

	FINISHED PRODUCT SPECIFICATION		Page No.	1 of 2
	Quality Control Department			
Product Name:	NOVOMIX 110248			
Colour:	Yellow			
Specification No.:	FP/NOVOMPS/C-1/ 110248/01	Supersedes No.:	NA	
Customer's Name:	MSN Laboratories			
Reference :	IN HOUSE	Effective Date :	05/07/2024	
Ref. Annexure No.:	A/SOP/QC/030/19-00	Review Month :	Jun'2024	

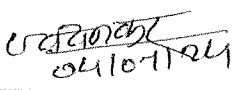
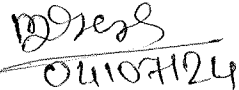
GENERAL INFORMATION

Pharmacopoeial reference : In House

Quantity to be sampled :	Analysis Sample	Control sample
	25 g	75 g

Shelf Life : 36 Months

Storage : Store in dry place, in well closed container, away from direct heat and light.

	PREPARED BY	REVIEWED BY	APPROVED BY
Name	Jagdish Dinkar	Manisha Dhesi	Sonam Grel
Sign/Date	 04/07/24	 04/07/24	 05/07/2024
Designation	QC officer	SO. Executive	So. Manager QA/QC
Department	quality control	Quality Control	Quality Assurance

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Product Name	NOVOMIX 110248		
Specification No.	FP/NOVOMPS/C-1/ 110248/01		

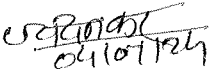
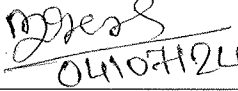
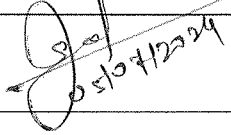
Qualitative Formula:

1. Hydroxypropyl methyl cellulose USP
2. Polyethylene Glycol USP
3. Titanium Dioxide USP
4. Yellow Iron Oxide USP

Sr. No.	Test	Specification	Reference
1.	Appearance	Yellow powder	GTP/QC/001
2.	Identification by IR	IR spectrum of test sample should be concordant with the IR spectrum of standard.	GTP/QC/009
3.	Colour Difference		
	1) DE (By colour spectrophotometer)	NMT 2.0	GTP/QC/008
	2) Visually	Colour shade should match visually with Standard	
4.	Ash Content	21.10 % w/w to 28.54 % w/w	GTP/QC/004
5.	Dispersion	Should Pass	GTP/QC/010

REVISION HISTORY FOR SPECIFICATION:

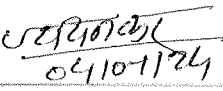
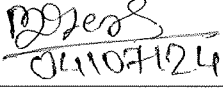
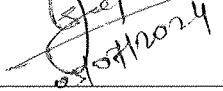
Revision No.	Revision Description	Effective Date
01	New Document	05/07/2024

	PREPARED BY	REVIEWED BY	APPROVED BY
Sign/Date	 04/07/24	 04/07/24	 05/07/2024

	FINISHED PRODUCT STANDARD TEST PROCEDURE (STP)		Page No.	1 of 4
	Quality Control Department			
Product Name:	NOVOMIX 110248			
Colour :	Yellow			
STP No. :	FP/NOVOMSTP/C-1/ 110248/01			
Customer's Name:	MSN Laboratories			
Reference :	IN HOUSE	Supersedes No. :	NA	
Ref. SPEC No. :	FP/NOVOMPS/C-1/ 110248/01	Effective Date :	05/07/2024	
Ref. Annexure No. :	A/SOP/QC/030/21-00	Review Month :	Jun'2023	

01. Appearance :
 Instrument: Balance
 Take about 2 to 3 g of test sample and transferred into a clean and dry petri dish. Spread it uniformly by spatula and observe.
 Specification: Yellow powder.

02. Identification by IR:
 Instrument: Balance, IR Spectrophotometer, Oven
 Take about 1 mg of sample to be analyzed and 100 mg IR grade KBr onto piece of weighing paper. The KBr should be store in the desiccator when not in used. Transfer the sample /KBr mixture to the agate mortar. Thoroughly disperse the mixture using the spatula or spoon. The pestle is then used with a grinding motion to homogenously disperse the mixture component. Completed homogeneity takes approximately 1-2 minutes of grinding the components with the pestle. Prepare a KBr pellet using an appropriate apparatus (Press Kit, E- Z press etc.) carefully examine the pallet film to ensure that it is intact and somewhat transparent. Run the pallet on suitable spectrophotometer from 4000 cm^{-1} to 650 cm^{-1} according to the operating instruments. All peak should be match the reference with relation to wavelength location and approximate magnitude location. Overlap the sample spectra with reference spectra.
 Note: Sample and KBr to be dried at 105°C for about 30 minutes before use
 Or

	PREPARED BY	REVIEWED BY	APPROVED BY
Name	Jagdish Dinkar	Manisha Dhere	Sonam Geol
Sign/Date	 04/10/24	 04/10/24	 04/10/24
Designation	QC officer	Sr. Executive	Sr. Manager
Department	quality control	Quality Control	Quality Assurance

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By ATR Accessory:

Make sure the crystal is free from any residue by wiping clean with IPA or methanol and delicate wipe. Perform the background measurement. Grind a small amount of sample using agate mortar. Transfer enough of the undiluted sample to completely cover the crystal. Lower the ATR press all the way down with sufficient pressure to ensure a well-defined scan. Collect a spectrum of sample from 4000 cm⁻¹ to 650 cm⁻¹.

All peak should be match the reference with relation to wavelength location and approximate magnitude location. Overlap the sample spectra with reference spectra.

Specification: IR spectrum of test sample should be concordant with the IR spectrum of standard.

03. Colour Difference:

Instrument: Balance, Applicator, Colour matching spectrophotometer

1) Visually: Transfer mixture of 16 ml of dichloromethane and 8 ml methanol into a suitable beaker. Then lower the paddle into the solvent mixture and switch on the stirrer. Adjust the speed of the stirrer so that a vortex is produced without pulling in any air. Check that the head of stirrer is turning without any 'wobble'. Then add 2.0 g of test sample as quickly as the stirrer will allow without excess build-up of product on the surface. The speed of the stirrer will need to be increased to maintain the vortex but must remain in the operating range of 800 to 1200 rpm. Mix for 20-30 minutes. After mixing pass the sample solution through 100 mesh.

Instrument Method parameters: Speed: 10 mm/sec.

Distance: 50 %

Thickness: 800 µm

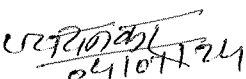
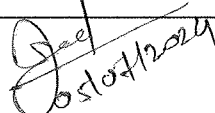
Volume: About 4 ml

Drying Time: 10-15 minutes

Drying at: Room Temperature

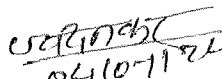
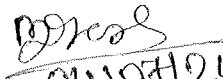
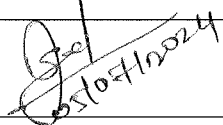
Place a labeled card (Ivory or equivalent) on the drawdown plate with the matte side facing up and apply a vacuum. Prepare colour shade card using above method.

Note: Dispersion media and sample quantity may vary as per requirement but final concentration

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Sign/Date	 04/10/24	 04/10/24	 05/10/24

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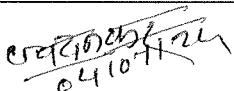
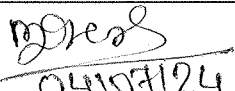
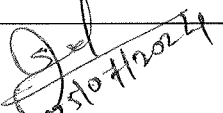
	should remain same. Compare the colour shade cards with a standard reference colour shade card. Specification: Colour shade should match visually with Standard. 2) DE (By colour spectrophotometer): Compare the colour of sample shade cards with a reference standard already stored in the colour matching system. Specification: NMT 2.0
04.	Ash Content : Instrument: Balance, Muffle Furnace Heat a silica crucible at $600 \pm 25^\circ \text{C}$ for 15 minutes, allow to cool in a desiccator and weigh. Take 1-2 g of sample to the crucible and weigh the crucible. Ignite the sample at $600 \pm 25^\circ \text{C}$ for 45 minutes. Allow the silica crucible to come to room temperature in a desiccator before weighing. Repeat the operation until two successive weighing do not differ by more than 0.5 mg. Calculation: $\% \text{ Ash} = \frac{(W4-W1)}{(W2-W1)} \times 100$ Where, W1 = Weight of the empty crucible (g) W2 = Weight of the crucible with test sample before ignition (g) W3 = Weight of the crucible with residue after ignition (g) W4= Weight of the crucible with residue after ignition (g) (Constant weight) Specification: 21.10 % w/w to 28.54 % w/w
05.	Dispersion: Instrument: Balance Procedure: Arrange the sieves as 30 mesh with receiver. Weigh accurately 10 g of sample. Sieve through the mesh without applying pressure. No retained material remains on sieve. Specification: Should Pass

	PREPARED BY	REVIEWED BY	APPROVED BY
Sign/Date	 04/10/24	 04/10/24	 05/10/24

	FINISHED PRODUCT STANDARD TEST PROCEDURE (STP)	Page No.	4 of 4
	Quality Control Department		
Product Name:	NOVOMIX 110248		
STP No. :	FP/NOVOMSTP/C-1/110248/01		

REVISION HISTORY FOR STANDARD TEST PROCEDURE:

Revision No.	Revision Description	Effective Date
01	New Document	05/07/2024

	PREPARED BY	REVIEWED BY	APPROVED BY
Sign/Date	 04/07/24	 04/07/24	 05/07/2024