			WASIL	KUUI
	RAW MATERIAL S	PECIFICATION L		1 of 3
NOVO EXCIPIENTS	Quality Control Department		Page No.	
Name of Raw Material	Sodium Alginate 800			<u> </u>
Specification No.	RM/SPEC/ IP /107-02	Supersedes No.:	01	
Reference	IP	Effective Date	21/05/201	-5.000
Ref. Annexure No.	A/SOP/QC/030/02	Review Month	Apr12e3	

GENERAL INFORMATION

Pharmacopeial reference

: IP

Special requirement of

: Material should be packed in food grade fiber bags.

pack

Approved vendor

: Please refer current approved vendor list.

Handling hazards

: Refer Material Safety Data Sheet

Quantity to be sampled

Analysis Sample	Control sample
60 g	120 g

Retest Period

: 12 Months

Storage

: Store protected from light.

	PREPARED BY	REVIEWED BY	APPROVED BY
Name	Manisha Dhere	Appa S. Shinde	Mariel m. I.
Sign/Date	102125 21105125	Air	Manus Malaje
Designation	So-Executive	21105125	7 21010
Department		Asst-Manager Quality Control	Manager Acuse

MASTER COPY

	RAW MATERIAL SPECIFICATION	Page	2 of 3
<u>novo</u> excipients PVT. LTD.	Quality Control Department	No.	
Name of Raw Material	Sodium Alginate 800		
Specification No.	RM/SPEC/IP/107-02	***************************************	

Sr. No.	TEST	SPECIFICATIONS	REFERENCE
01.	Description #	A cream-coloured to pale yellowish brown powder.	IP
02.	Solubility	Slowly soluble in water forming a viscous, colloidal solution; practically insoluble in ethanol (95%) and in ether.	IP
03.	Identification		
	Test A	A voluminous gelatinous precipitate should be produced.	
	Test B	A gelatinous mass should be produced.	
	Test C	The upper layer exhibits a deeper bluish red colour than the upper layer should be obtained by repeating the procedure without the substance under examination.	IP
	Test D : Reaction of Sodium salts	A dense white precipitate should be formed.	
04.	Heavy Metals	NMT 40 ppm	IP
05.	Chloride	NMT 1.0 %	IP
06.	Sulphated Ash	30.0 to 36.0 %	IP
07.	Loss On Drying #	NMT 15.0 %	IP
08.	Microbial Contamination		
	1. Microbial Enumeration Tests		
	Total Aerobic Viable Count (TAVC)	NMT 10 ³ cfu/g	
	2. Tests for Specified Microorganisms		IP
	Escherichia coli	Absent/1g	
Ī	Salmonella	Absent/10g	
	Shigella	Absent/10g	
: Re-eva	luation tests	· ·	

	PREPARED BY	REVIEWED BY	APPROVED BY
Sign/Date	21105125	21/05/25	700 80

MASTER COPY

	RAW MATERIAL SPECIFICATION	Page	3 of 3
NOVO EXCIPIENTS PVT. LTD.	Quality Control Department	No.	
Name of Raw Material	Sodium Alginate 800		
Specification No.	RM/SPEC/IP/107-02		

REVISION HISTORY FOR SPECIFICATION:

Revision No.	Revision Description	Effective Date
01	Specification prepared as per Approved Change control CC/PD/25/002	28/01/2025
02	SPEC and ATR prepared as per approved change control No. CC/QC/25/008	21/05/2005

	PREPARED BY	REVIEWED BY	APPROVED BY
Sign/Date	21105125	105/25	700 % C