



KAMLAAMRUT PHARMACEUTICAL LLP.
(Survey no. 53, 56, 57, Near Kamla Amrut Industrial Park, Indrad, Ta-Kadi,
Dist.-Mehsana, Gujarat, 382715, India)

QUALITY CONTROL DEPARTMENT

CERTIFICATE OF ANALYSIS

Generic Name : Sterile Water For Injections IP

Batch No. : K2010759	A.R. No. : KAPL/FP/23/K2010759
Batch Size : 3000 Ltrs.	Quantity sampled : 125 Nos
Fill Volume : 10.0 ml	Received Date : 12/12/23
Mfg. Date : 12/2023	Testing Date : 13/12/23
Exp. Date : 11/2028	Completion Date : 27/12/23

Sr. No.	Tests	Observation	Specifications	Reference to Test Method
1.0	Description	A clear, colorless liquid Confirms	A clear, colorless and Odorless liquid	IP Monograph
2.0	Appearance of solution	Confirms	Test solution is clear and colourless and practically free from suspended particles.	IP Monograph (2.4.1)
3.0	Conductivity	1.79 μscm^{-1} Confirms	NMT 25 μscm^{-1}	IP Monograph (2.4.9)
4.0	Acidity or Alkalinity	The solution is yellow, it becomes red on addition of 0.1ml of 0.01M sodium hydroxide Confirms	If the solution is yellow, it becomes red on addition of 0.1ml of 0.01M sodium hydroxide. If the solution is red, it becomes yellow on addition of 0.15ml of 0.01M hydrochloric acid.	IP Monograph
5.0	Extractable volume	10.2 ml Confirms	The volume is not less than the nominal volume.	IP Monograph
6.0	Ammonium	<0.2 ppm Confirms	The solution is not more intensely colored than standard. Not more than 0.2 ppm	IP Monograph
7.0	Calcium and Magnesium	Confirms	A pure blue colour is produced.	IP Monograph
8.0	Chlorides	Confirms	The appearance of the solution does not change for at least 15 minutes.	IP Monograph (2.3.12)
9.0	Nitrates	<0.2 ppm Confirms	Not more than 0.2 ppm	IP Monograph



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Sr. No.	Tests	Observation	Specifications	Reference to Test Method
10.0	Sulphates	Confirms	The appearance of the solution does not change for at least 1 hour.	IP Monograph
11.0	Oxidisable substances	Confirms	The pink colour of the solution does not disappear completely.	IP Monograph
12.0	Residue on evaporation	0.002% Confirms	The residue weighs not more than 4mg (0.004%)	IP Monograph
13.0	Particulate contamination (Sub- Visible Particulates)			
	For $\geq 10\mu$	146.67 particles per container Confirms	NMT 6000 particles per container	IP Monograph (2.5.9, Method II)
	For $\geq 25\mu$	13.33 particles per container Confirms	NMT 600 particles per container	
14.0	Aluminium	-NA-	Not more than 10 ppb	IP Monograph
	Test require in case of used for Homodialysis purpose			
15.0	Bacterial Endotoxins	<0.125EU/ml Confirms	Not more than 0.25 EU/ml	IP Monograph (2.2.3)
16.0	Sterility	Sterile Confirms	Should be sterile	IP Monograph (2.2.11)
17.0	Additional Test			
17.1	pH	5.52 Confirms	Between 5.0 to 7.0	In-House

Remarks: The finish product **Confirms** with the defined specifications.

	Analysed by	Checked by	Verified by
Signature	V. Shah	Savan Kadiya	Shashin Upadhyay
Date	27/12/23	27/12/23	27/12/23
Name	Vidhi Shah	Savan Kadiya	Shashin Upadhyay
Designation	Q.C. Analyst	Q.C. Officer/Executive	Asst. Manager-QA

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