THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Methocel K100M Premium Controlled-release (CR) (Hypromellose type 2208 USP) (Item No 41010815)	**Spec. No.** : SP-AK30-H22
Reference(s) : USP 43 p. 2279 - 2281	**Rev. No.** : 01
Other Requirements : GPO specification	**Page** : 1/2

USP 43

Test Items	Specification
Description	White to slightly off-white, fibrous or granular powder.
Solubility	Swells in water and produces a clear to opalescent, viscous, colloidal mixture. Insoluble in dehydrated alcohol, in ether, and in chloroform
Identification	
A. Chemical test	The powdered material aggregates on the surface.
B. Chemical test	A slurry is formed, but the powdered material does not dissolve. Cool the slurry to 10 °C, and stir using a magnetic stirrer. The resulting liquid is a clear or slightly turbid solution with thickness dependent on the viscosity grade.
C. Chemical test	A red color develops at first that changes to purple within 100 minutes.
D. Chemical test	A coherent, clear film forms on the glass slide.
E. Chemical test	The flocculation temperature is higher than 50 °C.
Viscosity	75% - 140% of the viscosity stated on the label (labeled viscosity = 100,000 mPa · S)
pH	Between 5.0 and 8.0.
Loss on drying	Not more than 5.0%.
Residue on ignition	Not more than 1.5%.
Assay for methoxy	19.0% - 24.0% of methoxy, calculated on the dried basis.
Assay for hydroxypropoxy	9.5% - 11.5% of hydroxypropoxy, calculated on the dried basis.

GPO specification

Test Items	Specification	
Fineness	Pass through sieve No. 40	: Not less than 99.0%.
	Pass through sieve No. 100	: Not less than 90.0%.
	Pass through sieve No. 230	: 50.0% – 80.0%

Prepared by :	Reviewed by :		Approved by : (Acting)	Eff. Date
Thunyatorn (Acting) / 09/04/21 Head of Raw Material Standard Section 1	Suwannee (Acting) 09/04/21 Director of Raw Material Standard Division	............/ 22/04/21 Director of Drug Registration and Pharmacovigilance Division	............/ 26/04/21 Director of Quality Assurance Department	30/04/21

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Product Information

Approved source (s)	Refer to current version of Approved Vendor List of Methocel K100M Premium Controlled-release (CR) (Hypromellose type 2208 USP) (Item No 41010815)
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-H22.
Storage condition	Preserve in well-closed containers. No storage requirements are specified.
Retest period	1 year after first testing date.

History of changes

Rev. No.	Description	Effective date
01	First issue, อ้างอิง USP 39 ตามที่สถาบันวิจัยฯ ยื่นขึ้นทะเบียน อ้างอิง Spec. No. : RMS-RA-79N60200 Rev. No. 00 และ source ที่สถาบันวิจัยฯ อ้างอิงคือ Dow chemical pacific/United states ใช้สำหรับยา Metformin 500 mg XR tablet (prolonged-release tablets) โดยเนื้อหาของ Monograph USP 39 และ USP 43 เหมือนกัน	30/04/21

Prepared by :	Reviewed by :		Approved by : (Acting)	Eff. Date
Thunyatorn (Acting) 09/04/21	Suwannee (Acting) 09/04/21	22/04/21	Tawnee 26/04/21	30/04/21
Head of Raw Material Standard Section 1	Director of Raw Material Standard Division	Director of Drug Registration and Pharmacovigilance Division	Director of Quality Assurance Department	