**I. Administrative Documents of Manufacture.**

1. Power of Attorney (legalization).

2. Documents confirming registration of medicine in other countries, Certificate of Pharmaceutical Product (CPP) (legalization). .

3. Document confirming registration of the manufacture as a body corporate (legalization).

4. Pharmacovigilance system description.

**II. Documents for the active substance used in the dosage form.**

5. Document confirming the correspondence of conditions of production to the international requirements, GMP certificate (legalization).

6. Short scheme and description of manufacturing process and the description of methods of control at all stages of production. Control of critical manufacturing stages and intermediate products.

7. Information on impurities

8. Specification, quality control methods

9. The results of the analysis of a series of pharmaceutical substance

10. A list of the standards

11. Description of the characteristics and properties of packaging materials and closures system.

12. Data on the stability of the pharmaceutical substance in the primary packaging (3 series), shelf life, storage conditions.

**III. Documents for the dosage form manufacturing.**

13. Document confirming the correspondence of conditions of production to the international requirements, GMP certificate (legalization).

14. Description and composition of the drug

15. Description of pharmaceutical development product

16. The scheme and description of manufacturing process and the description of methods of control at all stages of production.

17. Control of critical manufacturing stages and intermediate products.

18. A pharmaceutical compatibility.

19. Material balance series (batch number)

20. Description of the characteristics and properties of packaging materials and closures system

21. Validation of production process

22. Information about storage and transportation conditions.

**IV. Documents for the dosage form quality control.**

23. Certificates of analysis for 3 series of the medicine (one series should coincide with a series of sample preparation provided for registration).

24. Certificate of analysis for the active pharmaceutical substance, issued by the manufacturer of the active substance.

25. Certificates of Analysis on inactive substance (auxiliary), issued by the manufacturers of non-active substances specification.

26. Description of the control methods excipients included in the formulation.

27. Validation of methods used in the control of excipients (of USP/EP/BP/ChP/JP monographs).

28. Details of excipients of human or animal origin, and the new, not previously used excipients.

29. Microbiological Specifications

30. Specification, justification of specification.

31. Description of the medicines methods of control.

32. Validation of analytical methods of the medicine.

33. Characteristics of impurities

34. The list used to control standards.

35. Data on the stability of the medicine (3 series)

36. Documents confirming that the primary and secondary materials are permitted to be used in pharmaceutical industry in the country of origin.

**V. Investigations reports.**

37. The results of pre-clinical studies\*:

- Pharmacology - Research results confirm the pharmacological activity of the drug;

- Pharmacokinetics - the absorption, distribution, metabolism, excretion, interaction with other drugs;

- Toxicology - general toxicity, specific toxicity;

38. The results of the clinical studies\*

**VI. Information for patients (leaflet, instruction for medical use)** **approved in the country of origin.**

**VII. Mocks-up (primary and secondary packages).**

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***\*The volume and design of pre-clinical and clinical trials depends on the medicine, presence or absence of analogues in Russia and other facts. RegMed prof. company can organize and conduct the clinical and pre-clinical trials in purpose of state registration on the territory of Russia.*** ***Please, apply to our company for determination of necessary kind of trials. You can write to the addresses rs@regmed.biz; regmed@regmed.biz; or call the telephone number listed on the site, or +7(903)748-60-35***

***The optimal variant for foreign manufacturers is to represent the dossier in CTD format.***