

NORMATIVE INSTRUCTION – IN No. 183 OF 5 SEPTEMBER 2022

Establishes the list of oral medicines intended for local action in the gastrointestinal tract that are candidates for biowaiver, as provided for in Article 7, Item VI, of Collegiate Board Resolution – RDC No. 749 of 5 September 2022.

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 VII, Paragraph 1 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 a meeting held on 31 August and 1 September 2022 and I, Director-President, determine its publication.

Article 1. This Normative Instruction establishes, in the Annex, the list of oral medicines intended for local action in the gastrointestinal tract that are candidates for biowaiver in accordance with item VI of Article 7 of Collegiate Board Resolution – RDC No. 749 of 5 September 2022.

Article 2. This Normative Instruction shall come into effect on 3 October 2022.

ANTONIO BARRA TORRES

Director-President

ANNEX

Oral medicines intended for local action in the gastrointestinal tract that are candidates for biowaiver.

	Medicine
1	Bisacodyl
2	Homatropine
3	Nystatin
4	Pepsin
5	Calcium polystyrene sulfonate