RAW MATERIAL SPECIFICATION			Page	1 of 2
NOVO EXCIPIENTS PVT. LTD.	Quality Control Department		No.	
Name of Raw Material	Lake of Allura Red / FD & C Red # 40 Al Lake (38 % - 42 %)			%)
Specification No.	RM/SPEC/IH/099-01	Supersedes No.	NA	
Reference	IH	Effective Date		
Ref. Annexure No.	A/SOP/QC/030/02	Review Month		

GENERAL INFORMATION

Pharmacopoeial reference : IH

Special requirement of : Material should be packed in LDPE bag in HDPE/ Fiber drum

pack

Approved vendor : Please refer current approved vendor list.

Handling hazards : Refer Material Safety Data Sheet

Quantity to be sampled

Analysis Sample Control sample 30 g 60 g

Retest Period : 12 Months

Storage : Store in an ambient temperature and dry place

	PREPARED BY	REVIEWED BY	APPROVED BY
Name			
Sign/Date			
Designation			
Department			

	RAW MATERIAL SPECIFICATION	Page	2 of 2	
NOVO EXCIPIENTS PVT. LTD.	Quality Control Department	No.		
Name of Raw Material Lake of Allura Red / FD & C Red # 40 Al Lake (38 % - 42 %)				
Specification No.	RM/SPEC/IH/099-01			

Sr. No.	TEST	SPECIFICATIONS	REFERENCE
01.	Description #	Dark Red coloured powder	In-House
03.	pH (2% slurry) #	3.5 –5.5	In-House
04.	Loss on Drying #	NMT 17.0 %	In-House
05.	Particle Size	NMT 2.0 % w/w retained on 300 mesh	In-House
06.	Bleeding (2% slurry)	NMT 0.4 %	In-House
07.	Dye Content (As is basis) #	38.0% - 42.0%	In-House
# : Re-evaluation tests			

REVISION HISTORY FOR SPECIFICATION:

Revision No.	Revision Description	Effective Date
01	Specification prepared as per Approved Change	
O1	control CC/PD/24/003	

	PREPARED BY	REVIEWED BY	APPROVED BY
Sign/Date			