

COLLEGIATE BOARD RESOLUTION – RDC NO. 669 OF 30 MARCH 2022

Provides for the minimum requirements to guarantee the quality of imported biological products.

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, items III and IV of Law no. 9,782 of 26 January 1999, and item VI, paragraph 1 of Article 187 of the Internal Regulation approved by Collegiate Board Resolution – RDC no. 585 of 10 December 2021, adopts the following Collegiate Board Resolution, 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

Article 1. This Resolution establishes the minimum requirements to guarantee the quality of imported biological products.

Article 2. This Resolution applies to companies that hold an Operation Permit (AFE, in Portuguese) issued by Anvisa for the activity of importing medicinal products.

CHAPTER II

GENERAL PROVISIONS

Article 3. The importing company shall be responsible for the quality, effectiveness, and safety of imported batches of biological products in their primary packaging, as well as of finished biological products.

Article 4. Imported batches of biological products that are finished and in their primary packaging must have been submitted to complete quality control trials by the manufacturer and include the batch release certificate, issued by the manufacturing company, in accordance with the specifications established in the marketing authorization.

Sole paragraph. In the case of imported batches of biological products in their primary packaging, the batch release certificate referred to in the caption of this Article refers to the batch release certificate of the bulk product in its primary packaging.

Article 5. The importing company holding the marketing authorization must carry out, in the Brazilian territory, the complete quality control trials in all batches, for each import, and comply with the other requirements referring to the health legislation in force.

Article 6. The importing company holding the marketing authorization shall be exempt from carrying out the complete quality control trials referred to in Article 5 of this Resolution, provided that the following conditions are fully and cumulatively met:

I – the company that manufactures the biological product in its primary packaging and/ or finished biological products has been inspected by Anvisa and is certified as to compliance with the Good Manufacturing Practices for medicinal products, or is awaiting inspection, filed at Anvisa;

II – the importing company is a subsidiary of the manufacturing company and/ or maintains an exclusive, duly documented business relationship with the company that manufactures the biological products in their primary packaging and/ or finished biological products;

III – the importing company has submitted, when requesting the Import License (LI, in Portuguese), the following documents:

a) for biological products in their primary packaging, analytical report on the quality control of the active ingredient(s) and analytical report on the quality control of the bulk product, issued by the manufacturer; or

b) for finished biological products, analytical report on the quality control of the active ingredient(s), analytical report on the quality control of the finished product, and batch release certificate, issued by the manufacturer.

IV – the importing company has imported only primary packaging, containing the biological product, with identification on each container – number or alphanumeric code – identifying the production batch;

V – the importing company has a validated transportation chain, according to the stability characteristics of each product to be imported;

VI – the importing company has continuous temperature records of the transportation chain, which prove that the product has been kept within the storage and transportation conditions recommended by the manufacturer;

VII – the importing company has a quality assurance unit, in accordance with the Good Manufacturing Practices for medicinal products, which has the capability to:

a) technically evaluate all documentation pertinent to the imported product batch;

b) technically evaluate the temperature records that prove that the product was kept within the conditions recommended in the product marketing authorization, in order to guarantee quality, effectiveness, and safety; and

c) issue the finished biological product batch release certificate under the responsibility of the responsible pharmacist.

Sole paragraph. The storage and transportation conditions referred to in item VI of this Article must be specified in the Import License, and the temperature records must identify the product name, batch number, time and date of shipment, and receipt.

Article 7. The importing company holding the marketing authorization must submit the “Declaration of Custody and Responsibility” in the import dossier for the clearance of batches of finished biological product, until the request for the write-off of the respective term is submitted to Anvisa, accompanied by the release certificate of the imported batch, issued by the quality assurance department of the importing company, and by a copy of the temperature records, with all the information requested in item VI and sole paragraph of Article 6 of this Resolution.

Sole paragraph. The importing company is prohibited from marketing the finished biological product batches until the granting of the Declaration of Custody and Responsibility by Anvisa, referred to in the caption of this Article.

Article 8. The company that imports a biological product in its primary packaging must have an Operation Permit (AFE, in Portuguese) for the manufacturing activity, so that it can carry out labeling, final packaging, and storage activities.

Sole paragraph. The company referred to in the caption of this Article may clear imported batches of biological products in their primary packaging to label the primary packaging and place them in secondary packaging.

Article 9. The importing company holding the marketing authorization that imports raw material – active ingredient(s) and/ or bulk biological products – to manufacture, in the Brazilian territory, batches of finished biological products, must have its own quality control laboratory that performs all quality control trials, in accordance with the specifications established in the marketing authorization.

Paragraph 1. The company referred to in the caption of this Article, in order to manufacture batches of finished biological products in the Brazilian territory, must comply with all the requirements established in the health legislation in force for the manufacturing company.

Paragraph 2. The company referred to in the caption of this Article may hire a duly qualified company, authorized and certified by Anvisa, to carry out quality control tests.

Paragraph 3. The outsourcing of quality control of batches of finished biological product referred to in Paragraph 2 of this Article shall be allowed only if the requirements established in Collegiate Board Resolution – RDC No. 234 of 20 June 2018, or another one that may replace it.

Paragraph 4. The company referred to in the caption of this Article must have a quality assurance unit, in accordance with the Good Manufacturing Practices for medicinal products, which has the capability to:

I – technically evaluate all the documentation relevant to the batches of active ingredient(s) that are part of the batch of biological product in its primary packaging and/ or batch of finished biological product;

II – technically evaluate the manufacturing and quality control procedures carried out in the company;

III – technically evaluate the temperature records that prove that the imported batches were kept within the conditions recommended in the product marketing authorization, in order to guarantee quality, effectiveness, and safety; and

IV – issue the finished biological product batch release certificate under the responsibility of the responsible pharmacist.

Article 10. The company that imports a blood-derived biological product must comply with the requirements established in the current regulations referring to the General Guidelines on Good Manufacturing Practices for medicinal products and the complementary Good Manufacturing Practices for blood-derived medicinal products.

CHAPTER III

FINAL PROVISIONS

Article 11. Failure to comply with the provisions contained in this Resolution shall constitute a health infraction, pursuant to Law no. 6,437 of 20 August 1977, without prejudice to the applicable administrative, civil, and criminal liabilities.

Article 12. The following are hereby revoked:

I – Collegiate Board Resolution – RDC No. 234 of 17 August 2005, published in the Federal Official Gazette No. 165 of 26 August 2005, Section 1, page 98;

II – Collegiate Board Resolution – RDC No. 38 of 18 August 2010, published in the Federal Official Gazette No. 159 of 19 August 2010, Section 1, page 37; and

III – Collegiate Board Resolution – RDC No. 58 of 29 November 2012, published in the Federal Official Gazette No. 231 of 30 November 2012, Section 1, page 111.

Article 13. This Resolution shall enter into force on 2 May 2022.

ANTONIO BARRA TORRES