	NOVO EXCIPIENTS PVT. LTD., NAVI MUMBAI FORMULATION DEVELOPMENT DEPARTMENT		
Annexure Title:	Master Reference Formula		
Annexure No.	A/SOP/FD/009/03-03	Revision No.	04
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1. DESCRIPTION:

Product Name	NOVOMIX	Colour	BROWN
Product Code No	30082	Reference Sample Batch No	20RD113
MRF No.	MRF/NM30082/116/04	Reference MFR. No.	MFR/NMPLAIN/001/01
Complying With Specification	FP/NOVOMPS/30082/01		
Standard Lot Size	1.000 Kgs		
Standard Pack Size	1 X 25 Kgs.		
Domestic /Export market In case of Export market mention RM Grades	DOMESTIC IP		
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:20RD113		

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	Smita Naphade	Sachin Waghmare	Rahul Bankar
Sign/Date	<i>Smita Naphade</i> 27/08/24	<i>Sachin Waghmare</i> 27/08/24	<i>Rahul Bankar</i> 27/08/24
Designation	Sr. Executive	Manager - NPD	Sr. Executive
Department	Formulation Development	New Product Development	Quality Assurance

 EXCIPIENTS PVT. LTD.	NOVO EXCIPIENTS PVT. LTD., NAVI MUMBAI FORMULATION DEVELOPMENT 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	R021020	IP/USP	65.0	0.6500
2	Polyethylene Glycol 400	R048056	USP	13.0	0.1300
3	Polysorbate 80	R054033	IP/USP	2.0	0.0200
4	Titanium Dioxide	R075051	IP/USP	17.35	0.1735
5	Red Iron Oxide	R060002	USP	2.30	0.0230
6	*Lake Sunset Yellow	R031002	C.I No:15985	0.35	0.0035
	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 30082, Brown can be performed by optimized mixing of individual ingredients as per following sequence.

- Dry mixing of 20 # passed HPMC 6cps, Titanium Dioxide, Red Iron Oxide and Lake Sunset Yellow for 10 min at slow speed of impeller and chopper.
- Addition of 100 # muslin cloth passed PEG 400 & Polysorbate 80 with use of proper equipment and mixing for prescribed time at slow speed without chopper.
- Finally mixing for 5 min at fast speed of impeller and chopper
- Passing finished product through 40 #

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.

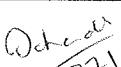
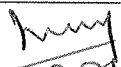
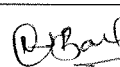
Note 3) In the manufacturing of Novomix 30082, Brown use Base HPMC6 cps/PEG 400/65/13 or HPMC 6cps/ PEG 400/60/12. Additional quantities such as HPMC6cps- 5%, PEG 400-1% should be added externally in the base to match actual composition All these changes should be reflected in Base BMR


Note 2) i) HPMC 6 cps RM code: R021067, R021074, R021089
iii) PEG 400 RM code: R048033

ii) Tio2 RM code: R075077

LIST OF CUSTOMERS:

1. LUPIN LIMITED

	PREPARED BY	REVIEWED BY	APPROVED BY
Sign/Date	 27/08/24	 27/08/24	 27/08/24


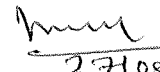
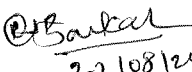
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REVISION HISTORY:

Sr. No.	Revision No.	Effective Date	Revision Description
01	00	20/07/2021	Prepared First Time
02	01	17/02/2022	MRF of Product Novomix 30082 revised as per Annexure of A/SOP/FD/009/03 and included of RM code
03	02	15/10/2022	Base manufacturing note added
04	03	08/08/2023	RM code for HPMC 6 cps, PEG 400 and Tio2 updated
05	04	27/08/24	Provision of mixing of individual Raw material

	PREPARED BY	REVIEWED BY	APPROVED BY
Sign/Date	 27/08/24	 27/08/24	 27/08/24