Technical Information

POVIDONE IODINE USP

Povidone-Iodine USP - Disinfectants

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Povidone-Iodine USP

Contents

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Introduction

Povidone-Iodine USP

Iodine was formerly used in the form of iodine tincture or Lugol's solution for disinfecting minor wounds.

Despite its good efficacy there were obstacles to its broad use because these two formulations triggered a number of side effects such as strong irritation, allergies etc.

Povidone iodine was first reported in the early 1950s.

This compound is a complex of polyvinyl pyrrolidone and iodine.
[1] showed that the solid product probably has the following.
structure (Fig. 1):

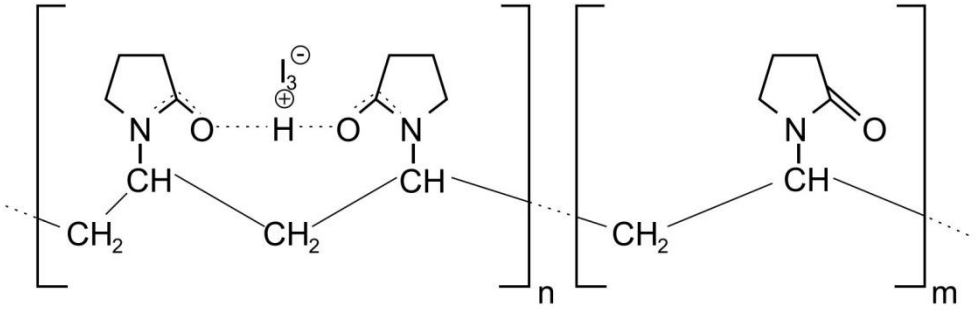

Fig. 1: Chemical structure of Povidone iodine (n : m = 1 : 18)

In connection with the structure and the methods of determination it seems important to explain some terms.

Available iodine = iodine that can be titrated with sodium thiosulphate
Total iodine = iodide + titratable iodine
Free iodine = non-complexed iodine that can be determined in a dialysis test [3]
= iodine that can be extracted with heptane from an aqueous Povidone iodine solution of defined concentration
= free iodine that can be determined in an electrochemical model [2]
Iodide = Iodide concentration required to form an iodine complex

An interesting and important factor in this context is the dependence of the concentration of free iodine on the concentration of Povidone iodine or available iodine, as shown in Fig. 2. Looking at this curve, two facts about the commonly used concentrations of Povidone iodine preparations (1 – 10% Povidone iodine = 1 – 10 g available iodine/l) stand out:

1. The free iodine content is extremely low at 1 – 8 ppm
2. The free iodine content is inversely proportional to the concentration of Povidone iodine or available iodine.

Tests on micro-organisms have shown that the rate of microbicidal action is proportional to the free iodine content.

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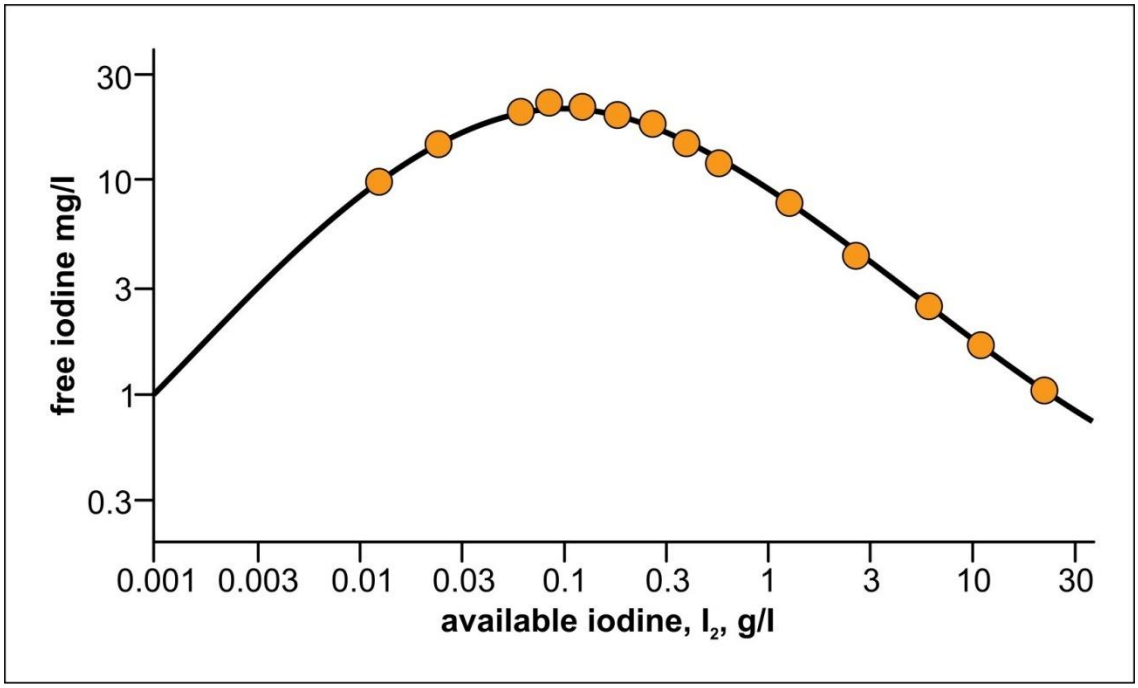

Fig. 2 Relationship between the free iodine concentration and the concentration of available iodine in aqueous solution..

Specifications

	Povidone iodine
Identity	Corresponds
Available iodine	9.0 – 12.0%
Iodide	≤ 6.0%
pH (10% in water)	1.5 – 5.0
Nitrogen	9.5 – 11.5%
Heavy metals	≤ 10.0 ppm
Losses on drying	≤ 8.0%
Ash	≤ 0.1%

The methods can be found in the current monographs “Povidone, iodinated” (Ph. Eur.) or “Povidone-Iodine” (USP). The particle size of Povidone iodine k30 is determined in a dispersion in heptane in the Malvern Mastersizer.

Regulatory status

Products meet current Povidone, iodinated Ph. Eur. and Povidone-Iodine USP monographs.

Production

For the production of the Povidone iodine k30 a Povidone K 30 is used that meets the requirements of the corresponding pharmacopoeia in accordance with the above Ph. Eur. monograph. The figure “30” in the Povidone iodine k30 nomenclature indicates the K value and thus the molecular weight of the povidone used

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Properties

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Description

Povidone iodine k30 is a brown, free-flowing powder. Micronisation of Povidone iodine k30 causes the color to change from pale brown to orange, as can be seen from the photograph opposite.

Solubility

Soluble in	Water
	Ethanol
	Propanol
Insoluble in	Acetone
	Chloroform
	Methylene chloride
	Heptane
	Hexane

Viscosity

	Water	Ethanol
5%	2	2
10%	7	5
20%	230	20

These guide values are based on measurements at 25 °C and are given in mPa · s.

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Stability

Povidone-Iodine K30 remain stable for 36 months in unopened containers at temperatures below 25 °C.

The following rapid test, corresponding to storage for about 15 months at room temperature, is suitable for easy and fast assessment of the stability of Povidone-Iodine K30 in aqueous preparations. It can be used for assessing the stability of Povidone-Iodine K30 from different sources and for preparing new formulations.

A Povidone-Iodine K30 solution containing 1% available iodine is produced. This solution is stored in a sealed glass flask for 14 days at 52 °C or 15 hours at 80 °C. The available iodine content is determined and the iodine loss calculated before and after storage.

An indication of stability is incorporated in the product name Povidone-Iodine K30. The figure "06" indicates that the iodine loss in the above stress test does not exceed 6%.

One of the above stress tests was employed to predict the stability of practically all aqueous formulations that have been developed in the **septapharma kimya** laboratory. These tests are also highly suitable for predicting the compatibility of Povidone iodine with different excipients and packaging materials. Fig. 3 shows by way of example the result of testing the compatibility of aqueous Povidone iodine solutions with glass and two high- and low-density .polyethylene grades using one of these stress tests

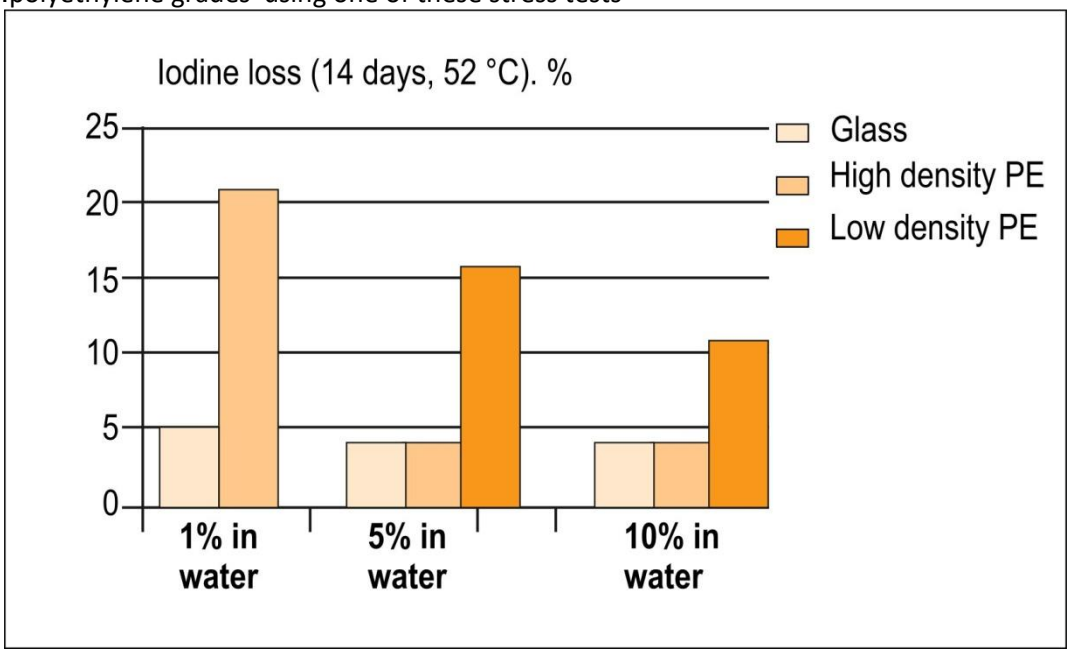

Fig. 3: Influence of the packaging material on the stability of povidone iodine solution

Incompatibilities

Povidone iodine is not stable in combination with reducing agents and many surfactants. Even some other excipients or their impurities like rests of solvents (e.g. Acetone) can impair the stability of povidone Iodine preparations. Furthermore, a pH above 5 has a marked adverse effect on the stability of a formulation (see Fig. 4).

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Supplementary analytical methods

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K value

The average molecular weight of the povidone contained in povidone iodine can be indicated by the K value. It is determined in accordance with the Ph. Eur. monograph “Povidones”, but to measure the relative viscosity the solution must be decolourised before being adjusted to a concentration of 1% povidone by adding a 25% solution of sodium thiosulphate.

Free iodine (dialysis)

Determination is carried out e. g. in a Dianorm dialysis machine as shown on page 9.

The dialysis cells are filled by means of automatic pipettes with 2.00 ml Povidone iodine solution on one side and water on the other side. The membrane between the two sides consists of HDPE (e. g. Lupolen 1804 H) with a thickness of 50 – 70 µm. The dialysis time at a speed of 20 rpm is about 5 hours for normal aqueous Povidone iodine solutions.

0.25 ml of a 10% potassium iodide solution are placed in the measuring cells. 1.00 ml is taken from the water side of the dialysis cells and added quickly to the potassium iodide solution. After brief shaking the absorption is measured at 351 nm against a mixture of 0.25 ml potassium iodide solution and 1.00 ml water. The free iodine content is calculated by the following equation:

$$\text{Free iodine (ppm)} = \frac{\text{Absorption x } 316.25}{\text{Cell diameter x } 25}$$

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Application

General points

Povidone iodine is noted for its wide range of uses. Its major applications are in the field of prophylaxis:

– skin and mucous membrane antisepsis
– surgical and hygienic hand disinfection
and in the field of **treatment**:

– treatment of burns, decubitus and varicose ulcers
– use in the treatment of dermatomycosis, pyoderma and acne
– use in the treatment of vaginitis

The advantage of Povidone iodine is that it can be incorporated in a wide range of formulations.

pH

Povidone iodine is used primarily in ovules, vaginal tablets and powder sprays. The pH of the Povidone iodine preparation can be of great importance for its stability. As Fig. 4 shows, a pH of about 4.5 for aqueous solutions is a good compromise between good skin compatibility and acceptable stability.

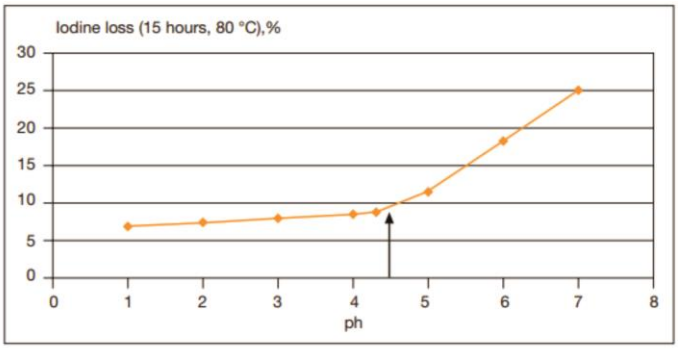

Fig. 4: Influence of the pH on the stability of Povidone iodine solutions

Concentration of Povidone iodine

The concentration of Povidone iodine in the preparation also has an influence on its stability. Fig. 5 shows why the commonly used concentrations are therefore never below 1% Povidone iodine. At lower values stability is too poor.

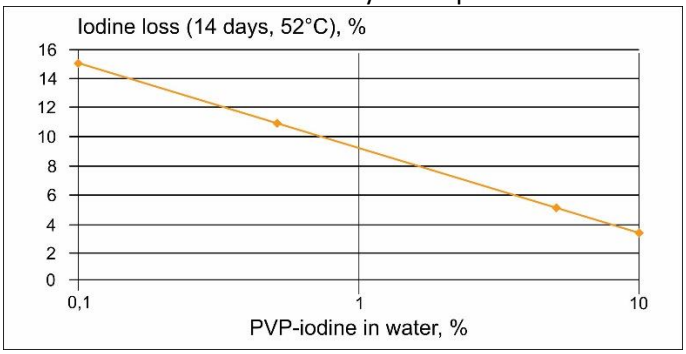

Fig. 5: Influence of the concentration on the stability of Povidone iodine solution

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Packaging

Povidone iodine:
25 kg PE lidded drum with PE inner bag
100 kg PE lidded drum with PE inner bag

NOT

Homogenization of the product is recommended prior to sampling or partial removal of the Povidone iodine powder from an individual drum,

Stability

Povidone iodine:
At room temperature the retest period for this product is 36 months when stored in unopened original containers.

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Safety data sheet Safety data sheets are available on request and are sent with every consignment

company information

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