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	EXCIPIENT SPECIFICATION	Effective Date	12/10/2022
Material Name	NOVOMIX MR (AQ)-107064 WHITE		
Specification No.	D/EXSPEC/2022/0060-000		

Item Code	RN0085	Retest Period	12 Months
Material Name	NOVOMIX MR (AQ)-107064 WHITE		
Reference STP Number	Follow the current version of D/EXSTP/2022/0059		
Pharmacopoeial status	In-house		

Sr. No	Tests	Specifications
1.	Appearance #	White to off white powder .
2.	Identification by IR	IR spectrum of test sample should be concordant with the IR spectrum of standard.
3.	Colour shade	Colour shade should match visually with standard.
4.	Particle Size # (Sieve Test done on Wet Slurry)	Not less than 99.00% w/w passes through 100 # mesh.
5.	Tapped density	Not more than 1.2 g/ml
6.	Ash (w/w)	Not more than 40.00%

Retesting Parameters


Note:

- 1) Visual shade difference in powder between two batches of the same code does not mean color difference in the material.
- 2) Material to be released as per the above specifications and along with the review of the supplier COA for the following ingredients mentioned in the supplier COA;
 - i) Polyvinyl alcohol IP
 - ii) Lecithin IP
 - iii) Titanium Dioxide IP
 - iv) Triacetin USP
 - v) Talc IP

	PREPARED BY	REVIEWED BY	APPROVED BY
e-Signature	Sejal.Bhende16225	Balaji. Subbarayalu19135	Arvind. Katkar1274
Date and Time	11/10/2022 16:58	12/10/2022 10:13	12/10/2022 11:32
Responsibility	ADL/CQA/QC	FRD/CQA/QC	DRA/CQA/QA

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Revision History

Sr.No.	Version No.	Revision Details	Reason for Revision
1	000	New Document prepared.	As per eCCP No. Q/CO/22/94

Reference Copy

	PREPARED BY	REVIEWED BY	APPROVED BY
e-Signature	Sejal.Bhende16225	Balaji. Subbarayalu19135	Arvind. Katkar1274
Date and Time	11/10/2022 16:58	12/10/2022 10:13	12/10/2022 11:32
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