KMCA Kurdistan Medical Control Agency دامەزراوەی کۆنترۆڵی جۆریی دەرمان

REGULATORY FORM

MEDICINAL PRODUCTS MANUFACTURING SITE REGISTRATION FORM

FOR-REGD-111-20

OCTOBER 2020

The information in this form may be updated based on scientific and regulatory developments. For the latest version, please refer to our website kmcakrg.org.

1. APPLICANT COMPANY [A] (KURDISTAN SUPPLIER)

1.1. GENERAL INFORMATION		
1.1.1. Name		
1.1.2. Address		
1.1.3. Email		
1.1.4. Website		
1.1.5. Contact details		
1.1.6. Authorized contact person name and contacts		
1.1.7. Store address		
1.1.8. MOH license No. & date (attach valid copy)		
1.1.9. Category	□ distributor □ legal representative □ others	If others, explain.

1.2. RESPONSIBLE PHARMACIST	
1.2.1. Name	
1.2.2. Address	
1.2.3. Email	
1.2.4. Website	
1.2.5. Contact details	
1.2.6. Syndicate registration No. & date (attach valid document copy)	

1.3. DECLARATION
We hereby declare that: **1.3.1. All provided information; data and all attached requirements are true and accurate to the best of our knowledge and believe.** **1.3.2. We will inform KMCA about any changes in manufacturing site information mentioned in this form.**
Responsible Pharmacist Signature & date: Stamp:

2. MANUFACTURING COMPANY (MARKETING AUTHORIZATION HOLDER)

2.1. GENERAL INFORMATION		
2.1.1. Name		
2.1.2. Office address		
2.1.3. Email		
2.1.4. Website		
2.1.5. Contact details		
2.1.6. Year of foundation		
2.1.7. Is the company owned or belong to other company or group of companies	□ Yes □ No	If yes, explain.
2.1.8. Activities	□ Marketing authorization holder □ Manufacturer □ Contract manufacturer □ Others	If others, please specify.
2.1.9. Manufacturing authorization No. & date		
2.1.10. GMP certificate		
2.1.11. Certifying authority name & address		
2.1.12. Name and address of company branch supplying Kurdistan market		
2.1.13. Name and address of other companies share activities in manufacturing medicinal products		
2.1.14. List of products intended to be marketed in Kurdistan	Attach (soft & hard copy) list contain trade name, composition & strength, dosage form, packing size, shelf life, batch size, name and address of all companies sharing manufacturing activities (processing, bulk manufacturing, primary and secondary packaging, labeling, quality control, batch certification) for each product, country names where it is authorized and marketed.	

3. MANUFACTURING SITE[B]

3.1. GENERAL INFORMATION		
3.1.1. Name		
3.1.2. Address		
3.1.3. Email		
3.1.4. Website		
3.1.5. Contact details		
3.1.6. GMP certificate		
3.1.7. Certifying authority name & address		
3.1.8. Total area occupied by plant		
3.1.9. Total area occupied by buildings		
3.1.10. Age of the buildings		
3.1.11. number of personnel	Technical	
	Production	
	Quality control	
	Quality assurance	
	warehouse	
3.1.12. Flow patterns are available for	□ personnel □ raw material □ in-process □ finished products □ waste products	If not available, explain why?
3.1.13. Patterns are available for	□ airflow □ differential pressure □ clean areas classification	If not available, explain why?
3.1.14. Manufacturing activities	□ processing □ bulk manufacturing □ packaging □ labeling □ quality □ batch certification	
3.1.15. Source of raw materials (countries)		
3.1.16 Source of packaging materials (countries)		
3.1.17. Warehouse available according to GMP& GSP?	□ Yes □ No	if No, explain why?
3.1.18. Do the manufacturer have contract manufacturing activity?	□ Yes □ No	If Yes, mention product types.

3.2. KEY PERSONNEL			
Title	**Name**	**Qualification**	**Experience**
Plant manager			
Qualified responsible person			
Production manager			
Technical manager			
Quality assurance manager			
Quality control manager			
R&D			
Others			

3.3. PRODUCTION AREA		
3.3.1. Production lines & capacity		
3.3.2. Facility equipped with heating, ventilation, air conditioning system	□ Yes □ No	if No, explain why?
3.3.3. Beta-lactams, hormones, cytotoxic, highly sensitizing compounds are manufactured in this facility?	□ Yes □ No	If yes, attach list of products
3.3.4. Separated dedicated areas are available with separated HVAC units?	□ Yes □ No	If No, explain why?

3.4. RESEARCH AND DEVELOPMENT [B]			
Manufacturer has R&D department or activities?	□ Yes □ No □ Outsourced	If Yes, full the table below. If No, explain why? If outsourced, what type of activity?	
	Personnel Qualification		**Number**

3.5. QUALITY CONTROL LABORATORY [B]		
3.5.1. Manufacturer has QC Lab department or activities?	□ Yes □ No	If Yes, full the table below. If No, explain why? If outsourced, what type of activity?

	□ Outsourced	
	Personnel Qualification	**Number**
3.5.2. Instrumentation for chemical, physical, microbiological tests	Inhouse	Outsourced
3.5.3. Type of tests	Attach list of tests performs on raw materials, in-process materials & finished products.	
3.5.4. Stability study performed through shelf life of products with proper documentation.	□ Yes □ No	If No, explain why?

3.6. QUALITY ASSURANCE [B]		
3.6.1. Site master file available	□ Yes □ No	If yes, attach soft copy. If No, explain why?
3.6.2. Validation master plan available	□ Yes □ No	If yes, attach soft copy. If No, explain why?
3.6.3. Vendors assessment available	□ Yes □ No	If yes, attach SOP. If No, explain why?
3.6.4. Is Internal GMP audit for full quality system available?	□ Yes □ No	If Yes, attach copy of last audit report. If No, explain why?
3.6.5. Do you have effective deviation control system?	□ Yes □ No	If Yes, attach list of deviations for last 2 years with one CAPA report. If No, explain why?
3.6.6. Do you have effective complains & recall system and resources?	□ Yes □ No	If Yes, attach list of complains & recall for last 2 years.

3.7. PRODUCTS INFORMATION [B]		
3.7.1. Manufactured products free from	□ Yes □ No	If Yes, attach a declaration letter & if No, explain why & mention products.

alcohol?		
3.7.2. Manufactured products free from pork contents?	□ Yes □ No	If Yes, attach a declaration letter. If No, explain why & mention products.
3.7.3. Manufactured products free from transmissible diseases like BSE/TSE?	□ Yes □ No	If Yes, attach a declaration letter.

2.8. DECLARATION
2.8.1. We hereby confirm that we attached all the requirements, and the provided information and data are true and accurate to the best of our knowledge and believes. **2.8.2. We declare that we will not use the KMCA registration form in any advertising or promotional activity.** **2.8.3. We declare that we will inform KMCA about any changes in manufacturing site information mentioned in this form.**
Qualified Responsible Person Signature & date: Stamp:

- [A] / to be fill by Kurdistan agent company
- [B] / to be filled by manufacturing site
- Pages 3-6 should be sign and stamp by person in charged
- When explaining deficiencies please use short sentences and statements.
- Please be careful in ticking boxes, unclear or confusing ticks will be refused and leads to registration process delay.
- Each manufacturing site must be submitted in a separate form.
- Submit the filled form, list of products and attachments in hard and soft copy in a format can ease the copy & paste information.

END