

NORMATIVE INSTRUCTION (IN) No. 132 OF 30 MARCH 2022

Provides for the Good Manufacturing Practices complementary to Liquid Medicines, Creams, or Ointments.

The Collegiate Board of Directors of the Brazilian Health Regulatory Agency, in the use of the attributions vested in it under Article 15, items III and IV, and Article 7, item III of Law no. 9,782 of 26 January 1999, and item VII, paragraphs 1 and 3 of Article 187 of the Internal Regulation approved by Collegiate Board Resolution – RDC no. 585 of 10 December 2021, adopts the following Normative Instruction, as decided upon in the Extraordinary Meeting – RExtra 6, held on 30 March 2022, and I, Director-President, determine its publication.

CHAPTER I

INITIAL PROVISIONS

Section I

Objective

Article 1. This Normative Instruction aims at adopting the guidelines on Good Manufacturing Practices for Liquid Medicines, Creams, or Ointments of the Pharmaceutical Inspection Cooperation Scheme (PIC/S), as complementary requirements to be followed in the manufacture of liquid medicines, creams, or ointments in addition to the General Guidelines on Good Manufacturing Practices for Medicinal Products.

Section II

Scope

Article 2. This Normative Instruction applies to companies that carry out operations involved in the manufacture of liquid medicines, creams, and ointments, including experimental medicines.

CHAPTER II

GENERAL PROVISIONS

Article 3. Due to the susceptibility of liquid medicines, creams, and ointments to microbiological contamination, special prevention measures must be adopted for such medicinal products.

Article 4. The manufacture of liquids, creams, and ointments must be carried out in accordance with the General Guidelines on Good Manufacturing Practices and specific applicable guidelines.

Sole paragraph. This guideline is solely intended to emphasize specific points of the regulation of such pharmaceutical forms.

CHAPTER III

SPECIFIC PROVISIONS

Section I

Facilities and Equipment

Article 5. The use of closed processing and transfer systems to protect the product against microbiological contamination must be the recommendation of choice.

Article 6. The production areas where open clean products or containers are exposed must be adequately insufflated with filtered air.

Article 7. Tanks, containers, pipes, and pumps must be designed and installed so that they can be easily cleaned and, if necessary, sanitized.

Sole paragraph. The equipment design must minimize dead stretches or places where waste can accumulate and promote microbial proliferation.

Article 8. The use of glass appliances must be avoided whenever possible, with high quality stainless steel being the most suitable material for the parts in contact with products, in most cases.

Section II

Production

Article 9. The chemical and microbiological quality of the water used in production must be specified and monitored.

Article 10. Specific maintenance procedures for the water system must be established in order to avoid the risk of microbial proliferation.

Article 11. After any chemical sanitization of water systems, a validated rinsing procedure must be followed to ensure that the sanitizing agent has been effectively removed.

Article 12. The quality of the materials received in transfer tanks must be checked before being transferred to the storage tanks.

Article 13. Additional precautions must be taken when transferring materials via pipelines to ensure that they are delivered to the correct destination.

Article 14. Materials with a susceptibility to dissipate fibers or other contaminants, such as cardboard, wooden pallets, must not enter areas where clean products or equipment are exposed.

Article 15. Special precautions must be taken to maintain the homogeneity of emulsions, suspensions, among other heterogeneous mixtures, during the filling process.

Paragraph 1. The mixing and filling processes must be validated.

Paragraph 2. The special precautions referred to in the caption of this article must above all guarantee the most critical steps of the process, such as the beginning and end of the filling process, and stops, in order to maintain homogeneity.

Article 16. When the filled product is not immediately packaged, the maximum storage periods and the storage conditions must be specified and complied with.

CHAPTER IV

FINAL PROVISIONS

Article 17. Non-compliance with the provisions contained in this Normative Instruction constitutes a health infraction, pursuant to Law no. 6,437 of 20 August 1977, without prejudice to the applicable civil, administrative, and criminal liabilities.

Article 18. Normative Instruction – IN No. 41 of 21 August 2019 is hereby revoked.

Article 19. This Normative Instruction enters into force on 2 May 2022.

ANTONIO BARRA TORRES