THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Hydrocortisone USP (Item No. 41010805)	**Spec. No.** : SP-AK30-H80
Reference(s) : USP 43 p. 2228 - 2229	**Rev. No.** : 02
Other Requirements : GPO specification	**Page** : 1/2

USP 43

Test Items	Specification	
Description	White to practically white, odorless, crystalline powder.	
Solubility	Sparingly soluble in acetone and in alcohol; slightly soluble in chloroform; very slightly soluble in water and in ether.	
Identification A. Infrared absorption <197M> B. Ultraviolet absorption <197U>	 Conforms to standard spectrum. Absorptivities, calculated on the dried basis, do not differ by more than 2.5%.	
Residue on ignition	Not more than 0.5%.	
Specific rotation	+150° to +156°.	
Loss on drying	Not more than 1.0% of its weight.	
Organic impurities	Individual impurities	: Not more than 0.5%.
	Total impurities	: Not more than 2.0%.
Assay	97.0% - 102.0% of $C_{21}H_{30}O_5$ calculated on the dried basis.	

GPO specification

Test Items	Specification	
Residual solvents	Methanol (1)	: Not more than 500 ppm.
	Ethanol (1)	: Not more than 2000 ppm.
	Acetone (1)	: Not more than 2000 ppm.
	Dimethyl formamide (1)	: Not more than 600 ppm.
	Methylene chloride (1)	: Not more than 600 ppm.
Particle size by Laser diffraction, Malvern	d(0.9)	: Not more than 15 microns.

Remark : Residual solvents (1) for Tianjin Jinjin Pharmaceutical Co, Ltd/ China

Prepared by :	Reviewed by :		Approved by :	Eff. Date
(Acting) Thunyatorn ..../22/04/22	Suwannee ....../22/04/22	................/23/04/22	(Acting) Tunina Luanburi ....../24/04/22	18/05/22
Head of Raw Material Standard Section 1	Director of Raw Material Standard Division	Director of Regulatory Strategy Division	Director of Quality Assurance Department	

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Product Information

Approved source (s)	Refer to current version of Approved Vendor List of Hydrocortisone USP (Item No. 41010805).
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-H80.
Storage condition	Preserve in well-closed containers. Store at controlled room temperature.
Retest period	1 year after first testing date.

History of changes

Rev. No.	Description	Effective date
01 02	First issue, อ้างอิง USP 38 โดยเนื้อหาของ USP 38 และ USP 36 เหมือนกัน และยื่นขึ้นทะเบียนด้วย USP 36 เอกสารมีอายุมากกกว่า 3 ปี จึงทบทวน และ Update spec. เป็น USP 43 โดยเนื้อหาของ USP 38 และ USP 43 เหมือนกัน	28/10/17 18/05/22

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