Documents submitted for state registration of medicines

Part 1. Administrative Documents

1.1. Content
1.2. Copies of certificates (notarized)
1.2.1. A copy of a certificate for a pharmaceutical product or a certificate of registration (registration certificate) of a medicinal product in the producing country

1.2.2. * GMP certificate
1.2.3. Certificates confirming registration in other countries
1.3 Brief description of the medicinal product, labeling and instructions for medical use 1.3.1. Brief description of the medicinal product
1.3.2. Marking
1.3.3. Copy of the instruction on the medical use of the medicinal product approved in the producing country in Russian and the draft instruction on the medical use of the medicinal product in the state language.
1.3.4. Colored packaging models on paper and electronic media in a scale of 1: 1
1.4. The normative document of the medicinal product (with the extension of the period for the registration of a copy - an approved regulatory document), as well as an explanatory note to the normative document
1.5. Detailed description of pharmacological surveillance and risk management system for medical use of a medicinal product
1.5.1. A document confirming the availability of a qualified person responsible for pharmacovigilance, for the collection and recording of adverse reactions detected in the territory of the Republic of Uzbekistan
1.5.2. Periodic updateable security report
1.6. Information on the possible environmental hazards
1.6.1. Information about the presence in the composition of the drug genetically modified organisms (GMOs)

The submission of a GMP certificate with a copy of the results of the latest inspection is mandatory only for foreign manufacturers.
Note.
With the participation of a number of manufacturers in the production process, the documents specified in paragraphs 1.3.2 and 1.3.4 are submitted to all participants in the production;

Part 2. Chemical, pharmaceutical and biological information on medicinal products that contain chemical and / or biological active substances

2.1. Content
2.2. Basic data
2.2.5. The active ingredient (a) (for medicinal products that contain more than one active substance, the information is provided in full with respect to each drug substance)
2.2.5.1. General information:
2.2.5. 1.1. Name
2.2.5. 1.2. Structure
2.2.5. 1.3. Common Properties
2.2.5.2. Production of active ingredient
2.2.5.2.1. Information about the manufacturer (s)
2.2.5.2.2. Description of the production process and its control
2.2.5.2.3. Monitoring of raw materials used in the technological process
2.2.5.2.4. Control of critical stages and intermediate products
2.2.5.2.5. Process validation and / or evaluation
2.2.5.2.6. Development of the production process
2.2.5.3. Characteristics of the active substance
2.2.5.3.1. Proof of structure and other characteristics
2.2.5.3.2. Impurities
2.2.5.4. Control of the active substance
2.2.5.4.1. Specification
2.2.5.4.2. Analytical test methods
2.2.5.4.3. Validation of analytical test methods
2.2.5.4.4. Test results of series
2.2.5.4.5. Justification of the specification
2.2.5.5. Standard samples or substances
2.2.5.6. Packaging / sealing system
2.2.5.7. Stability
2.2.5.7.1. Summary of Stability and Conclusions
2.2.5.7.2. Protocol of post-registration study of stability and obligations regarding stability
2.2.5.7.3. Stability data
2.2. P. Drug preparation:
2.2. P.1. Description and composition of the medicinal product
2.2. P.2. Pharmaceutical Development

2.2. P.2.1. Composite substances of the drug
2.2. P.2.1.1. Medicinal substances (substances) (i)
2.2. P.2.1.2. Excipients
2.2. P.2.2. Medicinal preparation
2.2. P.2.2.1. Development of the composition
2.2. P.2.2.2. Admissible surpluses
2.2. P.2.2.3. Physico-chemical and biological properties
2.2. P.2.3. Development of the production process
2.2. P.2.4. Packaging / sealing system
2.2. P.2.5. Microbiological characteristics
2.2. P.2.6. Compatibility
2.2. P.3. Production
2.2. P.3.1. Manufacturer (s)
2.2. P.3.2. Composition per series
2.2. P.3.3. Description of the production process and process control
2.2. P.3.4. Control of critical stages and intermediate products
2.2. P.3.5. Process validation and / or evaluation
2.2. P.4. Control of auxiliary substances
2.2. P.4.1. Specifications
2.2. P.4.2. Analytical test methods
2.2. P.4.3. Validation of analytical test methods
2.2. P.4.4. Justification of specifications
2.2. P.4.5. Auxiliary substances of human and animal origin
2.2. P.4.6. New excipients
2.2. P.5. Control of medicinal product:
2.2. P.5.1. Specification (s)
2.2. P.5.2. Analytical test methods
2.2. P.5.3. Validation of analytical test methods
2.2. P.5.4. Test results of series 2.2. R.5.5. Characteristics of impurities
2.2. P.5.6. Justification of the specification (s)
2.2. P.6. Standard samples and substances
2.2. P.7. Packaging / sealing system
2.2. P.8. Stability:
2.2. P.8.1. Summary and conclusion about stability
2.2. P.8.2. Protocol of post-registration study of stability and obligations regarding stability
2.2. P.8.3. Stability data
2.2. A. Additions
2.2. A.1. Technical means and equipment

2.2. A.2. Safety assessment of foreign microorganisms
2.2. A.3. New excipients
2.2. R. Regional information
2.3. References to used literary sources

Part 3. Reports of preclinical studies

3.1. Content
3.2. Research Reports
3.2.1. Pharmacology
3.2.1.1. Pharmacodynamics
3.2.2. Pharmacokinetics
3.2.3. Toxicology
3.2.3.1. Toxicity when administered a single dose
3.2.3.2. Toxicity in the administration of repeated doses
3.2.3.3. Genotoxicity
3.2.3.4. Carcinogenicity (long-term studies, studies of short or medium duration)
3.2.3.5. Reproductive and ontogenetic toxicity: gonadotoxicity, embryotoxicity, teratogenic effect.
3.2.3.6. Local tolerance (local irritant effect, allergenic effect).
3.2.3.7. Other toxicological studies: antigenicity, immunotoxicity, other.
3.3. References to used literary sources

Part 4. Reports of clinical trials

4.1. Content.
4.2. List of clinical studies.
4.3. Reports of clinical trials.
4.3.1. Biopharmaceutical research reports
4.3.2. Reports of studies relating to pharmacokinetics using human biomaterial.
4.3.3. Reports of pharmacokinetic studies in humans
4.3.4. Reports of pharmaco-dynamic studies in humans.
4.3.5. Efficiency and safety research reports:
4.3.6. Reports on the post-registration experience of application.
4.3.7. Samples of individual registration forms and individual patient lists
4.4. References to the used literary sources

Note.

The documents indicated in the list are required taking into account the origin, properties, features of the way of obtaining / producing medicinal products.

In the event that parts of the documents are not presented in the appropriate section, the reason should be indicated. For registration of medicinal substances (substances), the documents specified in clauses 1-L-1.3.4, 1.4.4, 1.5, 1.7.2.1-2.2.S.7.3 are submitted.

When the Certificate of Conformity of the European Pharmacopoeia (SER) is provided, the documents specified in clauses 2.2.S.2-2.2.S.3.2 and 2.2.S.7-2.2.S.7.3 are not required. The validity of the CER certificate is checked by a responsible employee in the electronic database of the European Directorate for Quality of Medicines and Health. Applications for renewal of the registration certificate must contain the data described in parts 1, 2. Requests for generic medicinal products should contain the data described in parts 1, 2, together with data demonstrating bioavailability and bioequivalence with the original medicinal product, provided that the latter is not a biological medicinal product.

Registration documents of medicinal plant raw materials should contain the data of parts 1 and 2. With respect to the nomenclature of medicinal plant raw materials, it is necessary to indicate the binomial scientific name of the plant (genus, species, species and author) and chemotype (if necessary), plant parts, plant substance definition, other names (synonyms indicated in another pharmacopeia).

For medicinal products of animal origin, the following additional information should be provided in Part 2: data on the species, age, diet and geographic region of origin of animals from which raw materials are obtained; data on the nature (category) of the tissue from which the raw material for the production of the medicinal product is derived, in terms of its danger with regard to the content of prions; technological scheme of processing raw materials with an indication of extractants, temperature conditions etc., methods of control of raw materials.