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	EXCIPIENT SPECIFICATION	Effective Date	09/04/2020
Material Name	Novomix Orange SP-58500		
Specification No.	D/EXSPEC/2020/0033-000		

Item Code	RN0066	Retest Period	12 Months
Reference STP Number	Follow the current version of D/EXSTP/2020/0020		
Pharmacopoeial status	In-house		

Sr. No	Tests	Specifications
1.	Appearance #	Orange coloured finely ground powder.
2.	Colour shade	Sample shade matches visually with standard.
3.	pH (2% Slurry) #	Between 4.0 and 7.0
4.	Particle Size # (Sieve Test done on Wet Slurry)	Not less than 99.00% w/w passes through 100 # ASTM sieve
5.	Tapped density	Not more than 1.2 g/cc
6.	Ash (w/w)	Not more than 25.00%
7.	Arsenic	Not more than 3 ppm
8.	Heavy metals	Not more than 20 ppm

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 USP
- iv) Hydroxypropyl methyl cellulose IP
- v) Lake Sunset Yellow C.I. No. 15985
- vi) Butter Scotch Flavour

	PREPARED BY	REVIEWED BY	APPROVED BY
Designation Department	Sr Executive ADL	Sr.Manager FDG	AGM DRA
e-Signature	Sejal.Bhende16225	Piumitali. Bera16148	Arvind. Katkar1274
Date and Time	07/04/2020 16:36	07/04/2020 23:12	08/04/2020 09:31

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Material Name	Novomix Orange SP-58500		
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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/20/118

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	PREPARED BY	REVIEWED BY	APPROVED BY
Designation Department	Sr Executive ADL	Sr.Manager FDG	AGM DRA
e-Signature	Sejal.Bhende16225	Piumitali. Bera16148	Arvind. Katkar1274
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