

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Kollidon CL-SF® (Crospovidone, Type B USP/NF) (Item No. 41010864)	Spec. No. : SP-AK30-K64
Reference(s) : USP 42/NF 37 p. 5691-5692	Rev. No. : 01
Other Requirements : —	Page : 1/2

USP 42/NF 37

Test Parameters	Specifications
Description	White to creamy white, hygroscopic powder, having a faint odor.
Solubility	Insoluble in water and in ordinary organic solvents.
Identification	
A. Infrared Absorption <197K>	Conforms to IR standard spectrum.
B. Chemical Test	No blue color develops.
C. Chemical Test	A suspension is formed and no clear solution is obtained within 15 minutes.
D. Sieving residue fraction	Not more than 15%, for Type B.
Loss on drying	Not more than 5.0%.
Residue on ignition	Not more than 0.1%, determined on 1.0 g.
Water-soluble substances	Not more than 1.5%.
Peroxides	Not more than 0.35. For type B, this corresponds to not more than 1000 ppm expressed as H ₂ O ₂ .
Vinylpyrrolidinone	Not more than 10 ppm.
Nitrogen Determination, Method II	11.0% to 12.8% of Nitrogen (N), calculated on the dried basis.

Prepared by : <i>Sunannee</i> / 30/05/19 Head of Raw Material Standard Section I	Reviewed by : <i>Tunnie</i> / 31/05/19 Director of Raw Material Standard Division	<i>[Signature]</i> / 04/06/19 Director of Regulatory Compliance and Documentation Division	Approved by : <i>Vichien</i> / 05/06/19 Director of Quality Assurance Department <i>Ching</i>	Eff. Date 20/06/19
---	--	--	--	-----------------------

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Kollidon CL-SF® (Crospovidone, Type B USP/NF) (Item No. 41010864)	Spec. No. : SP-AK30-K64
Reference(s) : USP 42/NF 37 p. 5691-5692	Rev. No. : 01
Other Requirements : —	Page : 2/2

Product Information

Approved source (s)	Refer to current version of Approved Vendor List of Kollidon CL-SF® (Crospovidone, Type B USP/NF) (Item No. 41010864).
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-K64.
Storage condition	Preserve in tight containers.
Retest period	1 year after first testing date.

History of changes

Rev. No.	Description	Effective date
01	ประกาศใช้เป็นครั้งแรก reference เป็น USP 42/NF 37	20/06/19

Prepared by : Sunanee / 30/05/19 Head of Raw Material Standard Section 1	Reviewed by : Tammie / 31/05/19 Director of Raw Material Standard Division	Approved by : Vichin Ruengyongroj / 05/06/19 Director of Regulatory Compliance and Documentation Division	Eff. Date 20/06/19
---	---	--	-----------------------