

# THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

## RAW MATERIAL SPECIFICATION

<b>Title :</b> Povidone-Iodine USP (Item No. 41023140)	<b>Spec. No. :</b> SP-AK30-P50
<b>Reference(s) :</b> USP 41 page 3392	<b>Rev. No. :</b> 05
<b>Other Requirements :</b> -	<b>Page :</b> 1/2

**USP 41**

**Description :** Yellowish-brown to reddish-brown, amorphous powder, having a slight, characteristic odor.

**Solubility :** Soluble in water and in alcohol; practically insoluble in chloroform, in carbon tetrachloride, in ether, in solvent hexane, and in acetone.

**Identification :**

- A. A deep blue color is produced.
- B. A brown, dry, non-smearing film is formed, and it dissolves readily in water.

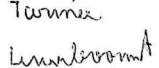

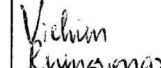
**Assay [available iodine] :** 9.0% to 12.0% of available iodine (I), calculated on the dried basis.

**Iodide ion :** Not more than 6.6%, calculated on the dried basis.

**Nitrogen determination :** 9.5% to 11.5% of Nitrogen (N) is found, calculated on the dried basis.

**Residue on ignition :** Not more than 0.025%.

**Loss on drying :** Not more than 8.0%.

<b>Prepared by :</b> J. Roppadech / 21/03/19 Head of Raw Material Standard Section 2	<b>Reviewed by :</b> <div style="display: flex; justify-content: space-between;"> <div>           Director of Raw Material          Standard Division       </div> <div>           Director of Regulatory Compliance          and Documentation Division       </div> </div>	<b>Approved by :</b> <div style="display: flex; justify-content: space-between;"> <div>           Director of Quality Assurance          Department (Achny)       </div> <div>         Eff. Date          15/05/19       </div> </div>
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### Product Information

Approved source(s)	Refer to current version of Approved Supplier List of Povidone-Iodine USP (Item No. 41023140).
Sampling plan	For Identification : 100%. For Other Tests : n plan.
Testing procedure	Tests to be performed as per current version of WI-AK30-P50.
Storage condition	Store at a condition stated on the label from the manufacturer. Preserve in tight containers.
Retest period	1 year after first testing date.

### History of changes

Rev. No.	Description	Effective Date
02	Update ข้อกำหนดตาม USP 31 และ GPO Specification	29/07/08
03	Update ข้อกำหนดตาม USP 34 และ GPO Specification (GPO Specification มี 3 หัวข้อทดสอบ คือ 1.pH 2.K-value 3.Stability test)	19/03/12
04	Update ข้อกำหนดตาม USP 35 เท่านั้น (ไม่มีหัวข้อทดสอบตาม GPO Specification)	05/10/17
05	Update ข้อกำหนดตาม USP 41	15/05/19

Prepared by : <i>J. Roppadech</i> / 21/03/19 Head of Raw Material Standard Section 2	Reviewed by : <i>Tanwut</i> <i>Linsunth</i> / 21/03/19 Director of Raw Material Standard Division	Approved by : <i>Vichien</i> <i>Rungwongroj</i> / 25/03/19 Director of Quality Assurance Department (Acting)	Eff. Date  15/05/19
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