COPY No. 3

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Croscarmellose Sodium USP (Item No. 41010380)	**Spec. No.** : SP-AK30-C011
Reference(s) : USP 43 p. 5736 - 5737	**Rev. No.** : 05
Other Requirements : GPO Specification	**Page** : 1/2

USP 43

Test Items	Specification	
Description	White to almost white, free-flowing powder, odorless.	
Solubility	Partially soluble in water; insoluble in alcohol, in ether and in other organic solvents.	
Identification A. Chemical test B. Chemical test C. Chemical test	 The Croscarmellose Sodium absorbs the methylene blue and settles as a blue, fibrous mass. A reddish-violet color develops at the interface. Sodium compounds impart an intense yellow color to a nonluminous flame.	
Residue on ignition	Between 14.0-28.0%, calculated on the dried basis.	
Sodium chloride and sodium glycolate	The sum of the percentages of sodium chloride and sodium glycolate is not more than 0.5%.	
Content of water-soluble material	Not more than 10.0%.	
Degree of substitution	Between 0.60 and 0.85, on the dried basis.	
Loss on drying	Not more than 10.0%.	
pH	Between 5.0 and 7.0.	
Settling volume	Between 10.0 and 30.0 ml.	
Microbial enumeration tests and Tests for Specified microorganisms.	The total aerobic microbial count	: does not exceed 1000 cfu/g.
	The total combined molds and yeasts count	: does not exceed 100 cfu/g.
	Escherichia coli	: absence.

GPO Specification

Test Items	Specification	
Heavy metals	Not more than 10 ppm, Method II.	
Fineness	Retained on sieve No. 200	: Not more than 10.0%.
	Retained on sieve No. 325	: Not more than 30.0%.

Prepared by :		Reviewed by :			Approved by :	Eff. Date
(acting) Thanyaporn / 20/08/21	chavalcom Jomjanarakul 20/08/21	Suwannee (Acting) / 20/08/21	Pongsa / 23/08/21	/ 24/08/21	Tasanee / 24/08/21	15/09/21
Head of Raw Material Standard Section 1	Head of Microbiological Analysis Section 2	Director of Raw Material Standard Division	Director of Microbiological Analysis Division	Director of Regulatory Strategy Division	Director of Quality Assurance Department	

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Croscarmellose Sodium USP (Item No. 41010380)	**Spec. No.** : SP-AK30-C011
Reference(s) : USP 43 p. 5736 - 5737	**Rev. No.** : 05
Other Requirements : GPO Specification	**Page** : 2/2

Product Information

Approved source (s)	Refer to current version of Approved Vendor List of Croscarmellose Sodium USP (Item No. 41010380)
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-C011.
Storage condition	Preserve in well-closed containers. No storage requirements specified.
Retest period	1 year after first testing date.

History of changes

Rev. No.	Description	Effective date
03	เปลี่ยน reference เป็น USP 36 (content เหมือน USP 32) เพื่อใช้ในการขึ้นทะเบียน Abacavir 300 mg tablets	15/04/14
04	Update spec. เป็น USP 39 โดยเนื้อหาของ USP 36 และ USP 39 เหมือนกัน เนื่องจากเอกสารมีอายุครบ 3 ปี จำเป็นต้องทบทวน	28/04/17
05	Update spec. เป็น USP 43 โดยเนื้อหาของ USP 39 และ USP 43 เหมือนกัน เนื่องจากเอกสารมีอายุครบ 3 ปี จำเป็นต้องทบทวน	15/09/21

Prepared by :		Reviewed by :			Approved by :	Eff. Date
20/08/21	20/08/21	20/08/21	23/08/21	24/08/21	24/08/21	15/09/21
Head of Raw Material Standard Section 1	Head of Microbiological Analysis Section 2	Director of Raw Material Standard Division	Director of Microbiological Analysis Division	Director of Regulatory Strategy Division	Director of Quality Assurance Department	