



**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 INJS. IP	A.R.No	QC/FP/24/711
Batch No	WA24F001	Packing Size	5 ML
Mfg. By.	Hindustan Polyfab	Mfg.lic .no.	MB/18/1038
Mfg Date	06/2024	Exp. Date	05/2028
Batch Size	1100 Ltr.	Quantity Sampled	230 Amps.
Testing Date	05/06/2024	Completion Date	19/06/2024

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	The resulting solution is red on the addition of 0.01M Sodium hydroxide and yellow on the addition of 0.01M HCL	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	0.0004% w/w
11	Particulate matter	≥ 10 µm particles, NMT 6000 per container ≥ 25 µm particles, NMT 600 per container	8.6 Particles/Container 0.3 Particles/Container
12	Extractable volume	The volume is not less than the nominal volume.	5.2 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	5.83
16	Conductivity	Not more than 25 µS/cm	1.937 µS/cm

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

	Prepared By	Checked By	Approved By
Name	Zeeshan Ali	Gautam Sharma	Imran
Signature			
Date	19/06/2024	19/06/2024	19/06/2024