Registration form For pharmaceutical companies

Appendix 3

First:- General Information

A	Name of company	
B	Main address	
C	Nature of activities (contract manufacturer , market authorize holder , etc	
D	Number of various working branches inside country of origin	
E	Number of various working branches outside country of origin	
F	name and address of branch supplying the Iraqi market. N.B. if the branch supplying the Iraqi market is not the mother company. Pleas fill separate application for the mother company.	
G	Name and addresses of other companies that cooperate or share in its activities in the field of drugs, what sort of relation	
H	Year of foundation	
I 1)	Registered annual capital	
2)	Working annual capital (optional)	
3)	Sales annual capital – (optional)	
J	Total number of employees	
K	Product list (trade & generic name) May be submitted seprately	
L-1	Are these preparations totally or partially manufactured by the firm itself?	
L-2	If partially manufactured, what are these products, where manufactured, and why?	
M	Research activities of the firm itself	

	during the last ten years.	
N	Other activities besides pharmaceutical manufacturing.	
O	Names other countries where products are marketed	
P	Availability of suitable storage for raw materials and final products according to GMP. specifications.	
Q	Availability of systems for batches registration and follow up the suitability of the final products within the shelf life (have you conducted stability studies to suitability of the product within the shelf life with appropriate documentation)	

Appendix 3

Second:- Research Division

A	Do you have research laboratories	
B	Number of specialized personnel working in these research laboratories (Excluding administrative) PHYSICIANS	
	PHARMACIST	
	CHEMISTS	
	OTHERS	
C	What research activities and trials carried by these laboratories?	
D	Do you own or have at your disposal hospitals or medical centers for carrying out tests and experiments on your products?	
E	Do you collaborate with universities or scientific centers in research fields? Give details	
F	What is the annual budget reserved for research and development?	
G	Number of square meters assigned for these laboratories.	

Appendix 3

Third: Production Division

A	Origin of all raw materials	
	Self manufacturing	
	Under license	
	Other sources	
B	Number and qualification of personnel working in the production division.	
C	Number of square meters assigned for production area	
D	Availability of sterile area for pharmaceutical products.	
E	Name, qualification and signature of the head of the dept.	

Appendix 3

Fourth: Control Laboratories

A	Do you have control laboratories	
	For testing raw materials	
	For in process control	
	For testing final products	
B	What type of laboratory tests you perform?	
	Physio- chemical tests	
	Microbiological tests	
	Pharmacological tests	
C	What type of laboratory equipments used for quality control?(may be submitted separately).	
D	Number and qualification of personnel working these labs?	
E	Do you revert to the aid of other laboratories for control purposes? Name these labs & indicate what sort of assistance.	
F	Number of square meters assigned for these labs.	
G	Give in details the activities performed by the competent authorities for controlling your establishment and production.(provide details & documentation)	
H	Name, qualification and signature of the head of the dept.	
I	I, the undersigned: ….., Hereby declare that all information are given above is true, and I assume full responsibility for this declaration with all consequences, which might arise from false or erroneous information.	

Appendix 3

	Date	
	Name of the establishment	
	Signature and Stamp:	

N.B.
Please sign and stamp each page of this form