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Research Article

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Synthesis and Physico-chemical Control of an Antiseptic Raw Material Used as Solution for Ophthalmic Washing

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Abstract In pharmaceutical industry, Boric Acid is used as an antiseptic active ingredient and it's marketed in combination with Borax, in form of solution for ophthalmic washing with local antiseptic action and light astringent, indicated mainly in case of eye irritation. We synthesized this active pharmaceutical ingredient in Therapeutic Chemistry laboratory of pharmacy department of Sidi Bel-Abbes and the yield obtained is 59.10 %. The physicochemical quality control of the synthesized Boric Acid is carried out according to the requirements of the European Pharmacopoeia 8th edition. It would be very interesting to introduce this work as a practical work of Therapeutic Chemistry module for the third-year pharmacy students and residents of Therapeutic Chemistry in post-graduate.

Keywords Boric Acid, Antiseptic, Active Ingredient, European Pharmacopoeia

1. Introduction

Boric Acid is used as an antimicrobial preservative and is used as a buffering agent to control the pH. Additionally, it can have the function of tonicity-adjusting agent [1]. In pharmaceutical industry, it's used as an antiseptic active pharmaceutical ingredient and it's marketed in combination with Borax, in form of solution for ophthalmic washing with local antiseptic action and light astringent, indicated mainly in case of eye irritation [2]. Boric acid and its salts of disodium tetraborate anhydrous, disodium tetraborate pentahydrate and disodium tetraborate decahydrate are not classified as skin irritants. They are neither skin nor respiratory sensitisers [3]. Several local adverse reactions (e.g. pruritus, dermatis) with boric acid medicine, has been reported in the WHO ADR data base Therefore there is no reprotoxic effect reported. There are several epidemiological studies in workers. Boron exposure data were measured in workplace and in biological samples [4], the Scientific Committee on consumer Safety conclude that the design of such studies are insufficient to demonstrate an effect or an absence of effect on fertility [4].

In this article, we synthesize the Boric Acid as an active pharmaceutical ingredient and we control its physicochemical quality according to the requirements of the European Pharmacopoeia 8th edition.

2. Materials and Methods

2.1. Synthesis of Boric Acid

In a 250 ml Erlenmeyer flask, hot-dissolved on hot plate and in a minimum of water, 20 g of borax and few drops of helianthine were added. To the hot solution obtained, 32% hydrochloric acid was added by burette, while stirring until the color indicator turned and the boric acid then precipitated. Cooling of Erlenmeyer flask for 15 minutes in ambient air and then in ice bath, when the temperature reaches 10 °C, filtration was carried out and finally, recrystallization in water and drying in the oven set to 50 °C [5].

2.2. Quality Control of Synthesized Boric Acid

The control of the synthesized Boric Acid is carried out according to the requirements of the European Pharmacopoeia 8th edition [6].

2.2.1. Organoleptic characteristics and solubility

We checked the appearance and odor of the synthesized Boric Acid, as well as its solubility in water and in ethanol 96% according to the requirements of the European Pharmacopoeia [6].

2.2.2. Melting point measurement

The melting point is a specific physical character of each solid substance; it plays an important role for its identification. The measurement was made using a device called: Köfler bench.

2.2.3. Characterization by chemical processes

0.1 g of boric acid was dissolved in 5 ml in methanol while warming slightly. 0.1 ml of sulfuric acid was added and finally the solution was inflamed. If boric acid is present, the solution burns, giving flame bordered in green color [6].

2.2.4. Dosage of boric acid by titration

1 g of boric acid was dissolved and heated in 100 ml of water containing 15 g of Mannitol; the obtained solution was titrated with sodium hydroxide solution 1M with burette in the presence of 0.5 ml of phenophthalein [6].

3. Results and Discussion

3.1. Synthesis of Boric Acid

The different steps of Boric Acid synthesis are illustrated in Figure 1 and 2.

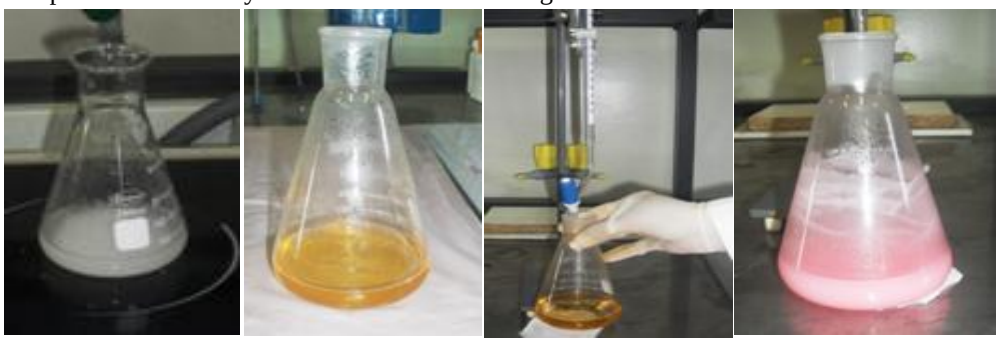

Figure 1: Dissolution, indicator turn and precipitation of boric acid

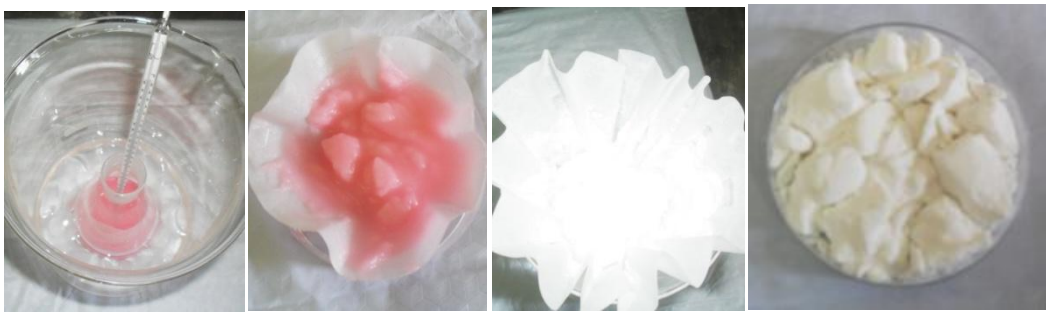

Figure 2: Cooling, filtration, recrystallization and drying

The calculated synthesis yield of Boric Acid is 59.10 %.

3.2. Quality Control of Synthesized Boric Acid

3.2.1. Organoleptic characteristics and solubility

Appearance: the synthesized boric acid is a substantially white powder, unctuous to the touch (figure 3).

Solubility: the solubility test showed that the synthesized boric acid is insoluble in water and soluble in ethanol at 96%.

Figure 3:. Organoleptic characteristics of boric acid

3.2.2. Melting point measurement

Measurement of the melting point revealed an average value of 170 °C, a value included in the range (169 °C and 171 °C) required by the European Pharmacopoeia.

3.2.3. Characterization by chemical processes

The solution burns by giving a flame lined in green. According to the European Pharmacopoeia, this test confirms the presence of boric acid (figure 4).

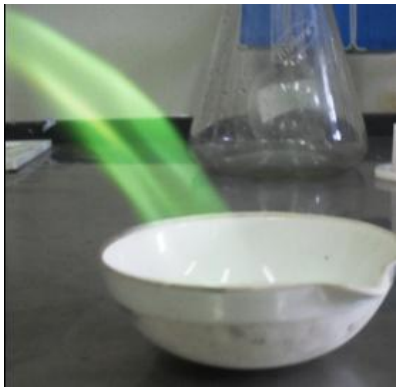

Figure 4: Identification reaction of boric acid

3.2.4. Dosage of boric acid by titration

At the point of equivalence, the volume of NaOH solution 1M required for the neutralization of 1 g of boric acid is 16.2 ml. According to the European Pharmacopoeia, 1ml of sodium hydroxide 1 M corresponds to 61.8 mg of boric acid, so after calculations, the boric acid titrate is 100.11%, value in accordance with the standards required by the European Pharmacopoeia [99%-100.5%].

4. Conclusion

The boric acid was synthesized and the calculated synthesis yield obtained is 59.10 %. The physicochemical quality control of the synthesized boric acid is carried out according to the requirements of the European Pharmacopoeia 8th edition. As prospects, it would be very interesting to introduce this work as a practical work of Therapeutic Chemistry module for the third-year pharmacy students and residents of therapeutic chemistry in post-graduate.

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