องค์การเภสัชกรรม COPY No. 9

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Lactose Anhydrous USP (Direct Compressed Grade) (Item No. 41032130)	**Spec. No.** : SP-AK30-L10
Reference(s) : USP 43 p. 5847 - 5849	**Rev. No.** : 05
Other Requirements : GPO specification	**Page** : 1/3

USP 43

Test Parameters	Specifications	
Description	White or almost white powder, odorless.	
Solubility	Freely soluble in water; practically insoluble in alcohol.	
Identification A. Infrared spectroscopy <197K> B. TLC	Conforms to IR standard spectrum. The principal spot from the Sample solution corresponds in appearance and Rf value to that from Standard solution A.	
Residue on ignition	Not more than 0.1%.	
Clarity and color of solution	- Not more than 0.04 for the absorbance divided by the path length in centimeters. - The clarity of the Sample solution is the same as that of water or its opalescence is not more pronounced than that of the ***Reference suspension***, and it is not more colored than the ***Reference solution***.	
Loss on drying	Not more than 0.5%.	
Water	Not more than 1.0%.	
Protein and light-absorbing impurities	- NMT 0.25 for the absorbance divided by the path length in centimeters at 210-220 nm. - NMT 0.07 for the absorbance divided by the path length in centimeters at 270-300 nm.	
Acidity or alkalinity	The solution is colorless and not more than 0.4 ml of 0.1 N Sodium hydroxide is required to produce a pink or red color.	
Specific rotation	Between +54.4° and +55.9°, calculated on the anhydrous basis, at 20 °C.	
Microbial Enumeration Tests and Tests for Specified Microorganisms.	The total aerobic microbial count	: NMT 10^2 cfu/g.
	The total combined molds and yeasts count	: NMT 50 cfu/g.
	Escherichia coli	: Absence.

Prepared by :		Reviewed by :			Approved by :	Eff. Date
Suvannee, 12/10/20	Jamjanakul, 12/10/20	, 14/10/20	, 19/10/20		, 19/10/20	30/11/20
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 Drug Registration and Pharmacovigilance Division	Director of Quality Assurance Department (Acting)	

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GPO specification

Test Parameters	Specifications
Heavy metals	Not more than 5 ppm, Method II.

Product Information

Approved source (s)	Refer to current version of Approved Vendor List of Lactose Anhydrous USP (Direct Compressed Grade) (Item No. 41032130).
Sampling plan	P plan : for Identification. $\sqrt{N} + 1$: for other tests.
Testing procedure	Tests to be performed as per current version of WI-AK30-L10.
Storage condition	To be stored in tight containers.
Retest period	1 year after first testing date.

Prepared by :		Reviewed by :			Approved by :	Eff. Date
Suwannee, 12/10/20	Chavalkorn Jamjanapolchai, 12/10/20	Jarunee Luanwong 14/10/20	19/10/20	19/10/20	19/10/20	30/11/20
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 Drug Registration and Pharmacovigilance Division	Director of Quality Assurance Department	

COPY No. 3

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History of changes

Rev. No.	Description	Effective date
03	Update spec. เป็น USP 37	28/11/14
04	Update spec. เป็น USP 39 เนื่องจากเอกสารอายุครบ 3 ปี ต้องทบทวน โดยเนื้อหาของ USP 37 และ USP 39 เหมือนกัน	20/01/17
05	เอกสารมีอายุครบ 3 ปี จึงต้องทบทวน โดย update spec. เป็น USP 43 โดยเนื้อหาของ USP 39 และ USP 43 เหมือนกัน	30/11/20

Prepared by :		Reviewed by :			Approved by :	Eff. Date
12/10/20	chavalum 12/10/20	14/10/20	14/10/20	19/10/20	19/10/20	30/11/20
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