



PRECISE BIO PHARMA PRIVATE LIMITED

8, Pharma City, Selaqui, Dehradun – 248011

CERTIFICATE OF ANALYSIS

Finished Goods

Product Name	ISOTOSE 1G	Report No	PRE-09250263/F
Generic Name	Iron (III) Isomaltoside 1000 Solution for Injection/Infusion 100 mg/ml	Ref. No.	GFI-022/25-26
Specification No.	PADL/FP/SPC/022-02	Date of Receipt	09/09/2025
Mfg. & Supp. By	Precise Bio Pharma Private Limited	Date of Analysis	09/09/2025
Page No	1/1	Date of Release	29/09/2025
Batch No.	Batch Size	Date of Mfg.	Date of Exp.
EIII2509C	50 Liter	09/2025	08/2027
			Sample Qty
			71 Vials

Sr. No	PARAMETERS	SPECIFICATIONS	RESULTS
01	Description	Dark brown non transparent solution	Dark brown non transparent solution
02	Identification Test (For Iron (III) Salt)	Brown precipitation should be observed	Complies
03	pH	5.00 to 7.00	6.29
04	Molecular weight Determination by GPC		
	A. Weight-Average molecular weight (Mw)	1,20,000 Da to 2,20,000 Da	143031 Da
	B. Number –Average molecular weight (Mn)	Not less than 60,000 Da	91258 Da
	C. Polydispersity Index (Mw/Mn)	Not more than 2.0	1.56733
05	Volume in Container	5.0 to 5.3 ml	5.05 ml
06	Density	1.10 gm/ml to 1.25 gm/ml	1.15 gm/ml
07	Chloride Content	Not more than 3 % w/v	0.29 % w/v
08	Free Ferric Iron	Should be absent	Absent
09	Assay of Iron	9.00 % to 11.00 % w/v (90.0 % to 110.00 %)	10.22 % w/v (101.80 %)
10	Assay of Isomaltoside	15.00 % to 25.00 % w/v	21.87 % w/v
11	Bacterial Endotoxins	Not more than 0.25 EU/mg	Less than 0.25 EU/mg
12	Sterility	No growth of micro-organism should occur	Complies
13	Additional Test:		
	Osmolality	To be recorded	356 mosmol /kg
	Particulate matter		
	a. Particles ≥ 10 µm	Not more than 3000 / container	280 / container
	b. Particles ≥ 25 µm	Not more than 300 / container	11 / container

Remarks : In the Opinion of the under signed, the sample referred to above is of /is not of standard quality as per IP, USP, BP, BIS, IHS, as defined in the act and the rules made there under.

	Analyzed By	Checked by	Approved by
Designation	Office/ly (QC)	Asst. Manager	Name : Anshuman Singh Manager
Sign			
Date	29/09/2025	29/09/2025	29/09/2025