

WINDLAS BIOTECH LIMITED

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RAW MATERIAL SPECIFICATION			
Material Name NOVOMIX YELLOW COLOUR (SI		Specification No.	RS/RMEXI000DIH04
	118512)		65 - 02
Item Code	RMEXI000DIH0465	Effective Date	11/04/2025
Reference	IH	Review Date	As and when Required
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	Name	Designation	Department	Date
Prepared by	Vanshita Singh	Computer Operator	Quality Control	11/04/2025
Checked by	Deepu	Assistant Manager	Quality Control	11/04/2025
Reviewed by	Deepak Kumar	Manager	Quality Control	11/04/2025
Approved by	Nidhi Rani	Sr. Officer	Quality Assuarance	11/04/2025

GENERAL INFORMATION

Category	Excipient(Pharmaceutical Aid)		
Reference STP No.	RM/STP/IH/EXI/139		
Sampling Procedure	As per SOP/QC/007		
Sampling Quantity	Analysis - 5g, PSD - 10g, BD - 20g, Control - 10g, Total - 45 g. [Identi. each container - 100 mg]		
Retest Period	24 Months		
Control Sample	ontrol Sample As per SOP/QA/030		
Storage Conditions	Preserve in tight container, store at controlled room temperature. Keep away from sunlight, heat and moisture.		
Precautions	 Sample container shall be visually clean and dry. Collect sample in different container for chemical analysis and control sample. All sample containers shall be labeled properly with detalis of material name, sampling date, sample quantity and sampled by. Take appropriate personal safety measures during sampling, wear personal protective Equipments. All samples shall be sampled as per standard approved procedure. 		

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Sr.No.	Test	Specification	
1*	Description	Yellow powder.	
2	Particle Size (100 #)	Not less than 99 % w/w passes through 100# ASTM sieve.	
3	Bulk Density	Not more than 1.2g/ml	
	(Tapped)		
4*	Ash	Not more than 25.0%	
5	Additional Test		
5a.	General Requirement	Material should be free from Foreign particles that can be observed on	
		visual inspection by unaided eye.	
5b	Identification	Positive for Yellow powder.	

Note: *Test to be carried out at the time of retesting.

Change History:

Change Control / Amendment No.	Revision No.	Effective Date	Reason for Revision
CC/P2/QC/23/122	00	21/11/2022	Sample quantity incorporated
CC/P2/QC/25/108	01	13/05/2023	Identification test incorporate
NA	02	11/04/2025	NA

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