



Committee on Technical Barriers to Trade

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6.

<b>1. Notifying Member:</b> BRAZIL <b>If applicable, name of local government involved (Articles 3.2 and 7.2):</b>
<b>2. Agency responsible:</b> Brazilian Health Regulatory Agency (Anvisa) <b>Name and address (including telephone and fax numbers, e-mail and web-site addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:</b>  National Institute of Metrology, Quality and Technology (INMETRO) Telephone: +(55) 21 2563.2765 Telefax: +(55) 21 2563.5637 Email: <a href="mailto:barreirastecnicas@inmetro.gov.br">barreirastecnicas@inmetro.gov.br</a> Web-site: <a href="http://www.inmetro.gov.br/barreirastecnicas">www.inmetro.gov.br/barreirastecnicas</a>  <b>The comments to this Draft Regulation shall be sent to</b> <a href="http://formsus.datasus.gov.br/site/formulario.php?id_aplicacao=29985">http://formsus.datasus.gov.br/site/formulario.php?id_aplicacao=29985</a>
<b>3. Notified under Article 2.9.2 [ X ], 2.10.1 [ ], 5.6.2 [ ], 5.7.1 [ ], other:</b>
<b>4. Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):</b> water for pharmaceutical use
<b>5. Title, number of pages and language(s) of the notified document:</b> Draft Technical Resolution n. 312, February 20 2017. 20 pages, Portuguese.
<b>6. Description of content:</b> This Draft Resolution defines the chapter "water for pharmaceutical purposes" of the Brazilian Pharmacopoeia.  In this chapter it is considered water for pharmaceutical use the various types of water used in the synthesis of ingredients; in the formulation and production of medicines; in laboratories; diagnostics and other applications related to health, including its use as the main component in the cleaning process of utensils, equipments and systems.  Purification process, storage and distribution of water must comply with the pharmacopoeia specifications. The water quality requirements will depend on its purpose and use, as well as the purification system designed to meet the purity level established. The user is responsible for selecting the type of water appropriate to its objectives, as well as for the necessary controls to guarantee the maintenance of the desired quality.  This chapter also addresses the two major groups of water contaminants: chemical and microbiological contaminants.  There are three types of water for pharmaceutical use: purified water (AP); water for injections (API) and ultra-purified water (AUP), whose monographs are found in this Pharmacopoeia. Official international compendiums specify, in addition to these, other

	<p>types of water, such as: packaged in bottles, sterile or bacteriostatic, for irrigation or inhalation. However, all have purity characteristics similar to the three fundamental types already mentioned.</p> <p>In addition to these, there are potable water and reagent water, which are widely used and have direct application in pharmaceutical facilities, mainly in general cleaning procedures. Thus, the five types of water are considered, in relation to their main characteristics and application. Specific monographs, where available, detail purity parameters established for each type.</p>
7.	<p><b>Objective and rationale, including the nature of urgent problems where applicable:</b> Protection of Human Health</p>
8.	<p><b>Relevant documents:</b> (1) Brazilian Official Journal (Diário Oficial da União) N° 37, 21 February 2017, section 1, page 38; (2) Resolution RDC nº 59, 3 February 2016; (3) Brazilian Official Journal; (4) Not stated.</p>
9.	<p><b>Proposed date of adoption:</b> to be determined after the end of the consultation period.</p> <p><b>Proposed date of entry into force:</b> to be determined after the end of the consultation period.</p>
10.	<p><b>Final date for comments:</b> March 29, 2017</p>
11.	<p><b>Texts available from: National enquiry point [X] or address, telephone and fax numbers, e-mail and web-site addresses, if available of the other body:</b></p> <p>Agency Responsible  Brazilian Health Regulatory Agency (Anvisa)  SIA, Trecho 5, Área Especial 57  Brasília – DF / Brazil  CEP: 71.205-050  Phone.: +(55) 61 3462.5402  Website: <a href="http://www.anvisa.gov.br">www.anvisa.gov.br</a></p> <p><a href="http://portal.anvisa.gov.br/documents/10181/2949405/CONSULTA+PUBLICA+N+312+C+OFAR.pdf/31ad3eb8-888c-434e-b7e6-119191479504">http://portal.anvisa.gov.br/documents/10181/2949405/CONSULTA+PUBLICA+N+312+C+OFAR.pdf/31ad3eb8-888c-434e-b7e6-119191479504</a></p>