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NOVO EXCIPIENTS PVT. LTD.	FINISHED PRODUCT SPECIFICATION Quality Control Department		Page No.	1 of 2
Product Name	NOVOMIX SP-88543			
Colour	Red			
Specification No.	FP/NOVOMPS/SP-88543/01	Supersedes No.	NA	
Reference	In House	Effective Date	16/07/2024	
Ref. Annexure No.	A/SOP/QC/030/04	Review Month	Jun' 2029	

GENERAL INFORMATION

Pharmacopoeial reference : In House

Quantity to be sampled :

Analysis Sample	Control sample
25 g	75 g

Shelf Life : 18 Months

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

	PREPARED BY	REVIEWED BY	APPROVED BY
Name	Rajanikant Gudekar	Manisha Dhere	Rahul Bankar
Sign/Date	15/07/24	15/07/24	15/07/24
Designation	Sr. Executive	Sr. Executive	Sr. Executive
Department	Quality control	Quality Control	Quality Assurance

Qualitative Formula:

1. Hydroxypropyl methyl cellulose IP/USP
2. Ethyl Cellulose IP/USP
3. Diethyl Phthalate IP/USP
4. Talc IP/USP
5. Titanium Dioxide IP/USP
6. Lake Ponceau 4R C.I.No. 16255
7. Lake Erythrosine C. I. No. 45430

Sr. No.	Test	Specification	Reference
1.	Appearance	Red 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 Shade		GTP/QC/008
	1) Visually	Colour shade should match visually with Standard	
	2) DE (By colour spectrophotometer)	NMT 2.0	
4.	Particle Size (Done on wet slurry)	Not less than 99.00 % w/w passes through 100 mesh	GTP/QC/006
5.	Tapped Density	Not more than 1.2 g/ml.	GTP/QC/003
6.	Ash Content	Not more than 20 % w/w.	GTP/QC/004

REVISION HISTORY FOR SPECIFICATION:

Revision No.	Revision Description	Effective Date
01	New Document	16/07/2024

	PREPARED BY	REVIEWED BY	APPROVED BY
Sign/Date	15/07/24	15/07/24	15/07/24

NOVO EXCIPIENTS PVT. LTD.	FINISHED PRODUCT STANDARD TEST PROCEDURE (STP) Quality Control Department	Page No.	1 of 4

Product Name	NOVOMIX SP-88543		
Colour	Red		
STP No.	FP/NOVOMSTP/SP-88543/01		
Reference	In House	Supersedes No.	NA
Ref. SPEC No.	FP/NOVOMPS/SP-88543/01	Effective Date	16/07/2024
Ref. Annexure No.	A/SOP/QC/030/08	Review Month	JUN/2029

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: Red 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 mortor. 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 By ATR Accessory: Make sure the crystal is free from any residue by wiping clean with IPA or methanol and delicate

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Name	Rajanikant Gudhkar	Manisha Dhere	Rahul Bankar
Sign/Date	15/07/24	15/07/24	15/07/24
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Department	Quality control	Quality Control	Quality Assurance

	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 Shade:** Instrument: Balance, Applicator, Colour matching spectrophotometer 1) Visually: Transfer mixture of 20 ml of dichloromethane and 10 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 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.	**Particle Size (Done on wet slurry):** Instrument: Balance, Stirrer, Oven Prepare a 5% dispersion of sample using the dispersion media of dichloromethane and isopropyl alcohol in proportion of 65:35(w/w). Take 5 g sample in 61.75 g (± 1 g) of dichloromethane and 33.25 g (±1 g) of isopropyl alcohol and stir the dispersion for about 45 minutes with constant stirring. Pour this dispersion on the top of the 100 mesh tarred mesh in a form of fine stream. Immediately rinse the mesh with three consecutive 50 ml portion of the dispersion media i.e. CH_2Cl_2 and IPA in proportion of 65:35; before there is any film formation on the mesh. Sieve the remaining particles on the mesh without applying any pressure with the help of running water. Continue the wet sieving process until the emerging liquid appears free of particles. Remove the mesh and dry it at 105°C.Allow the mesh to come to room temperature in a desiccator before weighing. Repeat the operation until two successive weighing do not differ by more than 1 mg. Determine the weight of dried material on the mesh. Percentage w/w passed through 100 mesh = $\frac{100 \times W1 - W5}{W1}$ Where, W1 = Weight of sample in g taken for mesh test. W2 = Weight of empty mesh W3= Weight of mesh plus residue after drying W4= Weight of mesh plus residue after drying (constant weight) W5= Weight of material remained on the mesh after drying to constant weight = W4-W2 Specification : Not less than 99.00 % w/w passes through 100 mesh

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05.	**Tapped Density:** Instrument: Balance, Densitometer Weigh 10 g of sample. Pour it in a 50 ml Graduated measuring cylinder. Set 100 taps for the densitometer. Note the volume (A) occupied by 10 g of the powder after 100 taps on the graduated cylinder. Calculations: Tapped Density in g/ml = $\frac{\text{Weight of sample}}{\text{Volume A}}$ Specification : Not more than1.2 g/ml
06.	**Ash Content** : Instrument: Balance, Muffle Furnace Heat a silica crucible at 600 ± 25° 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 ± 25° 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: Not more than 20 % w/w.

REVISION HISTORY FOR STANDARD TEST PROCEDURE:

Revision No.	Revision Description	Effective Date
01	New Document	16/07/2024

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