NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

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| **1.** | **Notifying Member:** Brazil  **If applicable, name of local government involved (Article 3.2 and 7.2):** |
| **2.** | **Agency responsible:**  National Institute of Metrology, Quality and Technology (INMETRO)  Telephone: +(55) 21 2563.2918  Telefax: +(55) 21 2563.5637  Email: [barreirastecnicas@inmetro.gov.br](mailto:barreirastecnicas@inmetro.gov.br)  Web-site: [www.inmetro.gov.br/barreirastecnicas](http://www.inmetro.gov.br/barreirastecnicas)  **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:**  The Brazilian Health Regulatory Agency (ANVISA) |
| **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):** HS Codes: 3003; 3004; 3005; 2941. |
| **5.** | **Title, number of pages and language(s) of the notified document:** Draft resolution (Consulta Publica) number 653, 21 May 2019. Published on D.O.U, 27 May 2019, page 57. (2 page(s), in Portuguese)  Comment form: http://formsus.datasus.gov.br/site/formulario.php?id\_aplicacao=47328 |
| **6.** | **Description of content:** This Draft Resolution corresponds to the adoption of the Guide to Good Manufacturing Practices for Medicinal Products of the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) of 1 July 2018. The resolution – RDC represents the [Part 1](http://portal.anvisa.gov.br/documents/10181/5389382/PE_009_14_GMP_Guide_Part_I_Basic_Requirements_for_Medicinal_Products_.pdf/bc4b65e3-b22d-438f-b33c-e13f05e79f3e) of the guide that applies to all medicines without distinction. The Normative Instructions (IN) correspond to the [annexes](http://portal.anvisa.gov.br/documents/10181/5389382/PE_009_14_GMP_Guide_xAnnexes_+%281%29.pdf/ba0e51c1-eb74-49f4-a7d5-d84cd222fb60) of the guide related to specific aspects of the good practices for the manufacture of medicines.  [RDC - Good Practice Guidelines for the Manufacture of Medicines](http://portal.anvisa.gov.br/documents/33880/5510597/Resolu%C3%A7%C3%A3o+da+Diretoria+Colegiada.pdf/e61560fb-ca20-4fdd-913f-e4b045c9f0d4): corresponds to Part I of the PIC/S guide;  [IN Complementary guidelines to the manufacture of sterile medicinal products](http://portal.anvisa.gov.br/documents/33880/5510597/Instru%C3%A7%C3%A3o+Normativa+-+Estereis.pdf/dc2767f0-5a92-4f9d-b0b1-2801462cc09a) (corresponds to annex 1 of the PIC/S guide);  [IN Complementary guidelines to the manufacture of biological medicinal substances and products for human use](http://portal.anvisa.gov.br/documents/33880/5510597/3.+Instru%C3%A7%C3%A3o+Normativa+-+Insumos+e+Medicamentos+Biol%C3%B3gicos.pdf/d72bf53a-d267-4e19-ace9-9a653a6720f0) (corresponds to annex 2 of the PIC/S guide);  [IN Complementary guidelines to the manufacture of radiopharmaceuticals](http://portal.anvisa.gov.br/documents/33880/5510597/4.+Instru%C3%A7%C3%A3o+Normativa+-+fabrica%C3%A7%C3%A3o+de+radiof%C3%A1rmacos.pdf/6f13694c-810d-433e-9be8-c1c5faecc18c) (corresponds to annex 3 of the PIC/S guide);  [IN Complementary guidelines to the manufacture of herbal medicinal products](http://portal.anvisa.gov.br/documents/33880/5510597/Instru%C3%A7%C3%A3o+Normativa+-+medicamentos+fitoter%C3%A1picos.pdf/5e5e4c91-d892-4417-91d7-2e82cf41eecc) (corresponds to annex 7 of the PIC/S guide);  [IN Complementary guidelines to the manufacture of medicinal gases](http://portal.anvisa.gov.br/documents/33880/5510597/Instru%C3%A7%C3%A3o+Normativa+-+Gases+Medicinais.pdf/f1d0af32-e9c4-4a29-825b-ab56240273bc) (corresponds to annex 6 of the PIC/S guide);  [IN Complementary guidelines to the sampling of starting and packaging materials](http://portal.anvisa.gov.br/documents/33880/5510597/Instru%C3%A7%C3%A3o+Normativa+-+materiais+embalagens.pdf/34012d4a-ab09-4d90-9085-cb44ac028470) (corresponds to annex 8 of the PIC/S guide);  [IN Complementary guidelines to the manufacture of liquids, creams and ointments](http://portal.anvisa.gov.br/documents/33880/5510597/Instru%C3%A7%C3%A3o+Normativa+-+Medicamentos+L%C3%ADquidos%2C+Cremes+ou+Pomadas.pdf/56976e16-51d8-4bf1-b7f6-3dee58d74ae4) (corresponds to annex 9 of the PIC/S guide);  [IN Complementary guidelines to the manufacture of pressurised metered dose aerosol preparations for inhalation](http://portal.anvisa.gov.br/documents/33880/5510597/Instru%C3%A7%C3%A3o+Normativa+-+Dosimetrados+para+Inala%C3%A7%C3%A3o.pdf/f44fbf50-6778-4aee-a164-50f5343708e6) (corresponds to annex 10 of the PIC/S guide);  [IN Complementary guidelines to computerised systems](http://portal.anvisa.gov.br/documents/33880/5510597/Instru%C3%A7%C3%A3o+Normativa+-+sistemas+computadorizados.pdf/1cb4924d-cbc2-49d4-be7e-870170e91026) (corresponds to annex 11 of the PIC/S guide);  [IN Complementary guidelines to the use of ionising radiation in the manufacture of medicinal products](http://portal.anvisa.gov.br/documents/33880/5510597/Instru%C3%A7%C3%A3o+Normativa+-+Radia%C3%A7%C3%A3o+Ionizante.pdf/f1bc9fbf-c5dd-443f-ae7c-1ef967086234) (corresponds to annex 12 of the PIC/S guide);  [IN Complementary guidelines to the manufacture of investigational medicinal products](http://portal.anvisa.gov.br/documents/33880/5510597/Instru%C3%A7%C3%A3o+Normativa+-+Medicamentos+Experimentais.pdf/be5bd6b2-308f-4767-bfd3-5f49914d781a) (corresponds to annex 13 of the PIC/S guide);  [IN Complementary guidelines to the manufacture of medicinal products derived from human blood or plasma](http://portal.anvisa.gov.br/documents/33880/5510597/Instru%C3%A7%C3%A3o+Normativa+-+Medicamentos+Hemoderivados.pdf/1e9fa0e2-e205-4678-b5db-4fa15fecc2d9) (corresponds to annex 14 of the PIC/S guide);  [IN Complementary guidelines to the qualification and validation](http://portal.anvisa.gov.br/documents/33880/5510597/Instru%C3%A7%C3%A3o+Normativa+-+qualifica%C3%A7%C3%A3o+e+valida%C3%A7%C3%A3o.pdf/36c30e2f-96e5-4028-bdcb-e7313d96e7c6) (corresponds to annex 15 of the PIC/S guide);  [IN Complementary guidelines to the reference and retention samples](http://portal.anvisa.gov.br/documents/33880/5510597/Instru%C3%A7%C3%A3o+Normativa+-+amostras+de+refer%C3%AAncia+e+de+reten%C3%A7%C3%A3o.pdf/77ae1356-f9f3-45e1-a45d-7baad7bee4da) (corresponds to annex 19 of the PIC/S guide);  Considering that this is the adoption of a set of guides widely adopted internationally, it is not desirable that in Brazil be adopted divergent good manufacturing practices (BPF)requirements, unless a necessity to adopt different requirements to reach an adequate level for protection to health be proved. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health |
| **8.** | **Relevant documents:**   * Guide to Good Manufacturing Practice for Medicinal Products of the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co‑operation Scheme (PIC/S) part I of 1 July 18.   <http://portal.anvisa.gov.br/documents/10181/5389382/PE_009_14_GMP_Guide_Part_I_Basic_Requirements_for_Medicinal_Products_.pdf/bc4b65e3-b22d-438f-b33c-e13f05e79f3e>   * Guide to Good Manufacturing Practice for Medicinal Products of the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co‑operation Scheme (PIC/S), Annexes.   <http://portal.anvisa.gov.br/documents/10181/5389382/PE_009_14_GMP_Guide_xAnnexes_+%281%29.pdf/ba0e51c1-eb74-49f4-a7d5-d84cd222fb60> |
| **9.** | **Proposed date of adoption:** To be determined after the end of the consultation period.  **Proposed date of entry into force:** To be determined after the end of the consultation period. |
| **10.** | **Final date for comments:** 1 August 2019 |
| **11.** | **Texts available from: National enquiry point [****X]** **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](http://www.anvisa.gov.br)  <http://portal.anvisa.gov.br/documents/10181/5389382/CP+653.pdf/62eebe70-a553-4b21-89ab-3924dfcd8e84> |