 <b>ALKEM</b>	<b>ALKEM LABORATORIES LIMITED</b>	<b>Page No.</b>	<b>Page 1 of 2</b>
	<b>EXCIPIENT SPECIFICATION</b>	<b>Effective Date</b>	<b>12/10/2022</b>
<b>Material Name</b>	<b>NOVOMIX 100111 WHITE</b>		
<b>Specification No.</b>	<b>D/EXSPEC/2022/0063-000</b>		

<b>Item Code</b>	<b>RN0087</b>	<b>Retest Period</b>	<b>12 Months</b>
<b>Material Name</b>	<b>NOVOMIX 100111 WHITE</b>		
<b>Reference STP Number</b>	<b>Follow the current version of D/EXSTP/2022/0061</b>		
<b>Pharmacopoeial status</b>	<b>In-house</b>		

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

	<b>PREPARED BY</b>	<b>REVIEWED BY</b>	<b>APPROVED BY</b>
<b>e-Signature</b>	<b>Sejal.Bhende16225</b>	<b>Balaji. Subbarayalu19135</b>	<b>Arvind. Katkar1274</b>
<b>Date and Time</b>	<b>11/10/2022 17:07</b>	<b>12/10/2022 10:18</b>	<b>12/10/2022 11:45</b>
<b>Responsibility</b>	<b>ADL/CQA/QC</b>	<b>FRD/CQA/QC</b>	<b>DRA/CQA/QA</b>

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	<b>EXCIPIENT SPECIFICATION</b>	<b>Effective Date</b>	<b>12/10/2022</b>
<b>Material Name</b>	<b>NOVOMIX 100111 WHITE</b>		
<b>Specification No.</b>	<b>D/EXSPEC/2022/0063-000</b>		

**Revision History**

<b>Sr.No.</b>	<b>Version No.</b>	<b>Revision Details</b>	<b>Reason for Revision</b>
<b>1</b>	<b>000</b>	<b>New Document prepared.</b>	<b>As per eCCP No. Q/CO/22/95</b>

	<b>PREPARED BY</b>	<b>REVIEWED BY</b>	<b>APPROVED BY</b>
<b>e-Signature</b>	<b>Sejal.Bhende16225</b>	<b>Balaji. Subbarayalu19135</b>	<b>Arvind. Katkar1274</b>
<b>Date and Time</b>	<b>11/10/2022 17:07</b>	<b>12/10/2022 10:18</b>	<b>12/10/2022 11:45</b>
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**CQA/0002-F0022-002**