MINISTRY OF HEALTH

NATIONAL HEALTH SURVEILLANCE AGENCY

BOARD

RESOLUTION RDC NO. 497, OF MAY 20, 2021

Provides for the administrative procedures for granting Certification of Good Manufacturing Practices and Certification of Good Distribution and/or Storage Practices.

Historical Series

The Collegiate Board of Directors of the National Health Surveillance Agency, in the exercise of the powers conferred on it by article 15, III and IV, together with article 7, III and IV of Law No. 9,782, of January 26, 1999 , and article 53, VI, paragraphs 1 and 3 of the Internal Regulations approved by the Resolution of the Collegiate Board of Directors - RDC No. 255, of December 10, 2018 , resolves to adopt the following Resolution, as resolved at a meeting held on May 20, 2021, and I, Chief Executive Officer, hereby order its publication.

CHAPTER I

INITIAL PROVISIONS

Section I

Goal

Art. 1 The purpose of this Resolution is to establish administrative procedures for the granting of Certifications of Good Manufacturing Practices for Medicines, Health Products, Cosmetics, Perfumes, Personal Hygiene Products, Sanitizing Products, Active Pharmaceutical Ingredients and Food and Certifications of Good Distribution and/or Storage Practices for Medicines, Health Products and Active Pharmaceutical Ingredients.

Section II

Scope

Art. 2 This Resolution applies to companies that manufacture Medicines, Health Products, Cosmetics, Perfumes, Personal Hygiene Products, Sanitizing Products, Active Pharmaceutical Ingredients and Food located in the national territory or in other countries and to the companies that store, distribute and import Medicines, Health Products and Active Pharmaceutical Ingredients located in the national territory.

Sole Paragraph. The enforceability, for their different purposes, of the Certificate of Good Manufacturing Practices or the Certificate of Good Distribution and/or Storage Practices is provided for in specific Anvisa rules and is not addressed in this Resolution.

Section III

Definitions

Art. 3 For the purposes of this Resolution, the following definitions are adopted:

I- storage: a set of operations that includes safekeeping, handling and conservation of products and related controls;

II- Certificate of Good Distribution and/or Storage Practices (CBPD/A): document issued by Anvisa attesting that a certain establishment complies with the technical requirements of Good Distribution and Storage Practices or Good Storage Practices, provided for in the legislation in force, necessary for the commercialization of the product;

III- Certificate of Good Manufacturing Practices (CBPF): document issued by Anvisa attesting that a certain establishment complies with the technical requirements of Good Manufacturing Practices, provided for in the legislation in force, necessary for the commercialization of the product;

IV – technical-operational conditions (CTO): classification applied in the national territory to establishments or production lines at the beginning of activities or also to existing production lines when a new pharmaceutical form/risk class is included, which have adequate technical and operational capacity for the industrial-scale manufacture of medicines or health products;

V – distribution: set of activities related to the movement of cargo that includes the supply, storage and shipment of products, excluding direct supply to the public;

VI – establishment: unit responsible for the performance of one or more activities that can be certified;

VII – manufacturing: all operations involved in the preparation of a given product, including the acquisition of materials, production, quality control, release, storage, shipment of products and related controls;

VIII – form of obtainment: method through which the pharmaceutical ingredient is obtained;

IX – pharmaceutical form: final state of presentation of a pharmaceutical preparation after one or more operations performed, with or without the addition of excipients, in order to facilitate its use in a given route of administration;

X – biological active pharmaceutical ingredient: these are the active pharmaceutical ingredients allergens, monoclonal antibodies, blood products, microorganisms used in the production of probiotics, immunobiologicals and active ingredients obtained from biological fluids or tissues of animal origin, as well as those obtained by biotechnological procedures;

XI – technical requirements of Good Manufacturing Practices or Good Distribution and/or Storage Practices necessary for the commercialization of the product: technical requirements recommended by the current standards of Good Manufacturing Practices and Good Distribution and/or Storage Practices, weighted by a risk-based approach that reflects a minimum level of compliance with good practices, sufficient to market the product;

XII- applicant: legal entity legally constituted in Brazil that requires the Certification of Good Manufacturing Practices and/or the Certification of Good Distribution and/or Storage Practices to the competent authority.

CHAPTER II

GENERAL CONDITIONS OF CERTIFICATION

Art. 4 The granting of Certification referred to in this Resolution is subject to analysis by means of risk management and issuance of a technical opinion attesting that the establishment meets the technical requirements of Good Manufacturing Practices or Good Distribution and/or Storage Practices necessary for the commercialization of the product. *(Text given by the Resolution of the Collegiate Board of Directors - RDC No. 982, of 07/28/2025)*

Previous Drafts

Paragraph 1 - The request for Certification referred to in this Resolution shall be rejected when there is a technical opinion attesting:

I- the non-compliance, by the establishment, with the technical requirements of Good Manufacturing Practices or Good Distribution and/or Storage Practices necessary for the commercialization of the product;

II- the unilateral cancellation by the establishment of inspections agreed between the parties;

III – the imposition of an obstacle by the establishment to receive Anvisa's sanitary inspections, including requests to change the inspection date unilaterally motivated by the establishment and not accepted by Anvisa; or

IV – the absence of documentation capable of proving the establishment's compliance with the technical requirements of Good Manufacturing Practices or Good Distribution and/or Storage Practices necessary for the commercialization of the product.

Paragraph 2 - To support the decision regarding Certification, Anvisa will use:

I- inspection report issued by Anvisa or by the State, District or Municipal Health Surveillance bodies, according to the organization of health surveillance actions and competencies exercised by the Union, States, Federal District and Municipalities;

II- information on inspections by regulatory authorities and third-party auditing bodies recognized by Anvisa, provided that they are equivalent in relation to the measures and controls applied to prove Good Practices; or

III - valid audit report, issued by a third-party auditing body recognized by Anvisa, according to specific regulations, being applicable to establishments installed in the national territory and in other countries.

Paragraph 3 - The decision regarding the Certification referred to in the caput must be formalized within the regulatory period applicable to the petition in question, defined in the resolution that establishes the classification of risks and the deadlines for responding to requests for public acts of release of responsibility by Anvisa, as provided for in the caput of article 3 and article 10 of Decree No. 10,178, of December 18, 2019 .

Art. 5 - The analysis of Certification petitions is carried out according to the chronological order of the filing date.

Sole Paragraph. Anvisa may establish an exception to the provisions of the caput of this article, in order to favor efficiency and optimization of resources, when the Certification petition refers to:

I- the same establishment with an inspection scheduled at the request of another applicant;

II- an establishment linked to another petition that has a deadline for completion defined in a specific resolution.

Art. 6 - Certification applicants may request the change of the inspection location when the originally indicated establishment no longer manufactures or distributes and/or stores the products related to the initial application, provided that the technical analysis has not begun and the equivalence of the inspection and health surveillance fees incident is respected.

Article 7 - Once the process of analysis of the Certification petition has begun, which constitutes the exercise of police power by Anvisa, requests to change the inspection site and reuse the fee for other purposes will not be admitted.

Art. 8 - The validity of the Certification of Good Manufacturing Practices is two years, counted from the date of its publication in the Official Gazette of the Union.

Paragraph 1 - The validity of the Certification of Good Manufacturing Practices of medical device manufacturers granted through the Single Audit Program in Medical Devices (MDSAP) is four years. *(Included by the Resolution of the Collegiate Board of Directors - RDC No. 850 of 03/20/2024)*

Paragraph 2 - The validity established in paragraph 1 is conditioned to the permanence of the manufacturer in the Single Audit Program in Medical Devices (MDSAP) during the entire period of validity of the certificate. *(Included by the Resolution of the Collegiate Board of Directors - RDC No. 850 of 03/20/2024)*

Paragraph 3 - Petitions for Certification of Good Manufacturing Practices of medical device manufacturers granted through the Single Audit Program in Medical Devices (MDSAP) and their renewals filed before the entry into force of the Resolution of the Collegiate Board of Directors - RDC No. 850, of March 20, 2024 , whose decision has not been published in the Federal Official Gazette, will be valid for four years. *(Included by the Resolution of the Collegiate Board of Directors - RDC No. 850 of 03/20/2024)*

Article 9 - The validity of the Certification of Good Distribution and/or Storage Practices is four years, counted from the date of its publication in the Federal Official Gazette.

Article 10. The Certification of Good Manufacturing Practices and the Certification of Good Distribution and/or Storage Practices must be canceled at any time, whenever there is an analysis through risk management and a technical opinion that attests that the establishment does not meet the technical requirements of Good Manufacturing Practices or Good Distribution and/or Storage Practices necessary for the commercialization of the product. *(Text given by the Resolution of the Collegiate Board of Directors - RDC No. 982, of 07/28/2025)*

Previous Drafts

Article 11. Requests for the inclusion of new items or modifications to the current Good Manufacturing Practices Certificates are possible, without changing the expiration date of the Certificate in force.

Paragraph 1 - For the purposes of the provisions of the caput, new items are considered to be the inclusion of new production stages, pharmaceutical forms, risk classes or active pharmaceutical ingredients in a given production line or form of obtaining already certified.

Paragraph 2 - For the cases provided for in the caput, in which requests for inclusion are allowed, these must be made by means of a petition for modification or addition to the current Certification.

Paragraph 3 - The instrument of inclusion provided for in the caput is not applicable to cases in which what is intended to be included requires a new Certification petition.

CHAPTER III

CONCESSION AND ITS CRITERIA

Section I

For Medicines

Article 12. The following Good Practice Certifications are subject to petition:

I- Certification of Good Manufacturing Practices for Medicines in the Country;

II- Certification of Good Manufacturing Practices for Medicines in other countries; and

III- Certification of Good Practices for the Distribution and/or Storage of Medicines in the Country.

Article 13. The Certification of Good Manufacturing Practices for Medicines will be granted to each establishment, by production line, with each line containing the description of the certified pharmaceutical forms in accordance with the current version of the Controlled Vocabulary of Pharmaceutical Forms, Routes of Administration and Packaging of Medicines published by Anvisa.

Paragraph 1 - When the establishment subject to the Certification is not responsible for all the production stages of a given pharmaceutical form, the Certificate shall describe only the respective intermediaries or production stages for which the establishment is responsible.

Paragraph 2 - Production lines restricted to secondary packaging will not have the pharmaceutical forms listed in the Certificate.

Paragraph 3 - The pharmaceutical forms related to penicillin, cephalosporin, carbapenem, and monobactanic products must be detailed in the Certificate.

Paragraph 4 - For the purposes of the provisions of the caput and for the different purposes for which the Certificate of Good Manufacturing Practices is provided, it is necessary to issue additional Certificates to different applicants from the same manufacturing establishment, in order to guarantee the individual evaluation of the products subject to certification.

Article 14. The following production lines are defined for the Certification of Good Manufacturing Practices for Medicines:

I- sterile products;

II- non-sterile solids;

III- non-sterile liquids;

IV – non-sterile semi-solids;

V- compressed or liquefied medicinal gases; and

VI- medicinal cryogenic liquids.

Article 15. In the case of establishments or production lines at the beginning of activities or inclusion of a new pharmaceutical form or stage in an existing production line, the Certificate of Good Manufacturing Practices must be issued when the technical opinion concludes that the establishment has Technical Operational Conditions (CTO) for the start of commercial manufacturing.

Sole Paragraph. The classification as CTO only applies when it is proven that the operation of a new establishment, production line or production of a new pharmaceutical form complies with the requirements of Good Manufacturing Practices necessary for manufacturing on an industrial scale.

Article 16. The Certification of Good Practices for the Distribution and/or Storage of Medicines will be granted to each establishment.

Section II

For Health Products

Article 17. The following Good Practice Certifications are subject to petition:

I- Certification of Good Manufacturing Practices for Health Products in the Country;

II- Certification of Good Manufacturing Practices for Health Products in other countries; and

III- Certification of Good Practices for Distribution and/or Storage of Health Products in the Country.

Article 18. The Certification of Good Manufacturing Practices for Health Products will be granted to each establishment, per production line.

Paragraph 1 - The Certificate shall describe for each production line the respective risk classes of products for which the establishment complies with the requirements recommended by the current standards of Good Practices.

Paragraph 2 - Health products classified in risk classes I and II are not eligible for Certification.

Paragraph 3 - For the purposes of the provisions of the caput and for the different purposes for which the Certificate of Good Manufacturing Practices is provided, it is necessary to issue additional Certificates for different applicants from the same manufacturing establishment, in order to guarantee the individual evaluation of the products subject to certification.

Article 19. The following production lines are defined for the Certification of Good Manufacturing Practices for Health Products:

I- materials and equipment for medical use; and

II- products for in vitro diagnosis.

Article 20. In the case of establishments or production lines in the beginning of activities, the Certificate of Good Manufacturing Practices must be issued when the technical opinion concludes that the establishment has Technical Operational Conditions (CTO) for the start of commercial manufacturing.

Sole Paragraph. The classification as CTO only applies when it is proven that the operation of a new establishment or new production line complies with the requirements of Good Manufacturing Practices necessary for manufacturing on an industrial scale.

Article 21. The Certification of Good Practices for the Distribution and/or Storage of Health Products will be granted to each establishment.

Section III

For Cosmetics, Perfumes & Personal Care Products

Article 22. The following Good Practice Certifications are subject to petition:

I- Certification of Good Manufacturing Practices for Cosmetics, Personal Care Products and Perfumes in the Country;

II- Certification of Good Manufacturing Practices for Cosmetics, Personal Care Products and Perfumes in other countries.

Article 23. The Certification of Good Manufacturing Practices for Cosmetics, Personal Care Products and Perfumes will be granted to each establishment, per production line.

Sole Paragraph. For the purposes of the provisions of the caput and for the different purposes for which the Certificate of Good Manufacturing Practices is provided, it is necessary to issue additional Certificates for different applicants from the same manufacturing establishment, in order to ensure the individual evaluation of the products subject to certification.

Article 24. The following production lines are defined for the Good Manufacturing Practices Certification of Cosmetics, Personal Care Products and Perfumes:

I- liquids;

II- solids;

III- semi-solids; and

IV - aerosols.

Section IV

For Sanitizing Products

Article 25. The following Good Practice Certifications are subject to petition:

I- Certification of Good Manufacturing Practices for Sanitizing Products in the Country; and

II- Certification of Good Manufacturing Practices for Sanitizing Products in other countries.

Article 26. The Certification of Good Manufacturing Practices for Sanitizing Products will be granted to each establishment, by production line.

Sole Paragraph. For the purposes of the provisions of the caput and for the different purposes for which the Certificate of Good Manufacturing Practices is provided, it is necessary to issue additional Certificates for different applicants from the same manufacturing establishment, in order to ensure the individual evaluation of the products subject to certification.

Article 27. The following production lines are defined for the Certification of Good Manufacturing Practices for Sanitizing Products:

I- liquids;

II- solids;

III- semi-solids; and

IV - aerosols.

Section V

For Active Pharmaceutical Ingredients

Article 28. The following Good Practice Certifications are subject to petition:

I- Certification of Good Manufacturing Practices for Active Pharmaceutical Ingredients in the Country;

II- Certification of Good Manufacturing Practices for Active Pharmaceutical Ingredients in other countries; and

III- Certification of Good Practices for Distribution and/or Storage of Active Pharmaceutical Ingredients in the Country.

Article 29. The Certification of Good Manufacturing Practices for Active Pharmaceutical Ingredients will be granted to each establishment, by way of obtaining, containing for each of them the respective active pharmaceutical ingredients.

Sole Paragraph. For the purposes of the provisions of the caput and for the different purposes for which the Certificate of Good Manufacturing Practices is provided, it is not necessary to issue additional Certificates to different applicants when there is already a Certification in force for the same establishment, the same form of obtaining and the same active pharmaceutical ingredient, in the case of active pharmaceutical ingredients obtained by chemical synthesis, classical fermentation or semisynthesis.

Article 30. For the purposes of Certification of Active Pharmaceutical Ingredients, the forms of obtaining are considered as the production lines, among them:

I- mineral extraction;

II- vegetable;

III- chemical synthesis;

IV - classic fermentation;

V- semisynthesis; and

VI - biological.

Sole Paragraph. The form of plant production covers active pharmaceutical ingredients isolated from plants or obtained from plant sources, whether they are plant extracts and pulverized or fragmented plants.

Article 31. In the case of establishments or production lines at the beginning of activities or inclusion of a new form of obtaining or stage in an existing production line, the Certificate of Good Manufacturing Practices must be issued when the technical opinion concludes that the establishment has Technical Operational Conditions (CTO) for the start of commercial manufacturing.

Sole Paragraph. The classification as CTO only applies when it is proven that the operation of a new establishment or new production line complies with the requirements of Good Manufacturing Practices necessary for manufacturing on an industrial scale.

Article 32. The Certification of Good Practices for the Distribution and/or Storage of Active Pharmaceutical Ingredients will be granted to each establishment.

Section VI

For Food

Article 33. The following Good Practice Certifications are subject to petition:

I- Certification of Good Manufacturing Practices for International Industry; and

II- Certification of Good Manufacturing Practices for Industry in the country.

Article 34. The Certification of Good Food Manufacturing Practices will be granted to each establishment, by production line.

Paragraph 1 - For the purposes of the provisions of the caput and for the different purposes for which the Certificate of Good Manufacturing Practices is provided, it is necessary to issue additional Certificates to different applicants from the same manufacturing establishment, in order to ensure the individual evaluation of the products subject to certification.

Paragraph 2 - In the case of canned heart of palm, the production lines are defined based on the species of heart of palm and the type of packaging of the product.

CHAPTER IV

CRITERIA FOR THE CERTIFICATION OF ESTABLISHMENTS PREVIOUSLY CERTIFIED BY ANVISA

Article 35. For the decision regarding the Certification of Good Practices referred to in this chapter, in the case of establishments located in MERCOSUR countries, except Brazil, Anvisa is responsible for the analysis through risk management and issuance of a technical opinion, based on the guidelines provided by the existing legislation within the scope of MERCOSUR. *(Text given by the Resolution of the Collegiate Board of Directors - RDC No. 982, of 07/28/2025)*

Previous Drafts

Article 36. In the case of establishments located in the national territory or in other countries outside MERCOSUR, the Certification referred to in this chapter must be granted through analysis through risk management and issuance of a technical opinion, which must consider the following items: *(Text given by the Resolution of the Collegiate Board of Directors - RDC No. 982, of 07/28/2025)*

Previous Drafts

I- history of compliance with Good Practices by the establishment to be Certified, obtained by Anvisa from its inspection database;

II- history of proven deviations, technical complaints and/or sanitary infractions proven by the competent authorities, obtained by Anvisa in its databases;

III- unaltered production lines and without the inclusion of products of therapeutic classes that cannot be produced in the same area previously inspected, according to the evaluation of the data presented by the applicant;

IV- public or confidential information about inspections, obtained directly or received within the scope of Agreements or Conventions with health authorities of other countries;

V – for active pharmaceutical ingredients, unaltered forms of obtaining and without the inclusion of inputs of therapeutic classes that cannot be produced in the same area previously inspected, according to the evaluation of the data presented by the applicant; and

VI – other documents provided for in the list of instruction documents of the Certification petition.

Sole Paragraph. The opinion provided for in the caput of this article may consider other factors defined through risk management. *(Text given by the Resolution of the Collegiate Board of Directors - RDC No. 982, of 07/28/2025)*

Previous Drafts

Article 37. In order for there to be Certification without interruption of continuity with the Certification in force, the petition for Certification of Good Practices must be filed within a period of time between 270 (two hundred and seventy) and 180 (one hundred and eighty) days before the expiration of the Certificate in force.

Article 38. In the hypothesis of articles 36 and 37, having evaluated the technical and protocol requirements set forth in this Resolution, Anvisa must express its opinion on the approval or rejection of the new certification until the expiration date of the Certificate.

Article 39. The absence of a manifestation, provided for in article 38, gives rise to the publication by the technical area of the automatic renewal of the Certificate until the expiration date of the Certificate in force.

Paragraph 1 - The automatic renewal of the Certificate does not exclude the possibility of its analysis and eventual cancellation, equally automatic, at any time, if it is proven that the establishment does not comply with the requirements of Good Practices necessary for the commercialization of the product.

Paragraph 2 - For the purposes of the provisions of the caput and except for the cases of paragraph 1 of this article, any situation of the petition for Certification of Good Practices that does not determine the publication of the approval or rejection in the Federal Official Gazette until the expiration date of the Certificate in force is considered to be the absence of manifestation.

CHAPTER V

FINAL AND TRANSITORY PROVISIONS

Article 40. Petitions for Certification of Good Manufacturing Practices and Certification of Good Distribution and/or Storage Practices filed before the effective date of this Resolution shall be analyzed as provided for in this Resolution, provided that the analysis has not been initiated.

Sole Paragraph. Cases of automatic renewal that fall under the hypothesis of article 39, paragraph 2 are excepted from the provisions of the caput.

Art. 41. Information will be published on Anvisa's website regarding the situation of the companies regarding the Certification of Good Practices and the legal basis that motivated the final decision of the petitions for Certification of Good Manufacturing Practices and Certification of Good Distribution and/or Storage Practices.

Art. 42. Failure to comply with or disobey the provisions of this Resolution constitutes an infraction of a sanitary nature, under the terms of Law No. 6437, of August 20, 1977 , subjecting the offender to the penalties provided for in this law.

Article 43. The Resolution of the Collegiate Board of Directors - RDC No. 39, of August 14, 2013 , published in the Federal Official Gazette No. 157, of August 15, 2013, Section 1, page 50, is hereby revoked.

Art. 44. This Resolution enters into force on June 1, 2021.

Sole Paragraph. *(Revoked by the Resolution of the Collegiate Board of Directors - RDC No. 666 of 03/30/2022)*

Previous Drafts

ANTONIO BARRA TORRES

PUB D.O.U., 05/26/2021 - Section 1

This text does not replace the Official Publication.