

COLLEGIATE BOARD RESOLUTION – RDC No. 972 OF 22 APRIL 2025

Amends Collegiate Board Resolution
– RDC No. 658 of 30 March 2022,
which establishes the General
Guidelines for Good Manufacturing
Practices for Medicinal Products.

The Collegiate Board of Directors of the Brazilian Health Regulatory Agency, in the use of the attributions vested in it under Article 7, item III, and Article 15, items III and IV of Law no. 9,782 of 26 January 1999, and Article 187, item VI, Paragraph 1 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 a meeting held on 16 April 2025, and I, Acting Director-President, determine its publication.

Article 1. Collegiate Board Resolution – RDC No. 658 of 30 March 2022, published in the Federal Official Gazette No. 62 of 31 March 2022, section 1, page 320, shall come into effect with the following alteration:

"Article 372. The implementation of the online control provided for in Article 215 may be waived when there is technical justification for doing so, provided that the company adopts other appropriate control strategies based on quality risk management." (new wording)

Article 2. Paragraphs 1 and 2 of Article 372 of Collegiate Board Resolution – RDC No. 658 of 30 March 2022 are hereby revoked.

RÔMISON RODRIGUES MOTA

Acting Director-President