**

Certified that the documents and information provided herein are genuine and correct and if found at any stage to be misrepresenting or incorrect it shall lead to legal action under the Drug Regulatory Authority of Pakistan Act, 2012 and the rules made there under. This certificate must be on stamp paper duly notarized and signed and stamped by Proprietor, Chief Executive, Managing Director or an authorized officer. In case of an authorized officer authority letter from the owner of the establishment shall be provided.

Name(s).....  
Designations.....  
Signature(s).....  
Stamp.....  
Date.....

**Note:**

- This form shall also be used if change is proposed regarding the particulars provided in relation to the licensed establishment to manufacture medical devices. For this purpose, provision of relative information is mandatory.
- Provide readable softcopy along with application in USB/CD.