



CHAITANYA BIOLOGICALS PVT. LTD.

75/2, Malkapur By-Pass, N.H. No. 06, Malkapur – 443101. Dist. Buldana (M.S.), India

Tel. (07267) 225570, 224105, 225435, Fax: (07267) 223570, 223433

E mail: chaitbio@rediffmail.com

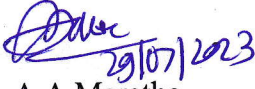
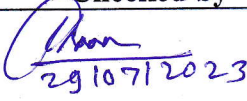

Web site: www.chaitanyabiological.com

CERTIFICATE OF ANALYSIS

Name of The Product	Iron (III) Hydroxide Polymaltose Complex 34%		Page 1 of 1
Batch No./Lot No	IPC34/B231111.	Batch Size	500.192 Kgs
Manufacturing Date	July – 2023.	Expiry Date	June – 2026.
A.R. No.	23FG0870	Date of Analysis complete	28/07/2023.

S.R No	Test parameter	Specification	Observed value
1.0	Description	Reddish brown to brown coloured spray dried powder.	Complies.
2.0	Identification:		
2.1	Test for Iron / Iron (III) Bound	To be positive.	Complies.
2.2	Test for Polymaltose	To be positive.	Complies.
2.3	Test for Oligomaltose	To be negative.	Complies.
2.4	Ionized/free iron (III)	To be negative.	Complies.
3.0	Solubility (5 % w/v.)	Soluble in water. Insoluble in organic solvent	Complies.
4.0	pH (5 % w/v. solution)	5.50 – 7.50 at 27°C	6.61 at 27°C
5.0	Loss on drying	Not more than 8.00 % w/w.	2.67 % w/w.
6.0	Total elemental iron	26.00 – 36.00 % w/w. (On dried basis)	33.51% w/w.
7.0	Polymaltose content	25.00 – 50.00 % w/w.	28.36 % w/w.
8.0	Sodium chloride content	Not more than 3.00 % w/w.	1.96 % w/w.
9.0	Arsenic	Not more than 3 ppm.	< 0.0005 ppm
	Mercury	Not more than 3 ppm.	< 0.0005 ppm
	Lead	Not more than 25 ppm.	0.857 ppm
	Cadmium	Not more than 25 ppm.	< 0.0005 ppm
	Copper	Not more than 60 ppm.	< 0.0005 ppm
	Zinc	Not more than 150 ppm.	21.951 ppm
10.0	Total aerobic microbial count	Not more than 1000 CFU /gm.	140 CFU/gm.
11.0	Total combined yeast and mould count	Not more than 100 CFU /gm.	< 10 CFU/gm.
12.0	Enterobacteriaceae count	Not more than 10 CFU /gm.	< 10 CFU/gm.
13.0	Pathogen		
13.1	E. coli.	To be absent.	Absent.
13.2	S. typhi	To be absent.	Absent.
13.3	S. aureus	To be absent.	Absent.
13.4	P. aeruginosa	To be absent.	Absent.

Remarks: The sample **complies/ does not comply** with respect to above test as per In-house Specification.

Prepared By	Checked by	Approved by
 Mr. A.A. Marathe. QC Analyst	 Mr. G. D. Kshirsagar. QC Manager	 Dr. R. B. Ingle QA Manager

F-(QC072)-01/00