



AGOG Pharma Ltd.

(WHO - GMP CERTIFIED - GOVT RECOGNISED EXPORT HOUSE)



Regd. Office & Factory : Plot No. 33, Sector II, The Vasai Taluka Industrial Co-op. Estate Ltd. Gauraipada, Vasai (E), Dist. Thane - 401 208, INDIA.
Tel. : 95250 - 2455801 / 2452714 / 2453525 • Fax : 95250 - 2452074 (0091 - 250 - 2452074) • Email : agoq@vsnl.net & agoqpharma@rediffmail.com

Brand Name : AGODINE-TS Generic Name : (Povidone - Iodine Tropical Solution USP 10% W/V)	2021
Module 1 1.5	Administrative Information and Product Information Product Information
	Confidential

1.5 PRODUCT INFORMATION

1.5.1 Prescribing Information (Summary of Products Characteristics)

1. NAME OF DRUG PRODUCT

1. Name of drug product

Povidone - Iodine Tropical Solution USP 10% W/V

1.1 (Trade) name of product

AGODINE-TS

1.2 Strength

Povidone - Iodine USP 10% W/V

1.3 Pharmaceutical Dosage Form

Semi-Solid dosage form



2. QUALITATIVE AND QUANTITATIVE COMPOSITIONS

2.1 Qualitative Declaration

Povidone - Iodine Tropical Solution USP 10% W/V

2.2 Quantitative Declaration

Ingredients	Specification	Label Claim	Overages	Qty. / unit (ml.)
<u>ACTIVE</u>				
Povidone Iodine	USP	10 % w/v	15.00 %	13.800 g
<u>NON ACTIVE</u>				
Citric acid (anhydrous)	BP	-	-	480.000 mg
Di sodium hydrogen ortho phosphate (anhydrous)	BP	-	-	1.754 g
Potassium iodate	BP	-	-	180.000 mg
Sodium lauryl sulphate	BP	-	-	150.000 mg
Peg-400	BP	-	-	150.000 mg

BP = British Pharmacopoeia.

USP = United State Pharmacopoeia.



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3. PHARMACEUTICAL DOSAGE FORM

Amber colour PET Bottle of 120 ml.
Dark brown coloured, clear, uniform solution.



AQOQ Pharma Ltd.

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CIN: 11-09615

Regd. Office & Factory : Plot No. 33, Sector II, The Vasai Taluka Industrial Co-op. Estate Ltd. Gaurapada, Vasai (E), Dist. Thane - 401 208, INDIA.
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4. CLINICAL PARTICULARS

Povidone – Iodine

Povidone-iodine is a broad spectrum antiseptic for topical application in the treatment and prevention of wound infection. It may be used in first aid for minor cuts, grazes, burns, abrasions and blisters. Povidone-iodine exhibits longer lasting antiseptic effects than tincture of iodine, due to its slow absorption via soft tissue, making it the choice for longer surgeries. Chlorhexidine provides superior results with equivalent adverse events.

Consequently, PVP-I has found broad application in medicine as a surgical scrub; for pre- and post-operative skin cleansing; for the treatment and prevention of infections in wounds, ulcers, cuts and burns; for the treatment of infections in decubitus ulcers and stasis ulcers; in gynecology for vaginitis associated with candidal, trichomonal or mixed infections. For these purposes PVP-I has been formulated at concentrations of 7.5–10.0% in solution, spray, surgical scrub, ointment, and swab dosage forms; however, use of 10% povidone-iodine though recommended, is infrequently used, as it is poorly accepted by health care workers and is excessively slow to dry.

Because of these critical indications, only sterile povidone-iodine should be used in most cases. Non-sterile product can be appropriate in limited circumstances in which people have intact, healthy skin that will not be compromised or cut. The non-sterile form of Povidone iodine has a long history of intrinsic contamination with *Burkholderia cepacia* (aka *Pseudomonas cepacia*), and other opportunistic pathogens. Its ability to harbor such microbes further underscores the importance of using sterile products in any clinical setting. Since these bacteria are resistant to povidone iodine, statements that bacteria do not develop resistance to PVP-I,^[10] should be regarded with great caution: some bacteria are intrinsically resistant to a range of biocides including povidone-iodine.

Antiseptic activity of PVP-I is because of free iodine (I₂) and PVP-I only acts as carrier of I₂ to the target cells. Most commonly used 10% PVP-I delivers about 1-3 ppm of I₂ in a compound of more than 31,600 ppm of total iodine atoms. All the toxic and staining effects of PVP-I is due to the inactive iodine only.



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5. PHARMACOLOGICAL PROPERTIES

Povidone – Iodine

5.1 Pharmacodynamic properties

Povidone-iodine has a wide antimicrobial spectrum with activity against gram-positive and gram-negative bacteria, fungi, protozoa, tubercle bacilli, viruses, and bacterial spores. Data show that povidone-iodine is bactericidal, fungicidal, and virucidal.

5.2 Pharmacokinetic properties

Povidone-iodine is a topical antiseptic agent used for the treatment and prevention of infection in wounds. Povidone-iodine is a stable chemical complex of polyvinylpyrrolidone (povidone, PVP) and elemental iodine. It contains from 9.0% to 12.0% available iodine, calculated on a dry basis.



6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Citric acid (Anhydrous)	BP	480.000
Di sodium hydrogen ortho phosphate (Anhydrous)	BP	1.754 mg
Potassium iodate	BP	180.000 g
Sodium lauryl sulphate	BP	150.000 mg
PEG-400	BP	150.000 mg

6.2 Incompatibilities

None reported

6.3 Shelf-Life

36 months from the date of manufacture.

6.4 Special Precautions for Storage

Store under normal storage condition (15°C -30°C)
Protect from light.

6.5 Nature and Contents of Container

Amber colour PET Bottle of 120 ml.



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**ANIL K. PANDEY
DIRECTOR**

**Date:
Director of the manufacturer
(Signature, Full name, Stamp)**



**ANIL K. PANDEY
DIRECTOR**

**Date:
Director of applicant company
(Signature, Full name, Stamp)**

