

List of documents, required for registration medicines in Kyrgyzstan

1. Application form
2. Documents for registration
 - a) Summary of Product characteristics
 - b) Manufacturing License
 - c) Registration in other countries
 - d) GMP certificate
 - e) Free Sale Certificate
 - f) Full composition of product (including active and in-active ingredients)
 - g) Finished Product Specifications & method of Analysis of finished product
 - h) Pack Insert (Leaflet)
 - i) Pharmacological & Toxicological documentation (Single & repeat dose toxicity, influence on reproductive potential, data on embryo-toxicity & teratogenicity, data on mutagenicity, data on canceragenicity, pharmacodynamics, pharmacokinetics)
 - j) Clinical Data
 - k) Bioequivalence Report
 - l) Pack Design in Russian language
 - m) Samples of product (6 packs) along with Certificate of Analysis
 - n) Sample of active substance along with Certificate of Analysis