Primary Registration Requirements for Medicines at KMCA

Drug Trade Name, Scientific Name, Concentration & Dosage Form:-
Kurdistan Applicant Company :-

Drug Marketing Authorization Holder (MAH) & Manufacturer / Country:

✓ Submit a copy of drug approval in national list.

✓ A copy of legalized Authorization Letter, or KMCA letter regarding change of authorization to your company.

✓ The registration committee has the right to ask for any additional information or documents.

No	**Registration File Content :**
1	Cover Letter from applicant.
2	Drug registration form (form A2) This form is provided by KMCA filled by the Marketing Authorization Holder or the Manufacturer (Signed and Stamped by the Marketing Authorization Holder or the Manufacturer).
3	Certificate of pharmaceutical products (CPP) legalized by Health Authority, the Ministry of foreign affairs and Iraqi Embassy in the country of origin.
4	A copy of the manufacturer's registration Certificate in KMCA.
5	Two samples & Mock-up of the package insert, inner label and outer pack. Outer pack: should contains :bar code , storage conditions numerically and identical to what mentioned in the stability study conclusion , batch number, manufacturing date and expiry date , trade name if any , generic name, concentration of active constituents , route of administration especially for critical & double uses, warnings for Excipients (that know to have some precautions) and special instruction for use. The inner label: should contain; trade name, scientific name, dosage form & strength. The inner leaflets : • Revision date. • For generics; submit an originator leaflet for comparison and should be identical for scientific & clinical information. * Name of the manufacturer & full address/country must be written either on the outer pack or on the leaflet. * The written language of the outer pack & leaflet must be in English and/or Arabic and/or Kurdish.
6	List of the countries where the product is registered and sold with registration number and date and a copy of the certificate(s), the product should be at least registered in the country of origin & one of these options: a. Registered in one of the reference countries. b. Registered in two other countries. Five products of the same manufacturer registered in Baghdad.
7	A certificate stating that the gelatin and other components of animal source are not of pork origin (signed & stamped by the manufacturer of the finished product).
8	A certificate stating that the gelatin and other components of animal source are free from contamination with TSE/BSE (signed & stamped by the manufacturer of the finished product).
9	A certificate from regulatory authority of the manufacturer country confirming that raw materials for oral liquid dosage forms are not contaminated with di-ethylene Glycol.
10	Specifications of the finished product.
11	KMCA pricing letter or price certificate signed and stamped by the manufacturer or marketing authorization holder and legalized by Chamber of Commerce in the country of origin. Note; The price must be in USD ($) and the certificate must contain the following information.

Trade Name of Product	
Concentration or Strength	
Pack Size	
Pharmaceutical Form (Dosage Form)	
Ex. Factory Price in Country of Origin	
CIF Price to Kurdistan / Iraq	
Wholesaler Price in Country of Origin	
Retail Price in Country of Origin	
CIF to Neighbor Countries and/or European Countries (if available)	