PHARMALEX
REGULATORY AFFAIRS · UZBEKISTAN

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Documents required for registration of a medicinal product in CTD format

Registration under the general procedure

Resolution of the Cabinet of Ministers of the Republic of Uzbekistan No. 738 of 24 November 2025

Items are listed in CTD order.

Module 1 General and administrative documents

1.1	Application in the form set out in Annex 2 to the Regulation; a power of attorney confirming the representative's authority.
1.2	Document confirming payment of the prescribed fee.
1.3	Marketing authorisation and/or a Certificate of Pharmaceutical Product (CPP) in the WHO format.
1.4	General description of the product: scope of use, marketing in other countries, information on discontinuation of marketing and adverse reactions.
1.5	Information on prions in substances of animal origin used in manufacturing the product.
1.6	Labelling of primary, secondary and intermediate packaging; mock-ups of intermediate packaging, labels and stickers.
1.7	Colour mock-ups of the consumer packaging, label and sticker.
1.8	Summary of Product Characteristics (SmPC), draft instructions for medical use and package leaflet. For generics and biosimilars, a comparative table demonstrating conformity with the current documents of the original (reference) product.
1.9	Quality documents: a copy of the CEP for the drug substance; a letter from the drug substance master file holder consenting to provide the restricted part upon the Centre's request; a draft manufacturer's pharmacopoeial specification for the product and an explanatory note.
1.10	Manufacturing documents: Uzbekistan national GMP certificate; for a foreign manufacturer, documents on GMP inspection results, the certificate and a complete copy of the latest inspection report, including deficiencies, CAPA, reassessment results and the final conclusion; licences for manufacturing medicinal products.
1.11	Technology transfer documents: a quality agreement between the parties, the transfer programme and the technology holder's report on the completed transfer.
1.12	Agreement for manufacturing a registered product at a local pharmaceutical organisation's facilities without changing the technology.
1.13	Information on the presence of genetically modified organisms or on the product being derived from them.
1.14	Documents on the pharmacovigilance system in Uzbekistan: pharmacovigilance system master file (PSMF); information on the responsible person; risk management plan (RMP); a periodic safety report where required.
1.15	Document protecting the intellectual property used, namely trademarks and industrial designs (certificate, patent and annexes), or an agreement for their use.

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Module 2 Registration dossier summaries

2.1	**Table of contents of Modules 2-5.**
2.2	**Introduction to the Common Technical Document (CTD).**
2.3	**Quality Overall Summary.**
2.3.S	**Drug substance.**
2.3.S.1	General information.
2.3.S.2	Manufacture.
2.3.S.3	Elucidation of structure and other characteristics.
2.3.S.4	Control of drug substance.
2.3.S.5	Reference standards or materials.
2.3.S.6	Container closure system.
2.3.S.7	Stability.
2.3.P	**Finished drug product.**
2.3.P.1	Description and composition.
2.3.P.2	Pharmaceutical development.
2.3.P.3	Manufacture.
2.3.P.4	Control of excipients.
2.3.P.5	Control of drug product.
2.3.P.6	Reference standards or materials.
2.3.P.7	Container closure system.
2.3.P.8	Stability.
2.3.A	**Appendices.**
2.3.A.1	Facilities and equipment.
2.3.A.2	Adventitious agents safety evaluation.
2.3.A.3	Excipients.
2.3.R	**Regional information.**
2.4	**Nonclinical Overview.**
2.5	**Clinical Overview.**
2.6	**Nonclinical summaries: written and tabulated materials.**
2.7	**Clinical summaries: written and tabulated materials.**

Module 3 Quality

3.1	**Table of contents of Module 3.**
3.2	**Body of data.**
3.2.S	**Drug substance.**
3.2.S.1	General information.
3.2.S.1.1	Nomenclature.

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3.2.S.1.2	Structure.
3.2.S.1.3	General properties.
3.2.S.2	Manufacture.
3.2.S.2.1	Manufacturer.
3.2.S.2.2	Description of manufacturing process and process controls.
3.2.S.2.3	Control of materials.
3.2.S.2.4	Controls of critical steps and intermediates.
3.2.S.2.5	Process validation and/or evaluation.
3.2.S.2.6	Manufacturing process development.
3.2.S.3	Characterisation of the drug substance.
3.2.S.3.1	Elucidation of structure and other characteristics.
3.2.S.3.2	Impurities.
3.2.S.4	Control of drug substance.
3.2.S.4.1	Specification.
3.2.S.4.2	Analytical procedures.
3.2.S.4.3	Validation of analytical procedures.
3.2.S.4.4	Batch analyses.
3.2.S.4.5	Justification of specification.
3.2.S.5	Reference standards or materials.
3.2.S.6	Container closure system.
3.2.S.7	Stability.
3.2.S.7.1	Stability summary and conclusions.
3.2.S.7.2	Post-approval stability protocol and stability commitment.
3.2.S.7.3	Stability data.
3.2.P	**Finished drug product.**
3.2.P.1	Description and composition of the drug product.
3.2.P.2	Pharmaceutical development.
3.2.P.2.1	Components of the drug product.
3.2.P.2.1.1	Drug substance.
3.2.P.2.1.2	Excipients.
3.2.P.2.2	Finished drug product.
3.2.P.2.2.1	Formulation development.
3.2.P.2.2.2	Overages.
3.2.P.2.2.3	Physicochemical and biological properties.
3.2.P.2.3	Manufacturing process development.
3.2.P.2.4	Container closure system.
3.2.P.2.5	Microbiological attributes.
3.2.P.2.6	Compatibility.

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3.2.P.3	Manufacture.
3.2.P.3.1	Manufacturer or manufacturers.
3.2.P.3.2	Batch formula.
3.2.P.3.3	Description of manufacturing process and process controls.
3.2.P.3.4	Controls of critical steps and intermediates.
3.2.P.3.5	Process validation and/or evaluation.
3.2.P.4	Control of excipients.
3.2.P.4.1	Specifications.
3.2.P.4.2	Analytical procedures.
3.2.P.4.3	Validation of analytical procedures.
3.2.P.4.4	Justification of specifications.
3.2.P.4.5	Excipients of human or animal origin.
3.2.P.4.6	Novel excipients.
3.2.P.5	Control of drug product.
3.2.P.5.1	Specifications.
3.2.P.5.2	Analytical procedures.
3.2.P.5.3	Validation of analytical procedures.
3.2.P.5.4	Batch analyses.
3.2.P.5.5	Characterisation of impurities.
3.2.P.5.6	Justification of specifications.
3.2.P.6	Reference standards or materials.
3.2.P.7	Container closure system.
3.2.P.8	Stability.
3.2.P.8.1	Stability summary and conclusions.
3.2.P.8.2	Post-approval stability protocol and stability commitment.
3.2.P.8.3	Stability data.
3.2.A	**Appendices.**
3.2.A.1	Manufacturing facilities and equipment.
3.2.A.2	Adventitious agents safety evaluation.
3.2.A.3	Excipients.
3.2.R	**Regional information.**
3.3	**Literature references.**

Module 4 Nonclinical studies

4.1	**Table of contents of Module 4.**
4.2	**Study reports.**
4.2.1	Pharmacology.
4.2.1.1	Primary pharmacodynamics.

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4.2.1.2	Secondary pharmacodynamics.
4.2.1.3	Safety pharmacology.
4.2.1.4	Pharmacodynamic interactions.
4.2.2	Pharmacokinetics.
4.2.2.1	Analytical methods and validation reports: separate reports.
4.2.2.2	Absorption.
4.2.2.3	Distribution.
4.2.2.4	Metabolism.
4.2.2.5	Excretion.
4.2.2.6	Nonclinical pharmacokinetic interactions.
4.2.2.7	Other pharmacokinetic studies.
4.2.3	Toxicology.
4.2.3.1	Single-dose toxicity.
4.2.3.2	Repeat-dose toxicity, including toxicokinetic evaluation.
4.2.3.3	Genotoxicity in vitro and in vivo, including toxicokinetic evaluation.
4.2.3.4	Carcinogenicity: short-, medium- and long-term studies.
4.2.3.5	Reproductive and developmental toxicity: fertility, early embryonic and embryofoetal development, prenatal and postnatal development, and studies in juvenile animals.
4.2.3.6	Local tolerance.
4.2.3.7	Other toxicity studies: antigenicity, immunotoxicity, mechanisms of action, dependence, metabolites, impurities and others.
4.3	**List or copies of the literature references used.**

Module 5 Clinical studies

5.1	**Table of contents of Module 5.**
5.2	**Tabular listing of all clinical studies.**
5.3	**Clinical study reports.**
5.3.1	Reports of biopharmaceutic studies.
5.3.2	Reports of studies using human biomaterials relevant to pharmacokinetics.
5.3.3	Reports of human pharmacokinetic studies.
5.3.4	Reports of human pharmacodynamic studies.
5.3.5	Reports of efficacy and safety studies.
5.3.6	Reports of post-marketing experience.
5.3.7	Case report forms and individual patient listings.
5.4	**Literature references.**

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Notes

1. Scope and submission. This list is intended for initial registration of a finished product from a foreign manufacturer. Submit an application under Annex 2 to the Regulation and an electronic dossier under Annex 3 in ICH CTD format, certified by the applicant's electronic signature. The applicability of documents depends on the product type and the registration basis. Special exceptions apply to cell-based products and are not detailed in this list.

2. Document languages. A foreign applicant may submit Modules 2-5 and documents under items 1.5, 1.9, 1.11, 1.13 and 1.14 in Russian or English. The general description under item 1.4 and draft instructions and package leaflet under item 1.8 must be submitted in Uzbek; other languages may be provided additionally.

3. Legalisation. Foreign official documents under items 1.3 and 1.10 must bear an apostille or consular certification in accordance with paragraph 14 of the Regulation. A notarised copy alone does not replace this general requirement.

4. Registration documents. If the CPP states that the product is not registered in the manufacturer's country, a marketing authorisation from another country must additionally be submitted in notarised or apostilled form; the general legalisation requirement of paragraph 14 must also be taken into account.

5. Conditional documents. The power of attorney under 1.1 is needed when submitting through a representative; information under 1.5 concerns the substances of animal origin used. Documents under 1.11 are submitted for technology transfer; item 1.12 applies to the specified manufacturing arrangement at a local organisation's facilities without changing the technology. The CEP and documents under 1.15 are submitted if available. Individual packaging elements and other information are included according to the product's characteristics and manufacturing arrangement.

6. SmPC and instructions. For a generic or biosimilar, the drafts must conform to the current documents of the original (reference) product; a comparative table must be attached. Differences in manufacturer, shelf life, excipient composition, bioavailability or pharmacokinetic parameters are permitted.

7. GMP and licences. The manufacturing documents under 1.10 cover sites for all manufacturing stages except drug substance manufacture. For a foreign manufacturer, submit GMP inspection results from the competent authority of the relevant country or another WLA / ML4 authority. Attach to the certificate a complete copy of the latest inspection report, including deficiencies, CAPA, reassessment results and the final conclusion. Licences are issued by authorities in the countries where the sites are located.

8. Pharmacovigilance. The PSMF and RMP are prepared under the national GVP standard. The responsible person in Uzbekistan must have a university degree in medicine or pharmacy and pharmacovigilance qualifications confirmed by a certificate. Item 1.14 expressly provides for a periodic report for renewal of the marketing authorisation and variations. A diploma, certificate, contact details and appointment document provide practical evidence of the responsible person's details; a CV and deputy's documents are not listed in this item as separate mandatory documents.

9. Drug substance data. For a combination product, information is compiled for each active substance; where there are multiple drug substance manufacturers, for each manufacturer. If a CEP is submitted, documents under 3.2.S may be omitted; the CEP's authenticity is checked in the EDQM database. The certificate must relate to the relevant substance and manufacturer.

10. Scope of Modules 2-5. For an original product, submit the applicable nonclinical and clinical data. For a generic, the note to Annex 3 provides for Modules 1-3 and reports on bioavailability and bioequivalence against the reference product; a biowaiver is permitted for BCS Classes I and III. This special rule does not apply to biosimilars. The scope of overviews and summaries is determined by the dossier basis. An item's inclusion in the CTD structure does not mean that every study must be repeated.

11. Missing and inapplicable information. Where particular documents or data are unavailable due to the product's characteristics, an official reasoned explanation may be provided under the note to Annex 3. This is not an automatic exemption from the requirement. Specifications, methods, batch analyses and stability results are checked for consistency with the proposed strengths, sites and packaging.

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12. National GMP under the general registration procedure. Item 1.10 provides for submission of the national certificate if available, but paragraph 11 requires it before state registration. Inspection of a foreign manufacturer may run in parallel with dossier review; the certificate must be submitted before registration. Paragraph 10 must also be considered for contract manufacturing and technology transfer.

13. Labelling and master file. Labelling under 1.6 is submitted in Uzbek; other languages may be provided additionally. The exception for current drug substance master files provided under the recognition procedure does not apply to the general registration procedure. The holder's consent to provide the restricted part upon the Centre's request is included under item 1.9.

14. Samples outside the CTD structure. Under paragraph 14, submit samples from a single commercial batch in quantities sufficient for testing in triplicate under the draft manufacturer's pharmacopoeial specification, with at least 50% of shelf life remaining, together with quality certificates; an exception to this requirement is provided for WHO-prequalified products. The number of packs is determined by testing consumption; no universal number is set for all products.

15. Laboratory materials. Under subparagraph (d) of paragraph 14, provide pharmacopoeial or reference standards of active substances, extraneous and related impurities, and control materials; where necessary, special reagents, test strains, chromatographic columns, and the manufacturer's special consumables and reagents. Attach documents confirming their quality. For multiple strengths, check the requirements and CoA for each strength.

16. Clinical sites. If clinical studies are conducted as part of registration, the applicant provides clinical sites with the necessary documents and samples in accordance with GCP and legislation. This does not create a universal obligation to conduct new local studies for every product.

Regulatory source

Resolution No. 738 of 24 November 2025: Annex 1, paragraphs 3, 10, 11 and 14 of the Regulation; Annexes 2 and 3 to the Regulation, including notes. LexUZ: https://lex.uz/docs/7853907. Checked as of 20 October 2026; the available version incorporates amendments through 3 July 2026.