Issuance Code: 2021Q0087985 Issued By and On: Rashid.Husain43771 05/06/2021

ALKEM	ALKEM LABORATORIES LIMITED	Page No.	Page 1 of 2	
	EXCIPIENT SPECIFICATION	Effective Date	04/06/2021	
Material Name	NOVOMIX 60062 (LIGHT PINK)			
Specification No.	D/EXSPEC/2021/0027-000			

Item Code	RN0071	Retest Period	12 Months
Material Name	NOVOMIX 60062 (LIGHT PINK)		
Reference STP Number	Follow the current version of D/EXSTP/2021/0023		
Pharmacopoeial status	In-house		

Sr. No	Tests	Specifications	
1.	Appearance #	Light Pink Powder.	
2.	Colour shade	Colour shade should match visually with standard	
3.	Particle Size # (Sieve Test done on Wet Slurry)	Not less than 99%w/w passes through 100 mesh.	
4.	Tapped density	Not more than 1.2 g/cc	
5.	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) Titanium Dioxide IP
 - ii) Talc IP
 - iii)Polyethylene Glycol IP
 - iv) Hydroxypropyl methyl cellulose IP
 - v) Red Iron Oxide USP
 - vi)Yellow Iron Oxide USP

	PREPARED BY	REVIEWED BY	APPROVED BY
e-Signature	Sejal.Bhende16225	Balaji. Subbarayalu19135	Arvind. Katkar1274
Date and Time	02/06/2021 17:22	04/06/2021 11:28	04/06/2021 12:27
Responsibility	ADL/CQA	FRD/CQA	DRA/CQA

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(A)	ALKEM LABORATORIES LIMITED	Page No.	Page 2 of 2
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Revision History

Sr.No.	Version No.	Revision Details	Reason for Revision
1	000	New Document prepared.	As per eCCP No. R/CO/21/2

	PREPARED BY	REVIEWED BY	APPROVED BY
e-Signature	Sejal.Bhende16225	Balaji. Subbarayalu19135	Arvind. Katkar1274
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