

List of documents, required for registration medicines in Tajikistan

1. Application form
2. Summary of Product characteristics
3. Manufacturing License
4. Registration in other countries
5. GMP certificate
6. Pack Insert (Leaflet)
7. Normative-technical documentation (qualitative & quantitative composition of the product, finished products specification and method of analysis, specifications and pharmacopoeia articles)
8. Certificate of Analysis
9. Label and product pack
10. Pharmacological and toxicological reports
11. Stability data
12. The short description of manufacturing process
13. Data on efficiency and safety of a product
14. Samples of a product (5 packs) and working standards