

Quality Control of Povidone Iodine Solutions Used in Public Health Services in Tucumán, Argentina

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Abstract: Povidone iodine solution 10% is widely used as an antiseptic in operating theatres of Public Health Services of the province of Tucumán, Argentina. The United States Pharmacopeia establishes values for iodine content in povidone iodine solutions. It is extremely important to verify whether the concentration of such solutions fits the values established by USP. The aim of the present work is to determine the value of samples of povidone iodine 10% which were obtained from several institutions and prepared by the pharmaceutical industry and the Official Pharmacy of the province of Tucumán. Iodine content present in all the solutions was determined by means of redox titrimetric method using a standardized solution of sodium thiosulphate. The results obtained show that only 50% of the samples evaluated are within the iodine concentration range required. This research intends to carry out the quality control of the solutions mentioned above and to implements the means for their conservation in proper conditions to guarantee their disinfecting power.

Key words: Povidone iodine solutions, quality control, health services, Argentina

INTRODUCTION

Essential medicines are the ones that satisfy the sanitary needs of most of the population. For this reason they should always be available in quantity, form and attainable price. Since 1977 WHO has made a Model List of Essential Drugs for a basic health care system, listing the most efficacious, safe and cost-effective medicines for priority conditions. 5% Chlorhexidine solution, 70% ethanol solution and 10% povidone iodine solution are included in the antiseptics section of this list (14th Edition, revised march 2005)^[1].

10% povidone-iodine solution is proved to be the antiseptic of current use in Public Health Services. An antiseptic is a type of disinfectant, which destroys or inhibits the growth of micro-organisms on living tissues without causing injurious effects when applied to surfaces of the body or to exposed tissues^[2]. Some antiseptics are applied to the unbroken skin or mucous membranes, to burns and to open wounds to prevent sepsis by removing or excluding microbes from these areas. Iodine has been modified to be used as an antiseptic.

Povidone iodine is the iodophore mostly used. Iodosphoros are compounds that consist of iodine and a carrier such as povidone. This combination increases iodine solubility and provides a iodine reservoir of long-lasting release. The term free iodine means the amount of iodine in the solution, while available iodine indicates that the product is free from iodine reservoir. Free iodine concentration is the greatest chemical and microbiological factor in iodophore activity. A povidone iodine solution 10% contains available iodine and releases (free iodine) to level at an equilibrium of approximately 1 ppm (part per million)^[3]. Free iodine levels are recommended for 1 to 2 mg L⁻¹ antiseptics. The antimicrobial iodophore effect is similar to that of iodine and they result from the cellular wall penetration, oxidation and substitution of microbial content with free iodine.

FDA includes iodine povidone in category II^[4]. Class II category for human and biological drugs is given in case of use, or exposure to a product of restrictive use which may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is

remote. Povidone iodine solution is effective against bacteria, fungi, viruses, protozoa, cysts and spores and reduces surgical wound infections significantly. The solution of povidone-iodine releases iodine in contact with the skin. The application of povidone iodine solution depends on the use to be given to the product. In the case of pre- and post-operating skin disinfection, it must be applied undiluted whereas as an antiseptic it could be applied twice a day for minor wounds and burns. It can cause adverse effects like irritation of skin and mucous membranes. It may interfere with thyroid function tests and systemic effects. Precautions must be taken in pregnancy, breastfeeding, broken skin, renal impairment.

As counter effects, regular or long lasting use should be avoided in patients with thyroid disorders, in those taking lithium and in neonates. Minimum quantities of this solution should be administered in case of very low birthweight infants. The application of povidone-iodine to large wounds or severe burns may produce systemic adverse effects such as metabolic acidosis, hypernatraemia and impairment of renal function.

Povidone iodine is a 2-pyrrolidinone-1-ethenyl homopolymer compound with iodine. It contains no less than 9.0% and no more than 12.0% of available iodine^[5]. It is a water and alcohol soluble compound and practically non soluble in chloroform.

MATERIALS AND METHODS

Reagents and apparatus:

- 0.0211 N Sodium thiosulfate standardized with potassium dichromate.
- Starch paste solution (1% in distilled water).
- Distilled Water.
- Titrimetry equipment: burette, erlenmeyer flask and glass accessories.

Method: Six samples of povidone iodine solution 10% collected from Public Health Services of the province of Tucumán in the NW of Argentina were analysed.

The method recommended by the USP^[6] redox titration with sodium thiosulfate was used for the labelling of iodine present in povidone iodine solution.

5 mL of povidone iodine solution 10% (equivalent to 50 mg of iodine) were placed in a 100 mL erlenmeyer flask. Distilled water was added until a total volume of 30 mL was reached. 1 mL of 0.1 N chloridric acid was added and it was standardized with 0.0211N sodium thiosulphate solution, adding 3 mL of starch paste solution as an indicator until the end point was reached.

Table 1: Iodine percent (w/v) determined in povidone iodine solutions from six health services of tucumán, Argentina

Sample No./Health service	Sodium thiosulfate vol. (mL)	Iodine weight (mg)	Iodine % (w/v)
Nº 1/La cocha hospital	18.04	48.34	0.9668
Nº 2/Concepción hospital	15.64	41.91	0.8382
Nº 3/Monteros hospital	17.50	46.89	0.9379
Nº 4/Simoca hospital	14.42	38.64	0.7728
Nº 5/Mutual aid association of the province	7.54	20.20	0.4041
Nº 6/Children hospital of tucumán	17.64	47.27	0.9454

Five determinations in each sample were carried out considering as the end value the corresponding average.

For the % iodine calculations the following expression was used:

$$\% w/v \text{ iodine} = t \cdot N \cdot \text{meq.} \frac{100}{v} \quad (1)$$

where:

% w/v iodine= percent (weigh/ volume) of iodine present.

t = 0.0211 N sodium thiosulfate volume.

N = sodium thiosulfate Normality (0.0211 N).

v = sample volume = 5 mL.

RESULTS AND DISCUSSION

The results obtained were indicated in Table 1.

According to USP (XXII Ed.) povidone iodine solutions 10% must contain between 85-120% of iodine. The results in Table 1 shows that three of the samples analyzed are outside the range allowed. These samples (number 2, 4 and 5) correspond both to the interior of the province and to the capital.

CONCLUSIÓN

It is posible to conclude that 50% of the institutions under quality control of povidone iodine solution normally used as antiseptic to clean surgical areas, do not perform in agreement with USP. It is extremly important for such solutions to fulfil their antiseptic effects efficiently to contain the levels of iodine required.

This research intends to carry out a periodical control of povidone iodine solutions. Thus, a simple and low cost method which allows to trace the quality control of the product used is suggested.

It was observed that the product was not kept outside the scope of light and in dark flasks in the different institutions. A strict fulfillment of storage and conservation conditions of povidone iodine solution is suggested to avoid postoperating infections and the consequent re-hospitalization of the patient.

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