**I. Administrative Documents of Manufacture.**

1. Power of Attorney (consulate legalization or Apostil).

2. Documents confirming registration of medicine in other countries (consulate legalization or Apostil).

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

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

4. GMP certificate (consulate legalization or Apostil).

5. Short scheme of manufacturing process and control methods.

6. Control of critical manufacturing stages and intermediate products.

7. Quality control methods, specification.

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

8. GMP certificate (consulate legalization or Apostil).

9. Short scheme of manufacturing process and control methods.

10. Batch formulae.

11. Control of critical manufacturing stages and intermediate products.

12. Validation (qualification) of the process.

13. Storing and transporting condition information.

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

14. Certificate of Pharmaceutical Product (CPP) (consulate legalization or Apostil).

15. Certificate of analysis, for 3 batches.

16. Certificate of analysis for the active substance issued by the manufacture of the active substance.

17. Certificates of analysis for the inactive substances issued by the manufactures of inactive substances.

18. Quality control methods description.

19. Reference standards or comparative materials.

20. Validation of analytical procedures.

21. Impurities characteristics.

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

**V. Investigations reports.**

23. Stability investigation (in primary packaging materials).

24. Toxicity studies reports\*:

25. Veterinary trials reports\*

**V. Information for veterinarians (leaflet, instruction for medical use).**

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

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

***\*The volume and design of toxicity and veterinary trials depends on the drug, presence or absence of analogues in Russia and other facts. Please, apply to our company for determination of necessary kind of trials. RegMed prof. company can organize and conduct the veterinary and pre-clinical trials in purpose of state registration on the territory of Russia.***

**The document is prepared by**

**Gulsyum Khusainova,**

**Medicine registration manager.**

**info@regmed.biz**

*The list of documents is worked out in the correspondence with the Federal Law No. 61-ФЗ “On circulation of medicines” of April 12, 2010 in latest version of 29/12/2015.*

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