



Hindustan Polyfab
Plot No.12 Ind. Area Davni Baddi (H.P.)
Quality Control Department

Certificate of Analysis for Finish Product

Department : Quality Control		Reference Specification No: FPS/001	
Product Name	STERILE WATER FOR INJECTIONS IP	A.R.No	QC/FP/25/447
Batch No	WD25C007	Packing Size	10ML
Mfg. By	Hindustan Polyfab	Mfg.lic .no.	MB/18/1038
Mfg Date	03/2025	Exp. Date	02/2029
Batch Size	3200 Ltr.	Quantity Sampled	115 Amps.
Testing Date	24/03/2025	Completion Date	07/04/2025

Sr.	Test	Specification	Result
01	Description	A clear, colourless liquid, odourless.	A clear, colourless liquid, odourless.
02	Appearance of solution	Clear, colourless and practically free from suspended particles	Clear, colourless and practically free from suspended particles.
03	Acidity or alkalinity	Should meet the requirements	Complies
04	Ammonium	Not more than 0.6 ppm	Complies
05	Calcium & magnesium	A pure blue colour is produced	Complies
06	Chlorides	Not more than 0.5 ppm	Complies
07	Nitrates	Not more than 0.2 ppm	Complies
08	Sulphates	The appearance of the solution does not change for at least 1 hour	Complies
09	Oxidisable substances	The pink colour of the solution does not disappear completely	Complies
10	Residue on evaporation	Not more than 0.004% w/w	0.0003% w/w
11	Particulate matter	≥ 10 µm particles, NMT 6000 per container ≥ 25 µm particles, NMT 600 per container	14.0 Particles/Container 1.3 Particles/Container
12	Extractable volume	The volume is not less than the nominal volume.	10.2 ml
13	Bacterial endotoxins	Not more than 0.25 Endotoxin Unit per ml.	Complies
14	Sterility	No growth observed during incubation period of 14 days.	Complies
15	pH	4.5 to 7.0	5.76
16	Conductivity	Not more than 25 µS/cm	1.704 µS/cm

Remark: The above product complies/ does not comply as per IP / In-house specification.

	Prepared By	Checked By	Approved By
Name	Anjali	Gautam Sharma	Imran
Signature			
Date	07/04/2025	07/04/2025	07/04/2025