THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Plasdone S-630 (Copovidone NF) (Item No. 41010335)	**Spec. No.** : SP-AK30-P65
Reference(s) : USP 42/NF 37 p. 5675 - 5677	**Rev. No.** : 03
Other Requirements : ----------------------	**Page** : 1/2

USP 42/NF 37

Test Parameters	Specifications	
Description	White to yellowish-white powder or flakes, hygroscopic.	
Solubility	Freely soluble in water, in alcohol, and in methylene chloride; practically insoluble in ether.	
Identification A. Infrared Absorption <197K> B. Chemical Test	 Conforms to IR standard spectrum. A deep red color is produced.	
Loss on drying	Not more than 5.0%.	
Clarity and color of solution	The solution is clear or slightly opalescent and colorless to pale yellow or pale red.	
K-value	90.0% - 110.0% of the nominal K-value stated on the label (nominal K value = 28).	
Residue on ignition	Not more than 0.1%.	
Limit of aldehydes	Not more than 0.05%, expressed as acetaldehyde.	
Limit of hydrazine	Not more than 1 ppm.	
Limit of peroxides	The absorbance is not more than 0.35 (corresponding to not more than 0.04%, expressed as hydrogen peroxide).	
Limit of monomers	1-Vinyl-2-pyrrolidone	: Not more than 0.001%.
	Vinyl acetate	: Not more than 0.001%.
	2-Pyrrolidone	: Not more than 0.5%.
Content of copolymerized vinyl acetate	35.3% - 41.4% of the copolymerized vinyl acetate component, calculated on the dried basis.	
Nitrogen determination, Method II	7.0% - 8.0% on the dried basis.	

เอกสารไม่ควบคุม
ใช้ในการจัดซื้อ

Prepared by :	Reviewed by :		Approved by :	Eff. Date
……/ 31/01/20	……/ 03/02/20	……/ 03/02/20	……/ 04/02/20	15/02/20
Head of Raw Material Standard Section I	Director of Raw Material Standard Division	Director of Drug Registration and Pharmacovigilance Division	Director of Quality Assurance Department (Acting)	

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Product Information

Approved source (s)	Refer to current version of Approved Vendor List of Plasdone S-630 (Copovidone USP/NF) (Item No. 41010335).
Sampling plan	1. N Plan ($\sqrt{N}+1$) : for other tests. 2. 100% Identification.
Testing procedure	Tests to be performed as per current version of WI-AK30-P65.
Storage condition	Preserve in tight containers. No storage requirements specified. Labeling : Label it to indicate its nominal K-value.
Retest period	1 year after first testing date.

History of changes

Rev. No.	Description	Effective date
01	ประกาศใช้เป็นครั้งแรก reference เป็น USP 30/NF 25	01/04/08
02	Update spec. เป็น USP 37/NF 32 โดยเนื้อหาของ USP 30/NF 25 และ USP 37/NF 32 เหมือนกัน	29/05/15
03	Update spec. เป็น USP 42/NF 37 ตามประกาศกระทรวงสาธารณสุข เรื่องระบุตำรายา พ.ศ. 2561 โดยให้ใช้ตำรายาฉบับ USP 39/BP 2016 ขึ้นไป โดยเนื้อหาของ USP 37/NF 32 และ USP 42/NF 37 เหมือนกัน	15/02/20

เอกสารไม่ควบคุม ใช้ในการจัดซื้อ

Prepared by :	Reviewed by :		Approved by :	Eff. Date
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