



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/24/717
Batch No	WD24F002	Packing Size	10ML
Mfg. By.	Hindustan Polyfab	Mfg.lic .no.	MB/18/1038
Mfg Date	06/2024	Exp. Date	05/2028
Batch Size	3200 Ltr.	Quantity Sampled	115 Amps.
Testing Date	06/06/2024	Completion Date	20/06/2024

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	0.0006% w/w
11	Particulate matter	≥ 10 µm particles, NMT 6000 per container ≥ 25 µm particles, NMT 600 per container	4.0 Particles/Container 0.0 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	1.582 µS/cm

Remarks: 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	20/06/2024	20/06/2024	20/06/2024