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Quality Assessment of Selected Marketed Povidone Iodine 10% Antiseptic Solution Products in Iraq

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Abstract
Povidone iodine solution 10% is widely used as an antiseptic in Iraq. 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 iodine in povidone iodine 10% marketed products which were obtained from several community pharmacies in Iraq. Iodine content present in all the solutions was determined by means of the redox titrimetric method using a standardized solution of sodium thiosulphate. The results obtained show that all of the samples evaluated are within the iodine concentration range required except Riodine whose content of iodine equal 83.5% [limit 85-120% of the labelled claim]. This research intends to carry out the quality control of the solutions under the assessment and to implement the means for their conservation in proper conditions to guarantee their disinfecting power.

Keywords: povidone iodine solutions, quality control, antiseptic solution

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 [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 adverse effects when applied to surfaces of the body or to exposed tissues Some antiseptics are applied to the unbroken skin or mucous membranes, to burn and to open wounds to prevent sepsis by removing or excluding microbes from these areas. Povidone iodine is the iodophor mostly used. Iodophors 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 ionosphere activity. Povidone iodine solution is effective against bacteria, fungi, viruses, protozoa, cysts and spores and reduces surgical walled 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 [2].

Materials and Methods
Materials
Sodium thiosulfate and starch was supplied by Al-Zahrawi University College, Karbala, Iraq.

Preparation of 0.1N of sodium thiosulfate
(2.482g) of pure sodium thiosulfate was dissolved in 100ml beaker with 50ml of distilled water with stirring the solution then transferred to 1L volumetric flask and the volume was completed with distilled water to the mark.

Starch solution preparation
To prepare starch indicator solution added 1g of starch into 10ml of distilled water, shake well and poured into 100ml of boiling water, stirred and left to cool down.

Marketed products
Riodine antiseptic solution, Orin Laboratories Pty Ltd. Australia
Povidone iodine disinfectant solution, Iraq
Poviofix antiseptic solution, Naturel Medikal Ilac Sanayi Ve Ticaret limited Sirketi, Turkey
Povidone iodine 10% dermal solution, Juman, Amman, Jordan.

Reagents
- 0.1 N Sodium thiosulfate standardized
- Starch paste solution (1% in distilled water).
- Distilled Water.

Evaluation tests for the selected products
Determination of pH of all selected marketed products
The pH measurement should be within the range (1.5 -6) according to USP [3].

Assay
Four samples of povidone iodine solution 10% collected from community pharmacies. The method recommended by the USP [3] 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 conical flask. Distilled

water was added until a total volume of 30 mL was reached. Titrated with 0.l N sodium thiosulphate solution, Percent of iodine was determined as each 1 ml of 0.l N sodium thiosulphate is equivalent to 12.69 mg of iodine [3].

Results and Discussion

According to USP povidone iodine solutions 10% must contain between 85-120% of the labelled claim. The results in Table 1 shows that one of the samples analyzed is outside the range allowed. 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. It is a water and alcohol soluble compound and practically non-soluble in chloroform [4]. The results obtained were indicated in Table 1.

Table 1: Physical and chemical properties of povidone iodine products

	Riodine	**Poviofix**	**Povidone iodine, Juman**	**Povidone iodine, Iraq**
Appearance	Clear brown solution	Clear brown solution	Clear brown solution	Clear brown solution
Odour	Characteristic	Characteristic	Characteristic	Characteristic
pH	2.4	4.9	5.3	4.2
Assay	83.5%	99%	91.4%	88.8%

Conclusion

It is possible to conclude that all the tested products complied to USP requirements except Riodine Antiseptic solution which showed 83.5% 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 extremely 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 selected marketed products in Iraq product

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