

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Lactose Monohydrate [SUPER-TAB] DC grade (Item No. 41021950)	Spec. No. : SP-AK30-L11
Reference(s) : USP 42/NF 37 page 5796 to 5797	Rev. No. : 03
Other Requirements : GPO Specification	Page : 1/3

<u>USP 42/NF 37</u>	Description	: White, free-flowing, crystalline powder.
	Solubility	: Freely but slowly soluble in water; practically insoluble in alcohol.
	Identification	: A. Infrared absorption. B. Thin-layer chromatographic identification test.
	Residue on ignition	: Not more than 0.1%.
	Clarity and color of solution	: The absorbance divided by the path length, in cm, is not more than 0.04.
	Optical rotation, Specific rotation <781S>	: +54.4° to +55.9°, calculated on the anhydrous basis, determined at 20 °C.
	Acidity or alkalinity	: The solution is colorless, and not more than 0.4 mL of 0.1 N sodium hydroxide VS is required to produce a pink or red color.
	Loss on drying	: Not more than 1.0%.
	Water determination	: 4.5% to 5.5%.

Prepared by : <u>J. Ropadech / 09/04/19</u> Head of Raw Material Standard Section 2	Reviewed by : <u>Tasme</u> <u>Lumduwmt / 14/04/19</u> Director of Raw Material Standard Division	<u>[Signature]</u> / 22/04/19 Director of Regulatory Compliance and Documentation Division	Approved by : <u>Vichien</u> <u>Rungwongroj / 22/04/19</u> Director of Quality Assurance Department <u>CA ding</u>	Eff. Date 15/05/19
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Protein and light-absorbing : The absorbance divided by the path length, in cm, is not more than 0.25 in the range of 210–220 nm and is not more than 0.07 in the range of 270–300 nm.

Microbial Enumeration Tests and Tests for Specified Microorganisms

- the total aerobic microbial count: not exceed 1×10^2 cfu/g,

- the total combined molds and yeasts count : not exceed 5×10^1 cfu/g,

- *Escherichia coli* : absence.

GPO Specification

Particle size

< 75 μ m (Sieve No. 200) : Not more than 20%.

< 150 μ m (Sieve No. 100) : 40% to 65%.

< 250 μ m (Sieve No. 60) : Not less than 90%.

Tapping volume

: 5.0-g portion occupies not more than 7.0 mL when tapped down 20 times at 3-mm drop height, and 250 drops/minute of tapping rate.

Prepared by : J. Koppachet / 09/04/19 Head of Raw Material Standard Section 2	Reviewed by : Tawin / 14/04/19 Director of Raw Material Standard Division	Approved by : Nithin / 22/04/19 Director of Regulatory Compliance and Documentation Division	Eff. Date 15/05/19
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Product Information

Approved source(s)	Refer to current version of Approved Supplier List of Lactose Monohydrate (SUPER-TAB) DC grade (Item No. 41021950).
Sampling plan	For Identification : 100%. For Other Tests : n plan.
Testing procedure	Tests to be performed as per current version of WI-AK30-L11.
Storage condition	Store at a condition stated on the label from the manufacturer or store in a cool, dry place ($\leq 80\%$ relative humidity). Preserve in tight containers.
Retest period	2 years after first testing date.

History of changes

Rev. No.	Description	Effective Date
01	อ้างอิงตาม USP 32/NF 27 และ GPO Specification	19/10/09
02	ทบทวนเอกสารให้ทันสมัย โดยอ้างอิงตาม USP 38/NF 33 และ GPO Specification	24/05/16
03	Update ข้อกำหนดตาม USP 42/NF 37 และ GPO Specification	15/05/19

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