



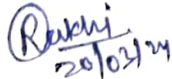

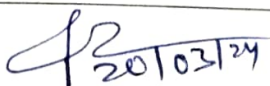
M/S IVM PHARMACIA
Plot No. 05, Industrial Township,
Bhatoli- Kalan, Baddi (H.P.) -173205
CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

QUALITY CONTROL DEPARTMENT

PRODUCT NAME	STERILE WATER FOR INJECTIONS IP	BATCH NO.	I0324002
GENERIC NAME	STERILE WATER FOR INJECTIONS IP	A. R. NO.	QC/FP/24/0363
MFG. DATE	02/2024	PRODUCT CODE	03
EXP. DATE	01/2028	BATCH SIZE	1500 LTR
SAMPLE SIZE	65 X 15 ML	PACK SIZE	15 ML
DATE TEST STARTED	06/03/2024	DATE TEST COMPLETED	20/03/2024
MFG. LIC. NO.	MB/18/1020	SPECIFICATION NO.	FPS/F014-04

S.NO.	TEST	OBSERVATION	SPECIFICATION
1	Description	Clear, colorless liquid, odorless	Clear, colorless liquid, odorless
2	Appearance of solution	Clear practically free from suspended particles	Clear, colorless and practically free from suspended particles.
3	pH	5.61	5.0 to 7.0
4	Conductivity	1.611 μ S/cm	For container with a nominal volume of 10 ml or less, it the conductivity is not greater than 25 μ S/cm, For container with a nominal volume of more than 10 ml, the conductivity is not greater than 5 μ S/cm.
5	Acidity or Alkalinity	Complies	Should meet the requirements
6	Ammonium	Less than 0.6 ppm	Not more than 0.6 ppm
7	Calcium & Magnesium	A pure blue color is produced	A pure blue color is produced
8	Chlorides	Less than 0.5 ppm	Not more than 0.5ppm
9	Nitrates	Less than 0.2 ppm	Not more than 0.2ppm
10	Sulphates	Complies	The appearance of the solution does not change for at least 1 hour
11	Oxidisable Substances	Complies	The pink colour of the solution does not disappear completely
12	Residue on evaporation	0.0016%	Not more than 0.004% for container 10 ml or less than 10ml Not more than 0.003% for container more than 10ml
13	Particulate contamination	52.00 particles/container 19.00 particles/container	$\geq 10 \mu$ m Not more than 6000 particles/ container $\geq 25 \mu$ m Not more than 600 particles/ container
14	Extractable Volume	15.5 ml	Not less than of nominal volume
15	Bacterial Endotoxins	Less than 0.25 EU/ml	Not more than 0.25 EU/ml
16	Sterility	Sterile	No growth observed during incubation period of 14 days.

Remark: The above sample complies / does not comply as per IP/ BP/ USP specification or external lab analysis report.

	ANALYSED BY	CHECKED BY	APPROVED BY
Signature/ Date	 20/03/24	 20/03/24	 20/03/24
	Officer-QC	Executive-QC	Quality Head