



24 february 2016

(16-1109)

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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: <u>BRAZIL</u> 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 2563.2840 Telefax: +(55) 21 2563.5637 Email: barreirastecnicas@inmetro.gov.br Web-site: http://www.inmetro.gov.br/barreirastecnicas The comments to this Draft Regulation shall be sent to http://formsus.datasus.gov.br/site/formulario.php?id_aplicacao=23639
3. Notified under Article 2.9.2 [X], 2.10.1 [], 5.6.2 [], 5.7.1 [], other:
4. Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable): Analytical methods validation
5. Title, number of pages and language(s) of the notified document: Draft Technical Resolution nº 129, February 12 2016, regarding analytical methods validation (28 pages, in Portuguese)
6. Description of content: Draft Technical Resolution nº 129, 12 February 2016, regarding analytical methods validation. Draft technical resolution regarding the validation of analytical methods on biological, microbiological, immunological, identification, impurity determination quantitative trials; impurity control limit trials, quantitative trials to pharmaceutical ingredients in raw material and medicines in every phase of production. This Resolution revokes the Resolution RE 899/2003 and the Annex I of Resolution RDC 31/2010.
7. Objective and rationale, including the nature of urgent problems where applicable: Protection of human health or safety
8. Relevant documents: 1) Brazilian Official Journal (Diário Oficial da União), 15 February 2016; Section 1, p. 44; 2) Not stated; 3) Brazilian Official Journal; 4) Not stated.
9. Proposed date of adoption: To be determined after the end of the consultation period Proposed date of entry into force: 90 days from the publication

10. Final date for comments: 22 April 2016

11. Texts available from: National enquiry point [X] or address, telephone and fax numbers and email and website addresses, if available, of other body:

Agency Responsible

Brazilian Health Regulatory Agency – ANVISA

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<http://portal.anvisa.gov.br/wps/wcm/connect/80fde6804bb125c8aaffaebab17fe222/CP+129-2016+-+Minuta.pdf?MOD=AJPERES>