Medical Products Registration Form

Form A2

Kurdistan Medical Control Agency (KMCA),
Erbil, Kurdistan region,
Iraq,
2012

Applicant Company (distributor)	Name: Main Address: Telephone no.: Fax: Email: Website:
Responsible pharmacist	Full name Main Address : Telephone no.: Fax : Website : Email
Marketing authorization holder	Name: Main Address: Telephone no.: Fax: Email: Website:
Manufacturer	Name: Main Address: Telephone no.: Fax: Email: Website:

1.1- Name of the medical product to be registered and dosage form	
1.2- Concentration of the medical product: the active constituents it contains, indicated as the quantity per dosage unit, quantity per unit of volume or quantity per unit of weight, depending upon the pharmaceutical form in this application.	
1.3- Brief summery of the product	
1.4- Identification (Physical appearance of the product to be registered)	
1.5- Is this product registered to be placed on the market for use in the country of origin?	Yes ☐ No ☐
1.6- Number and date of product registration in the country of origin	
1.7- Is this product actually freely soled in the country of origin?	Yes ☐ No ☐

2.1- Marketing authorization holder at country of origin	Name Main address Telephone no. Fax Email Website:
2.2- If marketing authorization lacking in the country of origin? State the cause	Not required ☐ Not requested ☐ Under consideration ☐ Refused ☐
2.3- Name and address of the manufacturer producing the dosage form:	Name Main address Telephone no. Fax Email Website:

2.4- Remarks	

3.1- Does the regulatory authority arrange periodic inspection of the manufacturing plant in which the dosage form is produced?	Yes ☐ No ☐ Not applicable ☐
3.2- Periodicity of inspection	( ) years
3.3- Has the manufacture site of this type of dosage form been inspected?	Yes ☐ No ☐

4. Regulatory authority in the country of origin :	Name Main address Telephone no. Fax Email Website:

5. Pharmaceutical Formula of the Product

6. Name, quantities and structural formula of the active ingredients are as follows
A) Approved or Chemical Name
B) Structural name and formula

7. Specifications for all the active and non-active raw materials used in the manufacturing Process (Attached)

8. Source of active pharmaceuticals ingredients, state whether

i. An Original research of the manufacturer, or

ii. **Completely produced by the manufacturer, or** iii. **Partially produced by the manufacturer, or** iv. **Others.**

9. Name and quantities of other constituents and additives (color, flavor, etc.)

10 – Containers (type of container used for the packaging):

11- Clinical Use:	
a. Therapeutic indications :	
b. Route of administration:	
c. Recommended dosage	
d. Contraindications	
e. Special warnings and special precautions for use	

f. Interaction with other medicaments and other forms of interaction :	
g. Pregnancy and lactation :	
h. Effects on ability to drive and use machines :	
i. Undesirable effects :	
j. Overdose :	

12- Pharmacological properties	
1. Pharmaco-dynamic properties	

2. Pharmacokinetic properties	
3. Preclinical safety data	

13-Pharmaceutical properties	
1. Incompatibilities	
2. Special precautions for storage	
3. Instruction for use/handling	

14.Stability studies and Shelf-life of the product:

a- Stability studies indicating the method used and method for analyzing the degradation products
b- Changes in the physical characteristics anticipated during storage
c- Changes in the chemical characteristics anticipated during storage
d- Accelerated stability and long term satiability (showing the degradation products numerically) , With shelf life and storage conditions
e- Stability chromatograms

15- Label and Inserts:	
1. Directions for use	
2. Contraindications	
3. Warnings	

16- A summary of the experimental details and results of the tests performed on the drug to confirm its Pharmacological effects.

17. A summary of the experimental details and Biological studies results of the tests performed on the drug to confirm its physiological availability.

18- Animal toxicology studies (toxicology, pathology, and teratology)

19- Bioavailability and Bioequivalence studies	
1. Number of trails	
2. Number of patients	
3. Dosage used in trails	
4. Result achieved	
5. Adverse reactions reported during studies	
6. Biological availability	
7. Conclusions and comments	

The undersigned here declares that all the information contained herein is correct to the best of my knowledge and belief.

Signature of Responsible person (Of the manufacturer)	**Name of Responsible person (Of the manufacturer)**
Date	**Manufacturer stamp**

Medicines registration Requirements at KMCA:

1- Drug registration form (this form is provided by KMCA) filled by Manufacturer (signed and stamped)
2- Certificate of Pharmaceutical products (CPP) legalized by Health Authority, the Ministry of foreign affairs, Iraqi Embassy in the country of origin, this certificate should include the following:
   - a statement that the product is freely sold and used in the country of origin with the registration number and date
   - quantities of active and non active ingredient (s)
   - name and address of manufacturing company and marketing authorization holder
3- Certificate of analysis of finished product legalized by Ministry of Health, Ministry of foreign affairs, Iraqi Embassy in the country of origin
4- Price structure certificate Issued by Health authority clarifying the profit margins for the wholesaler and the pharmacist in the country of origin legalized by chamber of commerce, Ministry of foreign affairs, and Iraqi Embassy in the country of origin.
5- Two samples of the package insert, inner label and outer pack (the outer pack should contains the bar code, storage conditions numerically and identical to what mentioned in the stability study, batch number, manufacturing date and expiry date, trade name if any , generic name , concentration Of active constituents, route of administration, storage conditions, warnings, name of manufacturer and full address and special instruction for use). The inner leaflets should be written in English .
6- A sample of the following with its certificate of analysis of the same batch for the use of KMCA –Quality Control.
   - Reference standard / official products.
   - Working standard / non pharmacopoeia products, submit minimum (20grams) of active constituent(s).
   - Degradation product (s) or related substance (s)
8- Samples for registration and for analysis as follow:

No.	Item	No. of Samples required for analysis (of the same Batch. no.) in the Quality Control Lab	No. Of Samples required for registration (of the same Batch no.) in the Quality Control Lab
1	Tablets & caps	150 tab or cap	2 packs
2	Vials, Amp. Vol.>1 ml	50 vial or amp.	2 packs
3	Vials, Amp. Vol. of 1 ml	100 vial or amp.	2 packs
4	Vials, Amp. Vol.<1 ml	200 vial or amp.	2 packs
5	Distilled water	1500 ml	2 packs
6	Syrup	5 bottles	2 packs
7	Oral Drops	5 containers	2 packs
8	Eye drops	20 containers	2 packs
9	Eye oint.	50 tubes	2 packs
10	Skin oint	5 tubes	2 packs
11	Suppositories	30 blister	2 packs
12	Vaginal cream	5 tubes	2 packs
13	Insulin	20 vials	2 packs
14	Heparin	30 vials	2 packs
15	Albumin	25 vials	2 packs
16	Factors	25 vials	2 packs
17	I.V.Fluids	10 bottle	2 packs

9- Method of analysis for the finished product
10- Method of validation for analysis methods
11- Stability studies of the product in the same formula and dosage form that will be submitted for registration:
- **Stability study protocol should be provided**
- **Accelerated stability studies**
- **Long term stability studies for the whole shelf life.**
- **Test interval are 0,3,6,9,12,18,24,36,48.**
- **Results and conclusions report should be enclosed , clarifying the proper shelf life and the storage conditions a cording to the study conditions**

12- Specifications of:
- **Finished product**
- **Raw material for both active and non active ingredient**
- **Both the inner and outer packaging material**

13- Method of manufacturing and filling of the finished product.
14- In process and finished product Q.C. test methods along with validation of that method unless the product is a pharmacopeias one.
15- A certificate stating the safety of blood products from HIV, HAV, HDV, BCV, HBS.
16- List of the countries where the product is registered and sold with registration number and date.
17- In case of under license product, a letter of the manufacturer clarifying the responsibilities that the new manufacturer holds (manufacturing, repackaging, marketing....etc) also confirming its approval to export this item to Iraq.
18- A certificate from regulatory authority of the manufacturer country confirming that raw materials for Oral Dosage Forms are not contaminated with diethylene Glycol.
19- Registration Fee should be paid by the applicant company
20- When applicable, append details of any restriction applied to the sale, distribution or administration of the product that is specified in the origin country,
21- If an application has been rejected or withdrawn in any country, give reasons.
22- A dosage form in a separate strength and pharmaceutical form shall be considered as a drug and need separate application form.
23- Bioequivalence study (for generics)
24- Bioavailability study for originators
25- No bioavailability or bioequivalence study is required for OTC drugs, however dissolution profile to be submitted.
26- Re registration is required after five years, and the requirements are:
a) **Sample of finished products.**
b) **CPP issued by the health authority of the country of origin.**
c) **Specification of finished product.**
d) **Formula.**
e) **Specifications of active and inactive ingredients.**
f) **A letter from the manufacturer declaring that there are no changes made on the formula, manufacturing method and specification, signed and stamped by the manufacture.**
g) **Re registration fee.**

27- The registration committee has the right to ask for any additional information or documents.
28- Files to be submitted should be numerated and have a table of contents.
29- Scientific data should be in English.