1. **Name and address of the applicant and of the manufacturer**
   a) Applicant  
   b) Manufacturer

2. **Place of manufacture**

3. **Name of the product**
   Short version of the name: ...
   (IMPORTANT: The name of the product and the short version of the name must be identical in all documents.)

4. **Components of the product by type and quantity, common or chemical name**

5. **Manufacturing procedure**

6. **Field of application**

7. **Pharmaceutical form**

8. **Shelf-life**

9. **Precautions and safety measures with regard to**
   a) Health risks for humans and animals
   b) Storage conditions
   c) Waste disposal

10. **Test methods applied by the manufacturer (sensitivity, specificity)**

11. **Results of validation tests including test period**

12. **Summary of product characteristics** (see information sheet “Summary of Product Characteristics”), **sample of container and outer package of the product, instructions for use** (see information sheet “Labelling requirements”)

13. **Manufacturing authorisation**

14. **Samples of the product**