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Research Article

Assessment of the Physico-Chemical Conformity of an Antiseptic Solution: Case of Polyvidone - Iodine 10%

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Abstract

Introduction: Antiseptics have been used for many years in human and veterinary medicine. Over the years, the lengthening of surgical procedures in human surgery and the increasingly frequent use of inert material has increased the risk of infections. This was why skin antisepsis has become very important in the prevention of infections of the surgical wound and resulting complications. In Mali, at the Gabriel Touré University Hospital, the most prescribed family of antiseptics was the halogenated ones, in particular 10% povidone iodine for wound and surgical site antisepsis. This study was aimed to control the quality of 10% povidone iodine used in the hospital. **Methodology**: We conducted at the Medicines Quality Control Service of the National Health Laboratory of Mali (LNS) a retrospective analytical study on the quality control of 10% povidone iodine. We obtained 10% povidone iodine samples from the *Pharmacie Populaire du Mali (PPM).* We analyzed 48 batches of samples in regards of visual inspection, average volume, titrimetry, colorimetric test and pH control. **Results:** All 48 analyzed batches were compliant, i.e. contained the active ingredient and could be used in health facilities or at home as an antiseptic. **Conclusion**: All analyzed batches of 10% povidone iodine samples did not show any cases of inconsistency and therefore could be used in the management of wound dressings. **Future Direction:** Use other analytical methods like HPLC to test the quality control of povidone and other types of antiseptics.

Keywords: antiseptic, povidone-iodine 10%, compliance, quality control

I. INTRODUCTION

Historically, the fight against infectious diseases has held an important place. Long before the word antiseptic was used, many substances were used to avoid the risk of contamination[1]. An antiseptic is a product intended to destroy micro-organisms present on living tissues (healthy skin, mucous membranes, wounds) used under defined conditions[2]. Povidone-Iodine is an antiseptic whose active ingredient is based on iodine, intended to be applied to the skin.

It contains 80–120% of the amount of iodine labeled on the bottle and may contain a small amount of alcohol[3]. The application of povidone iodine has very quickly been extended to various fields, in particular in several products of our daily life. As a result, the question of its safety in humans has been raised, as well as the risks of allergy associated with the use of povidone iodine[4]. In the strategy of asepsis, antiseptics and disinfectants retain a prominent place despite the advent of antibiotics in medicine, particularly in surgery, has led to a revolution in therapy, somewhat masking the interest of antiseptics[5].

Known under the name of BETADINE®, it is used in the surgical field, for the antisepsis of the skin, wounds, minor superficial burns and as adjunctive treatment of infections of the skin and mucous membranes. It is a yellow to brown aqueous solution with an alcoholic odor. The quality of this molecule is important because its non-compliance could eitherlead to infections (case of use of the product after its expiration date) and/or lengthen the duration of treatment (case of sub dosage). In SINGAPORE, tests have demonstrated the strong in vitro virucidal activity of BETADINE®, which eliminated 99.99% of SARS-cov-2 viral particles in 30 seconds. The products subjected to this test were BETADINE® antiseptic products based on Povidone Iodine (PVP-I), in particular in solution (10% PVP-I)[6].

Antiseptics including povidone iodine act locally by denaturing proteins, blocking metabolism or by altering the membranes of micro-organisms. Correct prescription and application of constantly monitored antiseptics can improve both the quantitative and qualitative management of the surgery patients[5]. CAMARA Issaka has reported in 2005 that povidone iodine has represented 20% of non-compliant drugs in all of the drugs received from the PPM[7]. We initiated this

retrospective study to evaluate the physico-chemical conformity of the Povidone-Iodine solution received at the Quality Control Service of Medicines of the National Laboratory of health.

II. MATERIAL AND METHODS

1. Study framework and duration

We carried out a retrospective study at the Medicines Quality Control Department from September 28 to December 28, 2020, i.e. three months to analyze the conformity of polyvidones iodines.

2. Material

We used glassware, a midon, 1N and 0.1 M hydrochloric acid, powdered sodium thiosulfate and 0.02 M, powdered sodium carbonate, Mettler toledo brand pH meter, and 1EL- automatic titrator 18-440.

3. Sampling

The samples analyzed came from the *Pharmacie Populaire du Mali* in Bamako. There were forty-eight (48) batches of five (5) bottles of Povidone Iodine 10%, W/V, received between May and June 2020. We followed the protocol approved by the British Pharmacopoeia (BP), 2019 volume III, 85 to analyze our samples,

4. Methods

The various analyzes focused on:

4.1. Organoleptic test and visual examination:

It consisted in carrying out an organoleptic examination of the samples through sight, touch and smell to ensure that they meet the determined quality specifications.

- For labeling: we made sure that the packaging met the standards of Good Manufacturing Practice (GMP). We checked that the following information appeared on the packaging: name of the product, name of the active ingredient, the quantity of the active ingredient contained in a bottle, batch number assigned by the manufacturer, date of manufacture and expiration date of the product, name and manufacturer's address.
- Organoleptic test consisted of determining: appearance, color and smell.

4.2. Visual examination:

It allowed us to check if the quantity (mL) marked on the packaging is the same as the capacity in the bottle. The capacity is poured into a 500 mL graduated cylinder. It is carried out to control the quantity decreed by the manufacturer if it fulfilled the average volume marked on the packaging [3].

4.3. pH:

It was performed on the samples to determine the acidity, alkalinity or neutrality of an aqueous solution.

4.4. Color test

The Colorimetric Test identified the active ingredient in the samples. Our case was the identification of iodine.

Average volume Vm = The average volume makes it possible to check whether the quantity (mL) marked on the packaging is the same as the capacity in the bottle. The capacity was poured into a 500 mL graduated cylinder. It was carried out to control the quantity decreed by the manufacturer if it met the average volume marked on the packaging[3].

$$Vm = \frac{(flc1 + flc2 \ldots . + flcn)}{n}$$

N/B: n= number of vials and Vm= average volume

4.5. Titrimetric test [8]

Titration is a chemical method which makes it possible to control the quantity of the active principle present in a solution. In our case, each mL of 0.02 M sodium thiosulfate was equivalent to 2.538 mg of iodine, the standard was given in the protocol.

- By reduction of iodate with sulphite/sulphur dioxide:

$2H+ + 2IO_3^- + 5HSO_3^- \rightarrow I_2 + 5HSO_4^- + H_2O$

- By introducing chlorine into an iodide solution:

$_+ 2I^- \rightarrow I_2 + 2Cl^-$

Figure 1: Oxidation/reduction equation by titration with sodium thiosulfate.

III.RESULTS AND DISCUSSION

The results obtained are recorded in the tables below.

3.1. Visual and organoleptic inspection

The analysis of the different vials made it possible to have results distributed in Table I.

Table I: Determination of visual and organoleptic inspection of samples

Designations	Attendance
Product Name	Povidone-Iodine
Name and amount of active ingredient	Povidone-Iodine 10% W/V
Expiration date/ Date of manufacture	Yes
Manufacturer's name and address	Yes
Aspect	Plastic yellow bottle
Solution color	brown yellow
Smell	alcoholic

The visual and organoleptic examinations met the standards of good manufacturing practice (GMP) (Table I). All batches of samples were all compliant, our results were similar to those obtained by BARBACHE Roumeila, et al, 2020[9] and CHABLA Younes et al, 2018[10] in Algeria. They have all reported that all the information was mentioned on either the packaging or the bottle.

3.2. Determination of average volume and pH

The values obtained from the batches are recorded in Table II.

This was to check the marked amount of PVI on the package. Povidone Iodine has an acid pH, it was a matter of determining the pH for the 48 batches to be analyzed.

Table II: Distribution of the average volume and the pH according to the batch number of povidone10%.

Batch number	Average volume ((mL)	pH value
200425	207.5	4.37
200426	207.5	4.70
200427	207.5	4.56
200428	207.5	4.70
200429	207.5	4.35
200430	207.5	4.42
200431	207.5	4.14
200432	210	4.59
200633	210	4.325
200634	210	4,254
200635	210	4,305
200636	210	4,316
200637	210	4,107
200638	210	4,515
200639	210	4,269
200640	207.5	4,318
200641	207.5	4,137
200642	210	4,236
200643	207.5	4,055
200644	207.5	4,316
200645	207.5	4,070
200646	207.5	4,062
200647	207.5	4,514
200648	207.5	4,167
200425	207.5	4.37
200426	207.5	4.70
200427	207.5	4.56
200428	207.5	4.70
200429	207.5	4.35
200430	207.5	4.42
200431	207.5	4.14
200432	210	4.59
200633	210	4.325
200634	210	4,254
200635	210	4,305
200636	210	4,316
200637	210	4,107
200638	210	4,515
200639	210	4,269
200640	207.5	4,318
200641	207.5	4,137
200642	210	4,236
200643	207.5	4,055
200644	207.5	4,316
200645	207.5	4,070
200646	207.5	4,062
200647	207.5	4,514
200648	207.5	4,167

The determination of the average volume (Vm) showed that all the analyzed batches of samples corresponded to the quantity indicated on the packaging (200 mL) in compliance with the 2019 British Pharmacopoeia.

The pH analysis of different batches of samples showed that they were all compliant. The pH values obtained ranged from 3 to 6.5, therefore meeting the standards required by the 2019 British Pharmacopoeia. Our results were similar to those of a study carried out by ARBACHE Roumeila, et al, 2020 [9] on the physico-chemical control of antiseptic preparations, showed that three batches of povidone iodine were compliant with the pH requirement. It seemed that the pH of antiseptics was variable depending on the active ingredient and the excipients that went into its formulation. According to the study carried out by CHABLA Younes, et al; 2018 of a solution of Dakin's antiseptic have reported that the pH of these batches of dakin was basic and between 8.61 and 10.98[10].

3.3. Determination of the active ingredient by titration

Table III shows the different percentages of iodine contained in each vial. This determination will highlight the amount of iodine (or active ingredient) present in each vial of analyzed batches.

Table III: Determination of percentage of iodine according to batches analyzed

Batch number	Iodine percentage (%)
20041	1.11
20042	1.1002
20043	1.08
20044	1.03
20045	1.012
20046	1.05
20047	1.10
20048	1.10
20049	1.07
200410	1.04
200411	1.01
200412	1.05
200413	1.00
200414	1.05
200415	1.07
200416	1.05
200417	1.06
200418	1.05
200419	1.04
200420	1.02
200421	1.04
200422	1.11
200423	1.06
200424	0.98
200425	0.99
200426	0.94
200427	0.99
200428	0.97
200429	0.96
200430	1.05
200431	1.01
200432	1.01
200633	1,058
200634	1,073
200635	1,106
200636	1,101
200637	1.027
200638	1,022
200639	1,121
200640	1,053
200641	1.015
200642	1,081
200643	1,068
200644	1.109
200645	1,109
200646	1,053
200647	1,121
200648	1,078

Observation of Table III shows us that all the samples met the standards laid down by the 2019 British Pharmacopoeia. In each 100 mL solution of Povidone-Iodine, a value of between 0.85 and 1.20% Iodine was required. ARBACHE Roumeila, *et al* , 2020[9] on the physico-chemical control of antiseptic preparations, showed the iodine content was close to 1.07%. They have reported that two (2) batches were compliant, one (1) batch was overdosed and the three (3) others were under dosed.

3.4. Colorimetric test

According to the pharmacopoeia, the presence of iodine as an active ingredient is characterized by a dark blue color at the color change. All our batches of povidones tested by colorimetry were compliant with the appearance of a deep blue color, which confirmed the presence of iodine as an active ingredient.

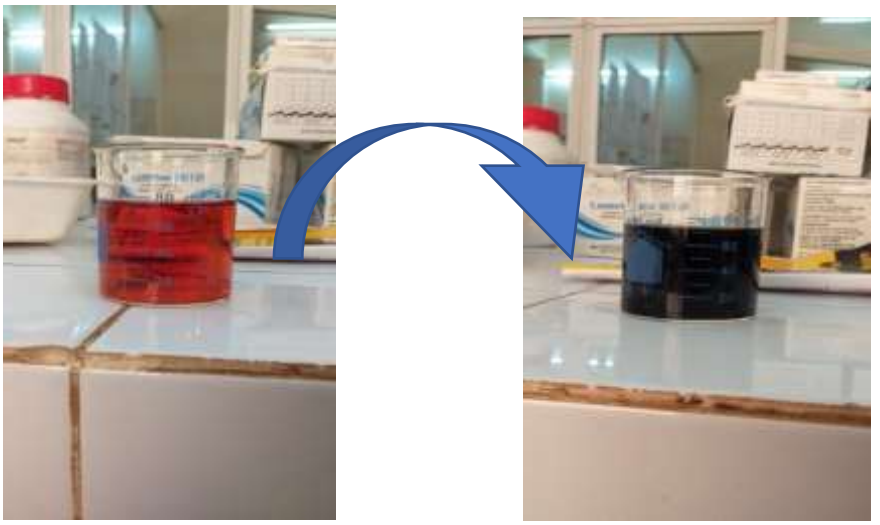

Figure 2: Color change with the addition of water in the presence of starch as a color indicator (photo LNS, 2021).

The quality of antiseptics was of utmost importance because a poor quality antiseptic is ineffective even if used correctly and regularly. All our sample batches of iodinated povidones analyzed at the SCQM of the LNS complied with the various analytical processes that we carried out (visual inspection, average volume, titrimetry, colorimetric test, pH).

IV. CONCLUSION

The objective of our study was to evaluate the physico-chemical quality of Povidone-Iodine 10% W/V used in sanitary environments in Mali. All 48 samples of Povidone-Iodine received and analyzed were suitable for use in surgical operations and in dressings. All values obtained met the standards according to the 2019 British Pharmacopoeia. In the future, we will carry out more in-depth studies to better clarify or explain the quality of Povidone-Iodine 10%.

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Conflicts of Interest: None, it was within the framework of public health and for the well-being of the Malian population

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