WORLD TRADE ORGANIZATION

G/TBT/N/BRA/1528

27 March 2024

(24-3461)

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Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1.	**Notifying Member:** BRAZIL **If applicable, name of local government involved (Article 3.2 and 7.2):**
2.	**Agency responsible:** Brazilian Health Regulatory Agency (ANVISA) **Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:** National Institute of Metrology, Quality and Technology (INMETRO) Telephone: +(55) 21 2145.3817 Telefax: +(55) 21 2563.5637 Email: barreirastecnicas@inmetro.gov.br Web-site: www.inmetro.gov.br/barreirastecnicas
3.	**Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [ ], 5.7.1 [ ], 3.2 [ ], 7.2 [ ], other:**
4.	**Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** Medicaments consisting of two or more constituents mixed together for therapeutic or prophylactic uses, not in measured doses or put up for retail sale (excl. goods of heading 3002, 3005 or 3006) (HS code(s): 3003); Medicaments consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses "incl. those for transdermal administration" or in forms or packings for retail sale (excl. goods of heading 3002, 3005 or 3006) (HS code(s): 3004); Medicaments (ICS code(s): 11.120.10)
5.	**Title, number of pages and language(s) of the notified document:** Draft resolution 1245, 20 March 2024; (5 page(s), in Portuguese)
6.	**Description of content:** This Draft Resolution contains provisions on the validation of bioanalytical methods and analysis of study samples for regulatory submissions of industrialized medicines for human use. The bioanalytical method used to quantify the drug in matrix biological must be described in detail, and Guide nº XX, of XX2024, which deals with the validation of bioanalytical methods and sample analysis study (ICH M10 - Bioanalytical method validation and study sample analysis /ICHM10 - validation of bioanalytical methods and analysis of study samples), and its updates.
7.	**Objective and rationale, including the nature of urgent problems where applicable:** This draft resolution aims to: update current regulations on Validation of bioanalytical methods; add updated tests for chromatographic and LBA bioanalytical methods to the standard; and implement Guide adopted by ICH, as a member of the institution.; Protection of human health or safety

8.	**Relevant documents:** -
9.	**Proposed date of adoption:** To be determined **Proposed date of entry into force:** To be determined
10.	**Final date for comments:** 15 May 2024
11.	**Texts available from: National enquiry point [ ] or address, telephone and fax numbers and email and website addresses, if available, of other body:** Brazilian Health Regulatory Agency (Anvisa) SIA, Trecho 5, Área Especial 57 Brasília – DF / Brazil CEP: 71.205-050 Phone.: +(55) 61 3462.5402 Website: www.anvisa.gov.br The final text is available only in Portuguese and can be downloaded at: Draft: http://antigo.anvisa.gov.br/documents/10181/3855414/CONSULTA+P%C3%9ABLICA+N%C2%BA+1245+DIRE2.pdf/c926d52e-08a6-4327-b90c-1a5b2420de63 Comment form: https://pesquisa.anvisa.gov.br/index.php/335465?lang=pt-BR The comment form link will be available only on 01 April 2024 https://members.wto.org/crnattachments/2024/TBT/BRA/24_02293_00_x.pdf