Issuance Code: 2022Q0169124 Issued By and On: Rupesh.Hake64146 12/10/2022

ALKEM	ALKEM LABORATORIES LIMITED	Page No.	Page 1 of 2
	EXCIPIENT SPECIFICATION	Effective Date	12/10/2022
Material Name	NOVOMIX 110143 YELLOW		
Specification No.	D/EXSPEC/2022/0061-000		

Item Code	RN0084	Retest Period	12 Months
Material Name	NOVOMIX 110143 YELLOW		
Reference STP Number	Follow the current version of D/EXSTP/2022/0062		
Pharmacopoeial status	In-house		

Sr. No	Tests	Specifications
110		
1.	Appearance #	Yellow 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 #	Not less than 99.00% w/w passes through 100 # mesh.
	(Sieve Test done on Wet Slurry)	
5.	Tapped density	Not more than 1.2 g/ml
6.	Ash (w/w)	Not more than 30.00%

[#] 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) Hydroxypropyl methyl cellulose IP
 - ii) Polyethylene Glycol IP
 - iii) Titanium Dioxide IP
 - iv)Yellow iron Oxide USP

	PREPARED BY	REVIEWED BY	APPROVED BY
e-Signature	Sejal.Bhende16225	Balaji. Subbarayalu19135	Arvind. Katkar1274
Date and Time	11/10/2022 17:01	12/10/2022 10:17	12/10/2022 11:40
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

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