The list of documents and data required for the medicinal products registration.

1. Administrative documents of the manufacturer of the medicinal product:
1.1 A notarized power of attorney issued by the manufacturer to the Applicant (apostilled or certified by consular legalization procedure, for a foreign manufacturer).
1.2 In case products are manufactured in accordance with contract-based manufacturing a notarized explanatory note shall be provided (apostilled or certified by consular legalization procedure, for a foreign manufacturer).
1.3. Notarized documents confirming the medicinal product registration, if registered outside the Russian Federation (apostilled or certified by consular legalization procedure, for a foreign manufacturer).
1.4. Notarized documents confirming the manufacturer's registration as a legal entity (apostilled or certified by consular legalization procedure, for a foreign manufacturer).
1.5. A document on the pharmacovigilance system of the holder or owner of the medicinal product marketing authorization/registration certificate.
1.6. A risk management plan for biological medicinal products for medical use

2. Documents on the production of the pharmaceutical substance(s) used in the manufacture of the medicinal product:
2.1. A document certifying the compliance of production environment with the international requirements. It can be a notarized GMP certificate, manufacturing license or other authorization documents certifying production environment compliance issued by the local authority (apostilled or certified by consular legalization procedure, for a foreign manufacturer).
2.2. A brief outline and description of the manufacturing process, a description of methods of production control at all stages
2.3 A description of the production process development
2.4. A description of the production critical stages and intermediate products control;
2.5. A documentary proof (validation) of processes and (or) assessment thereof;
2.6. The properties and structure of the active ingredients;
2.7. Impurities-related information
2.8. Specification, quality control methods
2.9 Analytical techniques used in the pharmaceutical substance quality control;
2.10. A documented (validation) of analytical methods used in the pharmaceutical substance quality control;
2.11. The results of pharmaceutical substances batch analysis
2.12. The list of standards used
2.13. Characterization and properties of packaging materials and closures
2.14. Data on the stability of the pharmaceutical substance in the primary packaging (3 batches), shelf life, storage conditions

3. Documents to be submitted by the medicinal product manufacturer.
3.1. A document confirming the compliance of production environment to the requirements of Russian authorities (a GMP certificate).
3.2. Medicinal product description and composition
3.3. A description of the pharmaceutical development of the product
3.4. A scheme and description of the production process as well as production control methods.
3.5. A description of the production critical stages and intermediate products control.
3.6. Pharmaceutical compatibility
3.7 Microbiological specifications
3.8 Batch physical balance
3.9 Characterization and properties of packaging materials and closures
3.10. Production validation
3.11 Analytical techniques used in the excipients quality control;
3.12. A documented (validation) of analytical methods used in the excipients quality control;
3.13. Information on the use of excipients of human and animal origin;
3.14 Information on the use of new excipients;
3.15. The requirements for quality of the human medicinal product (certificate, specification for the medicinal product and justification thereof);
3.11 Analytical techniques used in the control of quality

of the human medicinal product;
3.17. A documented (validation) of analytical methods used in human medicinal product quality control;
3.18. The results of analyses of the human medicinal product;
3.19. The characteristics of impurities;
3.20. A list of standard samples used in the control of quality of the human medicinal product;
3.21 The data on the stability of the human medicinal product
3.22. Information of storage conditions and transportation.

4. Reports on the medicinal product studies:
4.1 A pharmacodynamic studies report;
4.2. A pharmacokinetic studies report;
4.3. A toxicological studies report.
4.4. The results of the clinical studies conducted

5. The summary of product characteristics (Instructions for Use) approved in the country of origin

6. The layouts of the package (primary and secondary (consumer package)).