
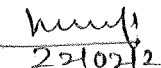
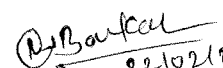
	NOVO EXCIPIENTS PVT. LTD., NAVI MUMBAI FORMULATION DEVELOPMENT DEPARTMENT		
Annexure Title:	Master Reference Formula		
Annexure No.	A/SOP/FD/009/03-03	Revision No.	09
Ref. SOP No.:	SOP/FD/009	Supersedes	08
Page No.	1 of 4	Effective Date:	22/02/2024


1. DESCRIPTION:

Product Name	NOVOMIX	Colour	ORANGE
Product Code No	GEN-55023	Reference Sample Batch No	250921
MRF No.	MRF/NMGEN-55023 025/09	Reference MFR. No.	MFR/NMGEN/002/01
Complying With Specification	FP/NOVOMPS/GEN-55023/02		
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 NA		
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	Tablet to tablet matching		
Storage Conditions	Store in dry place, in well closed container, away from direct heat and light.		
Other Details (If Any)	Tablet to be matched with Latest Commercial Batch		

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	 22/02/24	 22/02/24	 22/02/24
Designation	S. Executive	Manager - NPD	Sr. Executive
Department	Formulation Development	New Product Development	Quality Assurance

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Page No.	2 of 4	Effective Date:	22/02/2024

3. BILL OF MATERIAL

SR.NO	INGREDIENTS	RAW MATERIAL CODE	*GRADE	% W/W	STD QTY PER KG
1	Polyvinyl Alcohol	R055081	IP/USP	52.0	0.5200
2	Lecithin	R079083	IP/USP	2.0	0.0200
3	Polyethylene Glycol 4000	R049079	IP/USP	13.85	0.1385
4	Talc	R074050	IP/USP	15.00	0.1500
5	Titanium Dioxide	R075077	IP/USP	12.5	0.1250
6	FD&C Yellow#6 (D.C -20-28%)	R040002	C.I No:15985	3.0	0.0300
7.	Lake Tartrazine	R032002	C.I No:19140	0.65	0.0065
8.	Colloidal Silicon Dioxide	R009015	IP/USP	1.0	0.0100
	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 process of Novomix GEN-55023, Orange is as per following sequence.

SIEVING OF RAW MATERIALS

1. Sift Polyvinyl Alcohol, Lecithin, Polyethylene Glycol 4000, Colloidal Silicon Dioxide and Talc using 20 # sieve
2. Sift Titanium Dioxide, FD&C Yellow#6 and Lake Tartrazine using 40 # sieve

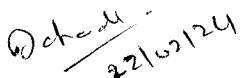
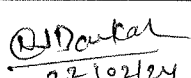
PREPARATION OF PREMIX


IN INDUSTRIAL MIXER/ RAPID MASS MIXER (APEX MIXER)

1. Take Lecithin and Talc in 1: 2 proportions in suitable mixer; mix it at fast speed for predetermined time.
2. Then sift it using 80 # sieve, and divide into lots as per capacity of mixer / RMG.

PREPARATION OF LOTS

Take Premix and other material in suitable mixer / RMG and prepare lots.

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Ref. SOP No.:	SOP/FD/009	Supersedes	08
Page No.	3 of 4	Effective Date:	22/02/2024

SIEVING OF FINISHED PRODUCT

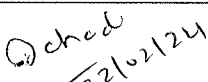
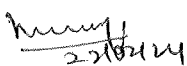
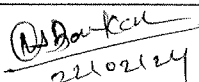
Sift all the lots through 40# sieve.


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

Note: i) Tio2 RM code: R075052, R07051 ii) PVA RM code: R055066, R055034, R055092, R055065
 iii) Lecithin RM code: R079069 iv) PEG 4000 RM code: R049033, R049090.
 v) Talc RM code: R104094

LIST OF CUSTOMERS:

1. UNIQUE PHARMACEUTICALS LABS (DIV OF J.B CHEMICALS & PHARMACEUTICALS LTD)- DOMESTIC
2. M/S TRENDS PHARMACEUTICALS A/C J.B CHEMICALS & PHARMACEUTICALS LTD (DOMESTIC)
3. M/S VAPI CARE PHARMA PVT LTD A/C J.B CHEMICALS & PHARMACEUTICALS LTD (DOMESTIC)
4. M/S J.B. CHEMICALS & PHARMACEUTICALS LTD A/C J.B. CHEMICALS & PHARMACEUTICALS LTD (DOMESTIC)
5. M/S UNIQUE PHARMACEUTICALS LABS A/C UNIQUE PHARMACEUTICALS LABS (DOMESTIC)
6. M/S CURIS LIFESCIENCES PVT LTD A/C J.B CHEMICALS & PHARMACEUTICALS LTD (DOMESTIC)
7. M/S CENTURION REMEDIES PVT LTD A/C J.B. CHEMICALS & PHARMACEUTICALS LTD (DOMESTIC)
8. M/S.KASHMIK FORMULATION PRIVATE LIMITED A/C JB CHEMICALS & PHARMA LTD (DOMESTIC)
9. M/S SOTAC PHARMACEUTICAL PVT LTD A/C J.B CHEMICALS & PHARMACEUTICALS LTD (DOMESTIC)

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Page No.	4 of 4	Effective Date:	22/02/2024

REVISION HISTORY:

Sr. No.	Revision No.	Effective Date	Revision Description
01	00	10/09/2020	Prepared First Time
02	01	26/02/2021	As per customer requirement Quantitative formulation changed, specification for ash test need to be revised as the quantitative formula changed
03	02	09/06/2021	Addition of Customer M/s Trends, M/s Vapi care Pharma & M/s J.B Chemicals A/c J.B Chemicals
04	03	19/10/2021	MRF of Product Novomix GEN-55023 revised as per Annexure of A/SOP/FD/009/03 and included customer Unique Pcals Labs A/c Unique Pcals Labs
05	04	05/01/2022	MRF of Product Novomix GEN-55023 revised as per Annexure of A/SOP/FD/009/03 and included customer Curis Lifesciences Pvt Ltd A/c J.B Chemicals & Pharmaceuticals Ltd
06	05	04/08/2022	Raw Material code for Tio2 (Cosmo) updated ,editorial changes
07	06	24/07/2023	RM code for PVA, Lecithin, PEG 4000 and Talc updated
08	07	18/11/2023	RM code for PVA updated
09	08	18/12/2023	RM code for Talc updated
10	09	22/02/2024	RM code for Tio2 :R075052, R07051 , PVA :RM055065 ,PEG 4000: R049090 updated and manufacturing process added.

	PREPARED BY	REVIEWED BY	APPROVED BY
Sign/Date	<i>Dechak</i> 22/02/24	<i>humpy</i> 22/02/24	<i>B. B. Kulkarni</i> 22/02/24