

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : ULTRA-SPERSE® 2000 (Item No. 41024350)	Spec. No. : SP-AK30-U2
Reference(s) : Manufacturer's Specification [Ingredion Incorporated / U.S.A.]	Rev. No. : 01
Other Requirements : GPO Specification	Page : 1/2

GPO Specification

Test Parameter	Requirement	
Description	White to off-white granular powder.	
pH	4.8 to 7.0.	
Moisture	Not more than 14.0%.	
Fineness	Pass through sieve No. 20	: Not less than 98%.
Microbial enumeration tests and Tests for Specified microorganisms.	The total aerobic microbial count	: Not more than 10000 cfu/g.
	The total combined molds and yeasts count	: Not more than 400 cfu/g.
	<i>Escherichia coli</i>	: Absence.
	<i>Salmonella species</i>	: Absence.

Prepared by : Benjawan Chawalern Ubanklee, 06/09/21 Jamjanandun, 06/09/21	Reviewed by : (Acting) Sunanwee, 06/09/21 Pongy., 07/09/21 [Signature], 15/09/21	Approved by : Yungap, 16/09/21	Eff. Date 27/09/21
Head of Raw Material Standard Section 2	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

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Product Information

Approved source(s)	Refer to current version of Approved Supplier List of Ultra-Sperse® 2000 (Item No. 41024350).
Sampling plan	For Identification: 100%. For Other Tests: N plan ($\sqrt{N} + 1$).
Testing procedure	Tests to be performed as per current version of WI-AK30-U2.
Storage condition	Store in a clean, dry, well-ventilated warehouse at ambient temperature and humidity, away from odorous materials.
Retest period	1 year after first testing date.

History of changes

Rev. No.	Description	Effective Date
01	จัดทำขึ้นเป็นครั้งแรก อ้างอิงตาม GPO Specification ตาม Manufacturer's Specification [Ingredion Incorporated / U.S.A.]	27/09/21

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