



# Pacebiotech Pharma (India) Pvt. Ltd.

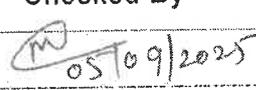
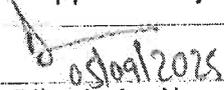
Surajpur, Nahan Road Paonta sahib Dist. Sirmour (H.P)

## CERTIFICATE OF FINISH PRODUCT ANALYSIS

Product Name:	Fortose FCM Injection (Ferric Carboxymaltose Injection 50 mg/ml)		
Batch No.	25VH101C	A.R. No.	FP250247
Batch Size	5010 Vials	Sample Quantity	60 Nos
Mfg. Date	08/2025	Date of Testing	20/08/2025
Exp. Date	07/2027	Date of Release	05/09/2025
Reference Batch No	25VH101	MFG. Lic. No.	N-MB-2023/263

Sr. No.	Test	Specification	Observation
1.	Description	A Dark Brown colored Liquid.	Dark Brown colored Liquid
2.	pH	Between 5.0 to 7.0	6.37
3.	Extractable Volume	NLT 10.0 ml	10.0 ml
4.	Bacterial Endotoxins	NMT 0.5 Endotoxin unit per mg	Less than 0.5 Endotoxin unit per mg
5.	Particulate Matter	Injections that are solutions, when examined under suitable conditions of visibility, are clear and practically free from particles that can be observed on visual inspection by the unaided eye.	Complies
6.	Sterility	Should be complies	Sterile
7.	Assay: Each ml contains: Ferric Carboxymaltose Eq. to Elemental Iron 50 mg	45.0 mg to 55.0 mg (90.0 % to 110.0 %)	52.5 mg 105.0 %

Remark: The sample is complies as per IP /BP/ USP/ICH specification.

	Prepared By	Checked By	Approved By
Sign/Date	 05/09/2025	 05/09/2025	 05/09/2025
Name	Prayash	Manisha Thakur	Bhupinder Navet
Designation	Officer QC	Executive-QC	Head-QC