The list of documents of the registration dossier for the examination of medicinal products in accordance with the order of the Minister of Health of the Republic of Kazakhstan dated November 18, 2009 No. 736 On approval of the Rules for the examination of medicinal products and medical devices (as amended dated April 19, 2019)

№	Name of documents
	Part 1.*
1.1.	General documentation
1.2.1	Certificate for a pharmaceutical product as recommended by the World Health Organization (notarized).
	In case of absence the following is provided:
	Certificate of registration (marketing authorization) in the producing country (notarized)
	GMP certificate (with the date and results of the last inspection) (notarized)
	Certificate allowing free sale (export)
1.2.2.	Certificate of origin (for domestic manufacturers)
1.2.3.	License agreement (contract) for the right to manufacture (before the expiration of the patent for the original medicinal product)
1.2.4.	Information about the registration of a medicinal product in other countries, indicating the number and date of the registration certificate (or a copy of the registration certificate or marketing authorization)
1.3.	Brief description of the medicinal product, labeling (color layouts) and instructions for the medical use
1.3.1.	Brief description of the medicinal product with the date of the last review
1.3.2.	Approved instruction on the medical use of the medicinal product (for companies-manufacturers of the countries of the Commonwealth of Independent States), certified by the company-manufacturer
1.3.3.	Draft instruction on the medical use of the medicinal product
1.3.4	Text of labeling of primary and secondary packing, labels, stickers in Kazakh and Russian
1.3.5.	Colored layouts of consumer packing, labels, stickers in an electronic form, jpeg format, 1:1 scale
1.4.	Information about experts
1.4.1.	Information about the quality expert
1.4.2.	Information about the expert on preclinical data
1.4.3.	Information about the expert on clinical data
1.5.	Special requirements for different types of applications
1.6.	Assessment of potential environmental hazards
1.6.1	Medicinal product containing or derived from genome-modified organisms
1.7.	Information regarding the applicant's pharmacovigilance in the Republic of Kazakhstan
1.7.1	Brief description of the pharmacovigilance system of the marketing authorization holder includes: evidence stating that the marketing authorization holder has a person responsible for the global pharmacovigilance at its disposal; contact details of a person responsible for the global pharmacovigilance;

	declaration signed by the marketing authorization holder stating that he/she has a pharmacovigilance system to fulfill the tasks and responsibilities for the post-registration control of medicinal product safety; reference to the place (address) where the pharmacovigilance system master file is kept
1.7.2	Document confirming that the applicant has a person responsible for the pharmacovigilance in the Republic of Kazakhstan
	Part 2.*
	Summary of general technical document
2.1.	Content of parts 2.3.4.5
2.2.	Introduction to general technical document
2.3.	General quality report
2.4.	Preclinical data review
2.5.	Clinical data review
2.6.	Preclinical data report
2.6.1.	Pharmacological data report in a text format
2.6.2.	Pharmacological data report in a tabular format
2.6.3.	Pharmacokinetic data report in a text format
2.6.4.	Pharmacokinetic data report in a tabular format
2.6.5.	Toxicological data report in a text format
2.6.6.	Toxicological data report in a tabular format
2.7.	Clinical data report
2.7.1.	Biopharmaceutical research report and related analytical methods
2.7.2.	Clinical pharmacology research report
2.7.3.	Clinical effectiveness report
2.7.4.	Clinical safety report
2.7.5.	Copy of used literary sources
2.7.6.	Short reviews of individual tests
	Part 3. Quality *
3.1.	Content
3.2.	Basic data
3.2.S.	Medicinal substance (for drugs that contain more than one active substance, information is provided in full regarding each of them) **
3.2.S.1.	General information**
3.2.S.1.1.	Title**
3.2.S.1.2.	Structure**
3.2.S.1.3.	General properties * *
3.2.S.2.	Production
3.2.S.2.1.	Manufacturer**
3.2.S.2.2.	Description of the production process and its control
3.2.S.2.3.	Control of basic materials
3.2.S.2.4.	Control of critical stages and intermediate products
3.2.S.2.5.	Initial examination of the process and/or its assessment

3.2.S.2.6.	Production process development
3.2.S.3.	Characteristics**
3.2.S.3.1.	Evidence of structure and characteristics
3.2.S.3.2.	Impurities **
3.2.S.4.	Active substance control **
3.2.S.4.1.	Specification**
3.2.S.4.2.	Analytical methods **
3.2.S.4.3.	Initial examination of analytical methods
3.2.S.4.4.	Series analyzes **
3.2.S.4.5.	Specification justification
3.2.S.5.	Standard samples or substances
3.2.S.6.	Container closure system**
3.2.S.7.	Stability**
3.2.S.7.1.	Summary of stability and conclusions **
3.2.S.7.2.	Report for the post-registration study of stability and commitments regarding the stability **
3.2.S.7.3.	Stability data * *
3.2.P.	Medicinal product
3.2.P.1.	Description and composition of the medicinal product
3.2.P.2.	Pharmaceutical development
3.2.P.2.1.	Components of the medicinal product
3.2.P.2.1.1.	Medicinal substance
3.2.P.2.1.2.	Excipients
3.2.P.2.2.	Medicinal product
3.2.P.2.2.1.	Composition development
3.2.P.2.2.2.	Surplus
3.2.P.2.2.3.	Physicochemical and biological properties
3.2.P.2.3.	Production process development
3.2.P.2.4.	Container closure system
3.2.P.2.5.	Microbiological characteristics
3.2.P.2.6.	Compatibility
3.2.P.3.	Production
3.2.P.3.1.	Manufacturer (s)
3.2.P.3.2.	Composition per series
3.2.P.3.3.	Description of the production process and process control
3.2.P.3.4.	Control of critical stages and intermediate products
3.2.P.3.5.	Initial examination of the process and/or its assessment
3.2.P.4.	Control of excipients
3.2.P.4.1.	Specifications
3.2.P.4.2.	Analytical methods
3.2.P.4.3.	Initial examination of analytical methods
3.2.P.4.4.	Specification justification
3.2.P.4.5.	Excipients of human and animal origin
3.2.P.4.6.	New excipients
3.2.P.5.	Medicinal product control
3.2.P.5.1.	Specification (s)

3.2.P.5.2.	Analytical methods
	Approved regulatory document on quality and safety control in an electronic form, doc format (in case of re-registration an additional copy of regulatory document approved in the Republic of Kazakhstan)
3.2.P.5.3.	Initial examination of analytical methods
3.2.P.5.4.	Series analyzes
3.2.P.5.5.	Characteristic of impurities
3.2.P.5.6.	Specification justification (s)
3.2.P.6.	Standard samples and substances
3.2.P.7.	Container closure system
3.2.P.8.	Stability
3.2.P.8.1.	Summary and conclusion on the stability
3.2.P.8.2.	Report for the post-registration study of stability and commitments regarding the stability
3.2.P.8.3.	Stability data
3.2.A.	Additions
3.2.A.1	Technical means and equipment
3.2.A.2	Safety assessment for extraneous microorganisms
3.2.A.3	New excipients
3.2.R.	Regional Information
3.3.	Copy of used literary sources
	Part 4. Reports on preclinical (nonclinical) studies
4.1.	Content
4.2.	Study reports
4.2.1.	Pharmacology
4.2.1.1.	Primary pharmacodynamics
4.2.1.2.	Secondary pharmacodynamics
4.2.1.3.	Safety pharmacology
4.2.1.4.	Pharmacodynamic medicinal interactions
4.2.2.	Pharmacokinetics
4.2.2.1	Analytical methods and report regarding their initial examination
4.2.2.2	Suction
4.2.2.3	Distribution
4.2.2.4	Metabolism
4.2.2.5	Elimination
4.2.2.6	Pharmacokinetic medicinal interactions (preclinical)
4.2.2.7	Other pharmacokinetic studies
4.2.3.	Toxicology
4.2.3.1.	Single dose toxicity
4.2.3.2.	Repeated dose toxicity
4.2.3.3.	Genotoxicity (in-vitro; in-vivo, toxicokinetic evaluation)
4.2.3.4	Carcinogenicity (long-term studies; short-term or medium-term research)
4.2.3.5.	Reproductive and ontogenetic toxicity: reproduction capability and early embryonic development; fetal embryonic development; intrauterine and postpartum development; studies in which the descendants (growing animals) were provided with a certain dose and/or evaluated in future.

4.2.3.6.	Local tolerance
4.2.3.7.	Other toxicity studies: antigenicity; immunotoxicity; mechanical studies; addiction; metabolites; impurities.
4.3.	Copy of used literary sources
	Part 5. Reports on clinical studies and/or trials
5.1.	Content
5.2.	List of all clinical trials in the form of tables
5.3.	Clinical trial reports
5.3.1.	Biopharmaceutical study reports: bioavailability study report; report on comparative studies for the bioavailability and bioequivalence; in-vitro in-vivo report on the correlation of studies; report on bioanalytical and analytical methods;
5.3.2.	Pharmacokinetic study reports on the use of human biomaterials: report on protein binding studies; report on the study of hepatic metabolism and interactions; study report on the use of human biomaterials.
5.3.3.	Reports on pharmacokinetic studies in human: report on pharmacokinetic studies in healthy volunteers and primary tolerability studies; report on pharmacokinetic studies in patients and primary tolerability studies; report on the internal factor research of pharmacokinetic studies; report on the external factor research of pharmacokinetic studies; report on pharmacokinetic studies in various populations;
5.3.4.	Reports on pharmacodynamic studies in human: report on pharmacodynamic and pharmacokinetic/pharmacodynamic studies in healthy volunteers; report on pharmacodynamic and pharmacokinetic/pharmacodynamic studies in patients;
5.3.5.	Reports on efficacy and safety studies: report of controlled clinical studies for the stated indications; report of uncontrolled clinical studies; data analysis reports for more than one study, including any official integrated analysis, meta-analysis and cross-analysis; other research reports
5.3.6.	Reports on post-registration experience of use
5.3.7.	Samples of individual registration forms and individual patient lists
5.4.	Copy of used literary sources

Note:

* When extending the validity period of the marketing authorization issued by the authorized body in the field of health care of the Republic of Kazakhstan in accordance with the Rules for the state registration, re-registration and amendments to the registration dossier of a medicinal product, medical device and medical equipment approved by order of the Minister of Health of the Republic of Kazakhstan dated November 18, 2009 No. 735 (registered in the Register of the state registration of regulatory legal acts under No. 5935) parts I-III of this list are provided.

** Minimum amount of information required for the submission in section 3.2.S.

If individual parts of the documentation are not included in the dossier, in the appropriate section, an explanation shall be provided.

For medicinal products of animal origin in the section 3.2.S, the following additional information shall be provided: data on species, age, diet of animals which the raw material was obtained from; data on the nature (category) of tissue which the raw material for the production of a medicinal product is obtained from, in terms of its danger in relation to the prion content; technological scheme for processing the raw materials with an indication of extractants and technological parameters; methods of the quality control of raw materials, including methods of detecting the prions in medicinal product (if necessary). It is allowed to submit documents of Parts 3, 4, 5 in English with translation into Kazakh and Russian concerning the following sections: Part 3 - specifications (3.2.P.5.1.), analytical methods (3.2.P.5.2.), specification justification (3.2. P.5.6.).

List of irrational combinations of medicinal products

№	Name of the medicinal products, their combinations
1.	Fixed combination of vitamins with tranquilizers
2.	Fixed combination of atropine/atropine-like medicinal substances with analgesics and antipyretics
3.	Fixed combination of yohimbine with testosterone and vitamins
4.	Fixed combination of iron with yohimbine
5.	Fixed combination of antihistamine medicinal products with antidiarrheal drugs
6.	Fixed combination of penicillins with sulfonamides
7.	Fixed combination of vitamins with analgesics (with the exception of paracetamol with vitamin C, acetylsalicylic acid with vitamin C)
8.	Fixed combination of quinolones with any other medicinal products, with the exception of drugs for the external use.
9.	Fixed combination of corticosteroids with any other medicinal products for oral administration.
10.	Fixed combination of chloramphenicol with any other medicinal products for oral administration.
11.	Fixed combination of vitamins with antituberculous medicinal products, with the exception of isoniazid with pyridoxine hydrochloride (vitamin B6)
12.	Fixed combination of steroid anabolics with other medicinal products
13.	Fixed combination of sedative/ hypnotic/ anxiolytic medicinal products with analgesics-antipyretics/non-steroidal anti-inflammatory medicinal products
14.	Fixed combination of H2-histamine receptor/proton pump inhibitors with antacids
15.	Fixed combinations containing more than one antihistamine medicinal products
16.	Fixed combination of anthelmintic medicinal products with laxatives
17.	Fixed combination of medicinal products with the bronchodilatory action with antitussive medicinal products of central action and/or antihistamines
18.	Fixed combination of mucolytics/expectorants with antitussive medicinal products and/or antihistamines
19.	Fixed combination of laxatives and/or antispasmodic medicinal products with enzyme preparations
20.	Fixed combination of antiemetic medicinal products dopamine receptor inhibitors with medicinal substances having the systemic absorption
21.	Fixed combination of antitussive medicinal products of central action with antihistamines
22.	Fixed combinations containing pectin and/or kaolin with any medicinal substances that are absorbed into the systemic circulation from the gastrointestinal tract, with the exception of combinations of pectin and/or kaolin with medicinal substances without the systemic absorption
23.	Fixed combination of antidiarrheal medicinal products with electrolytes
24.	Fixed combination of oxyphenbutazone or phenylbutazone with any medicinal products
25.	Fixed combination of analgin with any other medicinal products
26.	Fixed combination of non-steroidal anti-inflammatory medicinal products/ paracetamol/ analgin with atropine-like medicinal products/antispasmodics
27.	Fixed combination of non-steroidal anti-inflammatory medicinal products/ paracetamol/ analgin with opioid analgesics/opioid-non-opioid analgesics
28.	Fixed combination of two or more non-steroidal anti-inflammatory medicinal

	products
29.	Fixed combination of paracetamol with barbiturates, tranquilizers and other medicinal products, inducers of enzymes of the cytochrome system of the liver
30.	Fixed combination of paracetamol (above 200 mg in a single dose) with non-steroidal anti-inflammatory medicinal products, with the exception of medicinal products for the short-term use
31.	Fixed combination of penicillins with streptomycin in parenteral dosage forms
32.	Fixed combination of pancreatin or pacrealipase containing amylase, protease and lipase, with any other enzymes, including bovine bile, hemicellulose
33.	Fixed combination of nitrofurantoin and trimethoprim
34.	Fixed combination of barbiturates with other drugs, with the exception of those of the plant origin
35.	Fixed combination of medicinal products that depress the central nervous system with central nervous system stimulants
36.	Fixed combination of barbiturates with hyoscyamine and/or hyoscine, belladonna and other atropine-like medicinal products
37.	Fixed combination of barbiturates with ergotamine
38.	Fixed combination of haloperidol with any anticholinergic medicinal products
39.	Fixed combination of antibacterial and antiprotozoal medicinal products
40.	Fixed combination of loperamide hydrochloride with furazolidone
41.	Fixed combination of antibacterial medicinal products and probiotics, prebiotics
42.	Fixed combination of cyproheptadine with lysine or peptone
43.	Fixed combination of non-steroidal anti-inflammatory medicinal products/ paracetamol/ acetylsalicylic acid and antacids/ H2- blockers/ proton pump inhibitors