

# 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

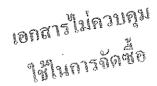
Other Requirements: -----

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### **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		
	ether.		
Identification			
A. Infrared Absorption <197K>	Conforms to IR standard spectrum.		
B. Chemical Test	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	35.3% - 41.4% of the copolymerized vinyl acetate component, calculated on the dried		
acetate	basis.		
Nitrogen determination, Method II	7.0% - 8.0% on the dried basis.		



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Head of Raw Material	Director of Raw Material	Director of Drug Registration and	Director of Quality Assurance	13/02/20
Standard Section I	Standard Division	Pharmacovigilance Division	Department (Activa)	



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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 (√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 โดยให้ใช้ดำรายา	15/02/20	
	ฉบับ USP 39/BP 2016 ขึ้นไป โดยเนื้อหาของ USP 37/NF 32 และ USP 42/NF 37 เหมือนกัน		

เอกสารให้ควบคุม เอกสารให้ควบคุม

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