

# EVALUATION OF HIPODERMIC NEEDLES BRANDS THROUGH THE TEST OF CORROSION RESISTANCE

## *AValiação de Marcas Comerciais de Agulhas Hipodérmicas Através de Teste de Resistência à Corrosão*

Luciene de Oliveira Morais<sup>1</sup>, Renata de Freitas Dalavia<sup>2</sup>, Vale, Ana Paula Alcides<sup>3</sup>, Filipe Quirino Soares<sup>4</sup> & Michele Feitoza-Silva<sup>5</sup>

<sup>1</sup>Mestranda da Pós-Graduação do Instituto Nacional de Controle da Qualidade em Saúde da Fundação Oswaldo Cruz – FIOCRUZ. Aluna da Pós-Graduação. E-mail: [lucieneom@yahoo.com.br](mailto:lucieneom@yahoo.com.br)

<sup>2</sup>Mestranda da Pós-Graduação do Instituto Nacional de Controle da Qualidade em Saúde da Fundação Oswaldo Cruz – FIOCRUZ. Servidora do departamento de Química (DQ/INCQS/FIOCRUZ) e aluna da pós-graduação. E-mail: [renata.dalavia@incqs.fiocruz.br](mailto:renata.dalavia@incqs.fiocruz.br).

<sup>3</sup>Doutora em Vigilância sanitária. Servidora do departamento de Microbiologia (DM/INCQS/FIOCRUZ). E-mail: [ana.alcides@incqs.fiocruz.br](mailto:ana.alcides@incqs.fiocruz.br).

<sup>4</sup>Doutor em Vigilância sanitária. Servidor do departamento de Química (DQ/INCQS/FIOCRUZ) - Chefe do Departamento de Química. E-mail: [filipe.soares@incqs.fiocruz.br](mailto:filipe.soares@incqs.fiocruz.br).

<sup>5</sup>Mestre em Ciências farmacêuticas . Servidora do departamento de Química (DQ INCQS/FIOCRUZ), professora da pós-graduação do INCQS e Coordenadora do GT de artigos de saúde/ INCQS. E-mail: [michele.feitoza@incqs.fiocruz.br](mailto:michele.feitoza@incqs.fiocruz.br).

### ABSTRACT

Needles are medical products, single use, which fully or partially penetrate into the human body through the body surface and can be used several ways, and even for biopsy, root canal treatment, among others. Are widely used in units of the medical, dental and hospital, both in the public and private sector. It is estimated that over 1 billion injections are administered each year, and the occurrence of bias and quality of these products can compromise a large number of people. The objective of this study was to evaluate the quality of needles sold in Brazil, using samples acquired BY INMETRO and the list of incidences of quality deviations NOTIVISA registered with the system and routed through a report by UTVIG/ANVISA . Corrosion resistance was realized according to the tests listed in NBR 9259 - Sterile hypodermic needles and Single-Use on 9 samples, and each sample corresponded to a trademark. Of the nine brands of needles analyzed, 3 were specification out. From these results, we conclude that there is a need to implement specific technical regulations for these products, despite being classified as low risk by RDC 185/2001 ANVISA, can have a major impact on population health

### RESUMO

*Agulhas são produtos médicos, de uso único, que penetram total ou parcialmente dentro do corpo através da superfície corporal, podendo ser utilizada por diversas vias, e ainda para realização de biópsia, tratamento de canal, entre outros. São amplamente utilizados nas unidades médica,*

*odontológica e hospitalar, tanto no sistema público, quanto privado. Estima-se que mais de 1 bilhão de injeções sejam administradas anualmente, e a ocorrência de desvios e qualidade neste produto podem comprometer um grande número de pessoas. O objetivo deste estudo foi avaliar a qualidade de agulhas comercializadas no Brasil, adquiridas pelo INMETRO, seguindo lista de incidências registradas pelo NOTIVISA e encaminhadas pelo UTVIG/ANVISA. Foi realizado ensaio de resistência à corrosão de acordo com a NBR 9259 - Agulhas hipodérmica de Uso Único em 9 amostras, sendo que, cada uma representava uma marca comercial. Das nove marcas analisadas 3 tiveram resultado insatisfatório. A partir disto, concluímos que, existe a necessidade de implantação de regulamentos técnicos sanitários específicos para este produto, que apesar de classificado como baixo risco pela RDC 185/2001 ANVISA, pode causar grande impacto à saúde da população.*

### **History manufacture of needles**

The needles were devised by Daniel Ferguson in 1853, and modified by Wood, to reach a fine tip, which facilitated further its penetration into tissues. His first advertisement, like what happened with the syringes, was also made in 1870 by the Dental Cosmos (USA) where it was mentioned that it was made of "hardened steel", however, did not mention to his caliber and size (GIROTTO apud GLENN & PICCK, 1998).

At this time the needles were manufactured in various materials such as platinum, iridium, gold and carbon steel. Only in 1920 they began to be manufactured in stainless steel. To designate the diameter of its tube, it was used then, a number in Arabic, equivalent to its nominal diameter, followed by the letter G (GIROTTO apud GLENN & PICCK, 1998). According to Ferreira (1998), this unit abbreviated "G" comes from the English word "Gauge", which means size, extent or pattern. This term is now used to determine the diameter of the cannula needle, Birmingham-based system / Stubbs created in 1840 in England in order to identify the diameter of solid wire (GIROTTO apud FARKASIAN & Weiner, 1998).

Between the years 1900 and 1915, there were several publications related to standardization of size and length of needles and in 1916 was also suggested that the needles had its surface coated with vaseline, in order to facilitate its introduction into the tissue, procedure done today. (Apud GIROTTO GLENN & PICCK, 1998).

### **Manufacturing technology of needles**

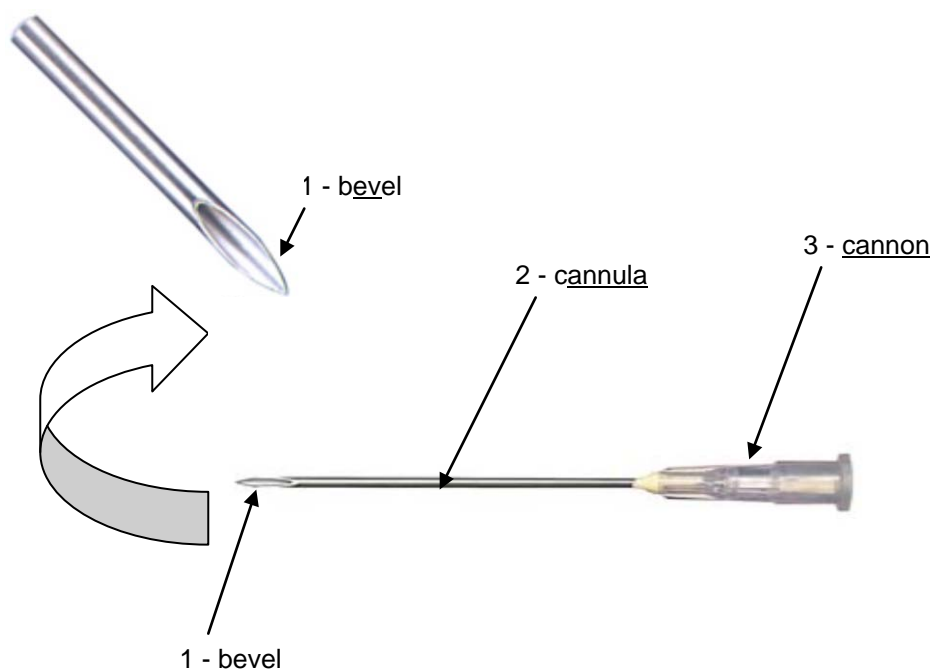
The needles are medical products, single use, which fully or partially penetrate into the human body through the body surface and can be used for intravenous, intramuscular,

subcutaneous, intradermal, intra-arterial, intracardiac, intrathecal, epidural and intra-articular at biopsy, root canal treatment, among others.

As described in the NBR 9259 (ABNT, 1997a), they consist of a stainless steel tube straight cylindrical and hollow, called a cannula, with specific dimensions, presenting a three-sided bevel and honed to facilitate drilling. The cannula should be properly leveled, polished, tough, free from sharp protrusions and / or waves, and lubricated with silicone purity pharmaceutical grade hospital doctor should also submit, on the other end, a structure that permits a perfect connection and secure the cannula, which is called a cannon, which can be made on appropriate non-toxic plastic material (polypropylene), or aluminum alloy or other alloys. This cannon must present different colors, in order to facilitate the identification of size, and should be free of defects or burrs, and 6% taper in its inner part for perfect fit and easy installation and removal in the nozzle of the syringe.

According to NBR 10333-1 (ABNT, 1997b) and NBR 10333-2 (ABNT, 1997c), the gun must be produced in size and format that is universally accepted to-female luer connection with luer-lock or luer slip, providing perfect fit .

The cannula of the needles must be protected by a component called the guard shall that consists of plastic, designed internally to keep the needle centered with part of the cannon available exteriorized to allow coupling to the syringe (ABNT, 1997a). These components, except the Guard, are shown in Figure 2.



**Figure 2. Needle components – Adapted from DOCTORSTOCK, 2009**

According to NBR 5601:1981, needles should be constructed of stainless steel type 304. According Tebecherani (2009) stainless steel is one that has a higher corrosion resistance when subjected to a given environment or aggressive agent, it is composed of a steel alloy which is added a percentage of chromium greater than 12%.

According to Ferreira (2005) stainless steel is classified into three groups according to their basic microstructure formed, they are: martensitic stainless steel, stainless steel, ferritic and austenitic stainless steel.

For Tebecherani (2009), the martensitic steel is one whose structure is characterized by high hardness and brittleness due to the presence of high levels of carbon. This type of steel has 12-17% chromium in their composition, and are hardly attacked by atmospheric corrosion in the hardened. Its standardization follows the standard established by AISI in which the numbering distinguishes the carbon, chromium and other alloying elements added. The most common types are the steels 403, 410, 414, 416, 420, 420F, 431, 440A, 440B, 440C and 440F.

Ferritic steels are those with greater corrosion resistance than martensitic steel due to the higher concentration of chromium, 16-30% of this element, and are resistant to atmospheric corrosion solutions and strong oxidizing, being ferromagnetic. The designation indicates as AISI types: 405, 406, 430, 430F, 442, 443 and 446 (TEBECHERANI, 2009).

Classified as austenitic steel and the alloy is more noble and obtained from the introduction of nickel as an alloying element, which provides a change in its structure capable of increasing their strength and toughness. Three groups of this type of steel is what has greater corrosion resistance, with 15-30% chromium. Other elements such as molybdenum, titanium and niobium, can be added to improve corrosion resistance. The most common form part of the series 300 (AISI 301, 302, 302B, 303, 304, 304-L, 305, 308, 309, 310, 314, 316, 316L, 317, 321, 347) (CHIAVERINI, 1990).

Therefore, according to Tebecherani (2009), the corrosion resistance of stainless steels depends primarily on the microstructure and chemical composition. In general, the austenitic stainless steels are more resistant to corrosion, and it is this type of steel that is used in the manufacture of hypodermic needles, as recommended by the NBR 5601:1985 is the 304, which presents in its composition 18-20% chromium, 8-10% nickel, small amounts of manganese and silicon and a carbon amount of less than 0.1%. Thus, the needles made of this material, may not submit changes in their external appearance or formation of microstructural defects with characteristics of corrosion.

## **The quality control of needles**

The needles are medical products class I by the RDC 185/01, for presenting low risk to health, as established by rules of the relevant resolution (BRAZIL, 2001a).

However, despite the classification of low risk products are widely used in units for medical, dental and hospital care in both the public and private sectors (UNICEF, 1998). It is estimated that over one billion injections are administered worldwide each year, only for immunization programs (WHO, 2002). Therefore, deviations from these quality products can compromise a large number of people, causing a major impact on public health.

Aiming to specify mandatory requirements for needles, was published by the Brazilian Association of Technical Standards (ABNT), the technical standard for quality control of these products, ISO 9259 - Sterile Hypodermic Needle, single use. However, for adverse events and complaints techniques in post-commercialization, gaps arise in applying those rules, since often the application is directly tied to lot size (ABNT, 1997a; ABNT, 2003).

## **Brazilian Market of syringes and needles**

Brazil has been importing more and more syringes (with and without needle). In October 2007 were 40.7 million units and 26.1 million (64%) with capacity greater than 2 mL, in September 2009 were 85.9 million units and 77 million (90%) with capacity greater than 2 mL. Given these data it is noticed that in two years, the total quantity imported has doubled and the number of syringes (with and without needle) over 2 mL tripled. In parallel, the average export price of these syringes more than 2 mL has performed significantly higher than the import and that difference has increased: in the last 12 months the difference was 30% and the previous 12 months was 26% in other words, we are importing these products cheaper and exporting our more expensive (INMETRO, 2009).

In these two years, the amount spent in Brazil with the importation of these products was 52.8 million dollars, of which 43.8 million (83%) refer to more than 2 ml syringes. The following charts present data on imports of more than 2 ml syringes (with and without needles) in the last 24 months (October 2007 to September 2009). (INMETRO, 2009)

## **The TecnoSurveillance**

"It's a surveillance system designed to monitor the occurrence of adverse events, quality deviations and irregularities associated with the use of health products in the post-marketing with a view to recommending measures to ensure the protection and promotion of health Brazilian

population" . The post-marketing surveillance can also be understood as the surveillance of adverse events (AE) and complaints techniques (CT) product under sanitary surveillance. Adverse event can be understood as an unintended effect in humans due to the use of products under health surveillance, or damage is caused to the health of a user or a patient that occurs during the routine use of a product and its use was carried out under the conditions and criteria prescribed by the manufacturer with the registration process of this product in ANVISA. It is understood by technical complaint as a complaint of suspected alteration / deficiency in a product that is related to technical or legal, and may or may not harm the individual and collective health.

Therefore, for a health product to remain on the market with the quality standards recommended, thus ensuring, their health security, it is necessary to the fulfillment of the requirements of compliance, efficiency, effectiveness and performance. Means for compliance and the compliance with technical standards that are applied to the product for the correct execution of their duties. Effectiveness is the effect resulting from the use of the product under controlled conditions. Effectiveness is the effect you get when you are using the product during routine service and performance of a product is directly involved in the execution of the activity for which the product was designed (ANTUNES et al. 2002).

### **Information system for health products**

The monitoring of information products under sanitary surveillance in the stage of post-marketing is done through a reporting system created by ANVISA. Historically, the first system was deployed in 2001, called SISTEC, and was intended to receive the notifications and promoting the broadcasting of alerts (ANVISA, 2008).

In 2003, it created a new module of the computerized system, unique among the Network and ANVISA, called SINEPS, whose purpose was to receive notifications from hospitals Network Sentry and remained operating until the end of 2006.

In December 2006, ANVISA implemented a new information system, called NOTIVISA (System Notifications in Health Surveillance). The advantage of this system is that it allows not only register but also the management of adverse event reports of abuse and technique. Furthermore, this system does not limit the notifications to hospitals Sentinel Network, so the companies holding registration of products and other health professionals may also notify the EA and QT ANVISA and other partners SNVS. Another advantage of this system is its easy access, because it is in the web platform and is available on the website of ANVISA.

The NOTIVISA is an important tool for systematic monitoring of the requirements of compliance, effectiveness, performance and safety of health products, and the information extracted

from this system in 2007, as shown in Figure 6, the health product that showed more reports of abuse techniques was the equipment. The syringe was the third product with the highest number of notifications and needle the seventh.

This study aimed to evaluate the quality of needles marketed in Brazil, according to NBR as to test their resistance to corrosion.

## **MATERIALS AND METHODS**

### **Universe and sample coding**

Were evaluated in this study nine needle marks. These samples were acquired on the market in March 2009, following the list of incidences of quality deviations NOTIVISA recorded by the system and sent through a report by UTVIG / ANVISA. To preserve the identity of each holder of record, each sample received an encoding formed by a letter.

### **Treatment of the sample**

All samples received through were separated and checked to confirm whether they were suitable for testing. Therefore, it was observed that the samples were properly sealed, if your primary packages were intact and were within the duration.

Moreover, was performed the checking of legality of the samples, comparing the number of record in this package to the information available at ANVISA.

### **Resistance to corrosion**

Before performing the test, all samples were carefully inspected visually for the presence of corrosion or any other defect. For tests of corrosion resistance of the cannula were used three samples of each batch of needles. Initially the samples were placed in a glass beaker (10 mL), immersed in a solution of citric acid 10% and kept at room temperature for 5h. Then, after removing the samples of this solution, they were boiled for 30 minutes in distilled water. In the next stage the needles were placed in a glass beaker (10 mL) and immersed in distilled water for 48 hours at room temperature. At the end of this step, each sample was placed in a glass petri dish (90 x 15 mm) to dry by evaporation at room temperature. After the analysis was done by visual inspection of all needles, using a stereomicroscope (CANON) to 7-fold increase (Micronal model 52111BR) (ABNT, 1996).

The evaluation was made using as criterion the appearance of steel, in other words, the presence of stains and spots of discoloration was investigated.

## **RESULTS AND DISCUSSION**

### **Sample Universe**

The first stage of the work was the collection of samples, based on the information of the reports of adverse events (AE) techniques and complaints (QT) for needles in the system NOTIVISA. The samples were acquired in the market, following the list of companies with a higher incidence of QT and EA, and sent them to the INCQS for verification of complaints.

The list of brands, products and companies with larger needles notifications provided by the UTVIG, comprise the database of the notifications in NOTIVISA. This database allows it to be carried out monitoring of the requirements of compliance, effectiveness, performance and safety of health products, until a behavioral analysis demonstrates the need to trigger initiation of an investigation or other actions.

In this first stage of work, INCQS accompanied the process of all relevant documents so he could start the evaluation laboratory.

### **Coding of samples**

The codification of the needle marks, made to preserve the identity of the companies that took part in this study is described in table 1.

Table 1. Established for the coding for needle marks

<b>Brand</b>	<b>Manufacturer</b>	<b>Product</b>	<b>Expire Date</b>
<b>A</b>	National	Neddle 25 x 0,70 mm	11/2012
<b>B</b>	Imported	Neddle 25 x 0,70 mm	09/2013
<b>C</b>	Imported	Neddle 25 x 0,70 mm	09/2013
<b>D</b>	Imported	Neddle 25 x 0,70 mm	06/2013
<b>E</b>	Imported	Neddle 25 x 0,70 mm	07/2013
<b>F</b>	Imported	Neddle 25 x 0,70 mm	07/2013
<b>G</b>	Imported	Neddle 25 x 0,70 mm	02/2013
<b>H</b>	National	Neddle 25 x 0,70 mm	01/2013
<b>I</b>	National	Neddle 25 x 0,70 mm	07/2013



## **Treatment of the sample**

All samples received by INCQS / FIOCRUZ, showed no damage to your primary container and its seals were not violated, therefore, were regarded as suitable for testing. This initial verification to provide reliable results

## **Evaluation of needle brands on the test for resistance to corrosion**

In this study, the nine brands of needles analyzed, 3 (33%) showed to be unsatisfactory, due to the presence of spots on the surface of the cannula that appeared after the test, indicating corrosion, demonstrating that the type of steel used is not recommended for this type material, or that the production process may not be appropriate.

Considering the role of needles to penetrate the human body, this type of non-compliance, health problems can cause the patient (GIROTTI et al, 2000).

This test is used to evaluate the needle cannula, which should be of stainless steel and therefore corrosion resistant (formation of rust, oxidation). This test is important because, even if using a stainless steel suitable faults can occur in the manufacturing process of the cannula itself, is in the welding that occurs during forming of the tube home, either in drawing or any other point in the process. These failures can result in susceptibility to corrosion of the tube, allowing the growth of microorganisms, and even a weakness of the needle, creating the risk of breakage during use.

Moreover, according to UTVIG / Anvisa, the use of oxidized needle can cause allergic or toxic reactions, especially in patients who need to make daily use of that product during treatment. Oxidation in a needle may not be visible to the naked eye, so to ABNT NBR 9259:1997 recommends viewing with magnifying glass sevenfold increase in its description of the test.

## **CONCLUSION**

This study evaluates the quality of needles. Of the nine brands of needles examined in the corrosion test, three brands were disapproved (33%). These unsatisfactoriness demonstrates that these companies are not looking at the technical standard, while pointing out weaknesses in the quality system.

The results found in this study indicates a need by ANVISA, to broaden the discussion on the subject, involving all sectors, as well as the need to think of health regulations more specific. Despite the extensive regulation of medical products for the most part, deals with issues inherent to all records in the ANVISA and the process of certification in Good Manufacturing Practices, but there is no specific regulation that establishes mandatory quality control for products to health

(imported and national) in the mold of a certification, as occurs for mandatory condom and electro medical equipment.

The risks of non-conformities found is worrying, because it is an invasive products and therefore requires a rigorous quality control in manufacturing and periodic reviews of design, transport, storage and marketing. In this case, any damage to the patient's health should be emphasized by the fact that, in general, who is subjected to the use of that type is already more impaired.

It is noteworthy that the greatest difficulty is evidenced by the lack of sanitary inspection for local manufacturers and importers of products falling within Class I.

It is also important to note that this study was not intended to be definitive or exhaustive on the subject, but point out the need for the development of research and actions related to the deficiencies identified herein.

## REFERENCES

- ASSOCIAÇÃO BRASILEIRA DE NORMAS TÉCNICAS. Rio de Janeiro. NBR 5601: Aços inoxidáveis – Classificação por composição Química - Padronização Uso Único. Rio de Janeiro, 1981.
- ASSOCIAÇÃO BRASILEIRA DE NORMAS TÉCNICAS. Rio de Janeiro. NBR 9259: Agulhas hipodérmica estéril e de Uso Único. Rio de Janeiro, 1997a.
- ASSOCIAÇÃO BRASILEIRA DE NORMAS TÉCNICAS. Rio de Janeiro. NBR 10333-1. Luer (montagem cônica com cone a 6%) para seringas, agulhas e outros dispositivos médicos – Parte 1: Requisitos gerais, 1997b.
- ASSOCIAÇÃO BRASILEIRA DE NORMAS TÉCNICAS. Rio de Janeiro. NBR 10333-2. Luer (montagem cônica com cone a 6%) para seringas, agulhas e outros dispositivos médicos – Parte 2: Luer com travamento, 1997c.
- AGÊNCIA NACIONAL DE VIGILÂNCIA SANITÁRIA. Manual de Tecnovigilância: abordagens para vigilância sanitária de produtos para a saúde comercializados no Brasil. Brasília, DF: Ministério da Saúde, 2008. 644p. Disponível em: <[http://www.anvisa.gov.br/tecnovigilancia/mat\\_apoio/bibliografias.htm](http://www.anvisa.gov.br/tecnovigilancia/mat_apoio/bibliografias.htm)>. Acesso em: 11 dez. 2009.
- ANTUNES, E. et al. Tecnovigilância. In: \_\_\_\_\_. Gestão da tecnologia biomédica: tecnovigilância e engenharia clínica. Paris: ACODESS, 2002. p. 27-41.
- ASSOCIAÇÃO BRASILEIRA DE NORMAS TÉCNICAS. Rio de Janeiro. NBR 7886-1: Seringa hipodérmicas estéril Para Uso Único. Parte 1: Seringa para Uso Manual. Rio de Janeiro, 2003.
- BRASIL. Resolução RDC nº 185, de 22 de outubro de 2001. Aprova o Regulamento Técnico que consta no anexo desta Resolução, que trata do registro, alteração, revalidação e cancelamento

do registro de produtos médicos na Agência Nacional de Vigilância Sanitária - ANVISA. Diário Oficial da República Federativa do Brasil. Brasília (DF): Ministério da Saúde; 2001a.

- CHIAVERINI, V., Aços e ferros fundidos – Características gerais e tratamentos térmicos, 6ª Ed – ABMM, 1990.
- DOCTORSTOCK. Disponível em <<http://www.doctorstock.com.br/site/images/NN-2425R.jpg>>. Acesso em: 29 Dez. 2009.
- FERREIRA, J. T. L. Avaliação da resistência à corrosão de materiais metálicos utilizados em aparelhos ortodônticos fixos. Rio de Janeiro: UFRJ, 2005. 257 p. Tese (Doutorado) - Universidade Federal do Rio de Janeiro , COPPE, Rio de Janeiro.
- GIROTTO, M. A.. Avaliação da padronização de agulhas anestésicas odontológicas comercializadas no Brasil. São Paulo, 1998. 95 p. Dissertação (Mestrado) – Universidade Estadual de Campinas, Faculdade de Odontologia de Piracicaba, São Paulo.
- GIROTTO, M. A.; VOLPATO, M. C.; RANALI, J. Avaliação da padronização de agulhas anestésicas odontológicas comercializadas no Brasil. *Pesqui Odontol Bras*, v. 14, n. 3, p. 294-299, jul./set. 2000.
- TEBECHERANI, C. T. P. Aços inoxidáveis. 2009. Disponível em:<[http://www.pipesystem.com.br/Artigos\\_Tecnicos/Aco\\_Inox/Artigo\\_para\\_pipesystem\\_sobre\\_inox1.pdf](http://www.pipesystem.com.br/Artigos_Tecnicos/Aco_Inox/Artigo_para_pipesystem_sobre_inox1.pdf)> Acesso em 28 Dez. 2009.
- UNICEF. A prescrição: Diretrizes para a utilização racional de medicamentos nos Serviços básicos de saúde. N. 15 p. 1-16, Mai. 1998. Disponível em: <[http://www.unifef.org/prescriber/port\\_p15.pdf](http://www.unifef.org/prescriber/port_p15.pdf)>. Acesso em 30 Dez. 2009.
- World Health Organization - WHO. Safe Injection Global Network (SIGN). Phnom Penh, Cambodia; 2002. p. 24-5. WHO/BCT/02.13