

Registration of drug producing plant in our department that did not registered Health Ministry of Federal Iraq.

- 1- Registration should be made by Drug Importer Company that must be registered in Ministry of health in Kurdistan region or by representative of manufacturer.
- 2- Demand letter for registration should be represented to our department, and in the letter the date and No. should be indicated.
- 3- List of presented documents (Index List)
- 4- The form of factory registration (**Form A1**) should be filled, sealed and signed by representative of drug producer factory and certified by ministry of health, ministry of foreign in manufacturer country and embassy of Iraq or Kurdistan Region's representative in English language.
- 5- Valid GMP certificate, issued and certified by concerned parties and foreign ministry of manufacturer country, embassy of Iraq or Kurdistan Region's representative in English language.
- 6- Copy of Valid GMP certificate issued and certified or copy of CPP certificate of Pharmaceutical product at least for two products (but if the factory produce one product one CPP is enough) according to WHO standard in English language and certified by concerned parties , foreign ministry of manufacturer country , embassy of Iraq or Kurdistan Region's representative and if issued by reference country that mentioned below they don't need test in contrary most be tested by our test team in purpose of registration:

Reference country:

- USA (FDA)
- European Union or one of its countries
- UK (MHRA)
- Health Products and Food Branch , therapeutic products Directorate of Canada (HPFB)
- Ministry of Health , Labor and Welfare / Pharmaceutical and Medical Safety Bureau Japan (MHLW)
- Australia (TGA)
- Switzerland (Swiss Medic)
- Gulf Countries Central Registration (GCC)

- 7- Copy of last factory test report that should be certified by concerned parties.
- 8- Manufacturing license in Manufacturer country certified by concerned parties , foreign ministry of manufacturer country , embassy of Iraq or Kurdistan Region's representative.
- 9- Authorization letter issued by manufacturer factory for demander for registration in our department should be certified by chamber of commerce , ministry of foreign affairs and embassy of Iraq or Kurdistan Region's representative in Manufacturer Country.
- 10- List of drug with date and number of registration in Manufacturer Country.
- 11- Recommendation letter and copy ID of Pharmacists Syndicate in Kurdistan for Demander.
- 12- Fee of factory registration
Registration of Drug Manufacture Factory that should be registered by Health ministry of Iraq.

Registration should be made by Drug Company in our department that registered by Ministry of health or through electing representative of manufacturer in a formal way that most have Iraqi ID and an occupation.

Required Documents:-

- 1- Demand letter for registration should be represented to our department, and in the letter the date and No. should be indicated.
- 2- Factory registration certificate in Iraqi Ministry of health.
- 3- Copy of valid GMP.
- 4- Authorization letter issued by manufacturer factory for demander for registration in our department should be certified by chamber of commerce, ministry of foreign affairs and embassy of Iraq or Kurdistan Region's representative in Manufacturer Country.
- 5- Recommendation letter and copy ID of Pharmacists Syndicate in Kurdistan for Demander.