



DERREN HEALTHCARE PVT. LTD.

Plot No. #33, 35/p & 36/p XCELON Industrial Park, Lane besides Chak-de-India
Weighbridge, Sarkhej-Bavla Highway Village: Vasna-Chacharvadi,
Ahmedabad-382 213, Gujarat (India)

CERTIFICATE OF ANALYSIS
(FINISHED PRODUCT)

Name of Product	Ferric Carboxymaltose Injection 50mg/ml (FORTOSE FCM)		
Batch No.	BY24001	A.R. No.	FP/24/0006
Mfg. Date	01/24	Exp. Date	12/25
Sampled Qty.	05 Nos.	Date of Analysis	13/01/24
Batch Size	60 Ltr.	Date of Release	01/02/24
Container Type	Amber colour Glass Vial	Fill volume	10.0 ml
Mfg. Lic. No.	G/28/1862		

Sr. No.	Test	Result	Specification
1	Description	A dark Brown aqueous, isotonic Colloidal Solution	A dark Brown aqueous, isotonic Colloidal Solution
2	Extractable volume	10.0 ml	NLT 10.0 ml
3	Identification		
3.1	Identification A by chemical	Red Colour is discharge	red colour should discharge
3.2	Identification B A) Molecular weight determination (Mw) [#]	2,26,864 Da	Between 100000 and 350000 Dalton
	B) Molecular weight determination (Mn) [#]	93,682 Da	Not less than 35000.
4	pH	6.3	5.0 to 7.0
5	Bacterial endotoxin	Less than 0.25 Eu/mg of iron	Not More than 0.25 EU/mg of Iron.
6	Particulate matter		
6.1	By Visual Inspection	The solution is free from particles of the foreign matter that is observed on visual inspection method.	The solution should be free from particles that can be observed by inspection with the unaided eye.
6.2	By Light Obscuration Method	≥10 microns= 84.67 /Container ≥ 25 Microns= 1.33 /Container	Sub visible particle by LPC ≥10 microns=NMT 6000/Container ≥ 25 Microns=NMT 600/Container
7	Sterility test	Sterile	Should be sterile
8	Assay		
8.1	Each ml Contains: Ferric carboxymaltose eq. to elemental iron 50 mg	102.7 %	90.0% and 110.0% of the labeled amount of Iron

Abbreviation: LPC – Liquid particle count, NLT – Not less than, EU – Endotoxin unit,

3.2 (A) and (B) tests are carried out at outside testing

Conclusion: The above sample complies as per In House specification. ✓
In the opinion of the undersigned the sample referred to above is of standard / ~~not of standard~~ quality as defined in the act and the rules made there under for the reasons given above.

Prepared By	Checked By	Approved By
 01/02/24 QC OFFICER/EXECUTIVE	 01/02/24 QC Sr. OFFICER/Sr. EXECUTIVE	 01/02/24 QUALITY MANAGER