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 Surveillance 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 Website: www.inmetro.gov.br/barreirastecnicas
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):** Draft resolution of the pharmacopeial monographs on the heparin sodium from bovine and porcine in the Brazilian Pharmacopoeia.
5.	**Title, number of pages and language(s) of the notified document:** Draft Resolution nº 38, June 9th 2014, of the pharmacopeial monographs on the heparin sodium from bovine and porcine in the Brazilian Pharmacopoeia. (13 pages, in Portuguese)
6.	**Description of content:** Draft resolution of the pharmacopeial monographs on the heparin sodium from bovine and porcine in the Brazilian Pharmacopoeia. The heparin sodium from bovine is extracted from the bovine intestine and contains a mix of polysaccharide chains with different molecular weight. It is composed of units of a-D-glucosamine e acid a-iduronic 2-sulfated. The units of a-D-glucosamine present a more heterogeneous pattern of sulphatation in comparison with the heparin from porcine. In special we observe higher proportion of units of a-D-glucosamine non-sulphated in the position 6. It has anticoagulant activity by the inhibition of many factors of the coagulation system, prolonging the time of coagulation in blood. This occurs mainly through potentiation of the Xa factor inactivation and of the thrombin through the antithrombin. It contains, at least, 160 units of anti-factor lla activity for mg of heparin, respectively, in relation to desiccated substance. The reason of the anti-factor Xa activity for the anti-factor lla activity must be of 1.0 ± 0.1. The animals from which the heparin is extracted must fulfil the sanitary requirements of the species and the manufacturing process must ensure the elimination or the inactivation of infectious agents. The heparin sodium from porcine is extracted from the intestine of the porcine and

	contains a mix of polysaccharide chains with different molecular weight. It is composed, preponderantly, for alternated units of a-D-glucosamine N- and 6- disulfated and acid a-iduronic 2-sulfated. It has anticoagulant activity due to the inhibition of many factors of the coagulation system, prolonging the time of coagulation in blood. This occurs mainly through potentiation of the Xa factor inactivation and of the thrombin through the antithrombin. It contains, at least, 180 units of anti-factor lla activity for mg of heparin, in relation to desiccated substance. The reason of the anti-factor Xa activity for the anti-factor lla activity must be 1.0 ± 0.1. The animals from which the heparin is extracted must fulfil the sanitary requirements of the species in question and the manufacturing process must ensure the elimination or the inactivation of infectious agents. These monograph proposals set standards for the identity, dosage (according to methods Anti-factor Xa activity and Anti-factor IIa activity / ion-exchange high-performance liquid chromatography technique for detection and separation of possible contaminants of the heparin), characteristics, purity assays, biological safety tests, packaging, storing and labeling of the heparin sodium from bovine and porcine in the Brazilian Pharmacopoeia.
7.	**Objective and rationale, including the nature of urgent problems where applicable:** Protection of Human Health
8.	**Relevant documents:** Brazilian Official Journal (Diário Oficial da União), June 10th 2014; Section 1, p. 43, Draft Resolution (Consulta Pública) number 38, June 9th 2014, issued by Brazilian Health Surveillance Agency – Anvisa. When adopted, it will be published at the Brazilian Official Journal. Available in Portuguese.
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:** 08 August 2014
11.	**Texts available from: National enquiry point [ ] or address, telephone and fax numbers email and website addresses, if available, of other body:** Agency responsible Brazilian Health Surveillance Agency – ANVISA SIA, Trecho 5, Área Especial 57 Brasília – DF / Brazil CEP: 71.205-050 Phone.: 55 61 3462-5402 E-mail: rel@anvisa.gov.br Websit http://portal.anvisa.gov.br/wps/wcm/connect/66e64a804451d511a4fcac7f5a7b924e/Consulta+P%C3%BAblica+n+38+COFAR.pdf?MOD=AJPERES