

	NOVO EXCIPIENTS PVT. LTD., NAVI MUMBAI FORMULATION DEVELOPMENT DEPARTMENT		
Annexure Title:	Master Reference Formula		
Annexure No.	A/SOP/FD/009/03-03	Revision No.	01
Ref. SOP No.:	SOP/FD/009	Supersedes	00
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1. DESCRIPTION:

Product Name	NOVOMIX	Colour	WHITE
Product Code No	100134	Reference Sample Batch No	22RD917
MRF No.	MRF/NM100134/293/01	Reference MFR. No.	MFR/NMPLAIN/001/01
Complying With Specification	FP/NOVOMPS/100134/01		
Standard Lot Size	1.000 Kgs		
Standard Pack Size	1 X 25 Kgs.		
Domestic /Export market In case of Export market mention RM Grades	EXPORT USP		
Retest Period /Shelf Life	One year from date of manufacturing / 36 Months		
Precautions and Special Instructions	Follow pre-manufacturing instructions		
Critical Control Care Points	1. Weighing : Critical quality point 2. Mixing & Blending : Critical control point		
Packaging Instructions	Primary packing of material should be in food grade transparent LDPE polybags		
In Process Parameters	Film to Film matching		
Storage Conditions	Store in dry place, in well closed container, away from direct heat and light.		
Other Details (If Any)	Films to be matched with Std. B.No:22RD915		

2. EQUIPMENTS REQUIRED

Sr. No.	Instrument
1.	Rapid Mixer Granulator
2.	Vibratory Sifter
3.	Weighing balance
4.	Industrial Mixer
5.	Octagonal Blender
6.	Rapid Mass Mixer
7.	Drum Blender

	PREPARED BY	REVIEWED BY	APPROVED BY
Name			
Sign/Date			
Designation			
Department			

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3. BILL OF MATERIAL

SR.NO	INGREDIENTS	RAW MATERIAL CODE	*GRADE	% W/W	STD QTY PER KG
1	Hydroxypropyl Methyl Cellulose 6 cps	R021067	IP/USP	62.5	0.6250
2	Polyethylene Glycol 400	R048033	IP/USP	6.25	0.0625
3	Titanium Dioxide	R075051	IP/USP	31.25	0.3125
	TOTAL			100.0	1.0000

* Pharmacopoeial grade of RM will be used for manufacturing as per customer requirement.

For addition of any new Customers/Raw Materials with code number:-

Note 1) Manufacturing of Novomix 100134, White can be performed by optimized mixing of individual ingredients as per following sequence.

- i. Dry mixing of 40 # passed HPMC 6cps and Titanium Dioxide for 10 min at slow speed of impeller and fast speed of chopper.
- ii. Addition of 100 # muslin cloth passed PEG 400 with use of proper equipment and mixing for 4 min at slow speed without chopper.
- iii. Mixing for 3 min at fast speed of impeller and fast speed of chopper
- iv. Passing finished product through 40 #

OR In the manufacturing of Novomix 100134, White use Base HPMC 6cps/PEG 400 /62.5/6.25

Note 2): The above parameters and time are based on Laboratory trial; however there may be change in the parameters at shop floor batches based on equipment capacity.

Note 3) i) HPMC 6 cps RM code: R021074,R021020,R021089 ii) Tio2 RM code: R075077

LIST OF CUSTOMERS:

1. STRIDES PHARMA SCIENCE LIMITED

	PREPARED BY	REVIEWED BY	APPROVED BY
Sign/Date			

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REVISION HISTORY:

Sr. No.	Revision No.	Effective Date	Revision Description
01	00	03/08/2023	Prepared First Time
02	01		Provision of mixing of individual Raw material

	PREPARED BY	REVIEWED BY	APPROVED BY
Sign/Date			