KamlaAmrut Pharmaceuticals LLP

QUALITY CONTROL DEPARTMENT

CERTIFICATE OF ANALYSIS

Generic Name	: PARACETAMOL INFUSION IP (1%W/V)		
Product Name	: 1% PARACETAMOL INFUSION IP - 100ML(PARACAN) - AMERICAN REMEDIES - NH		
Batch No.	: AC2656001	A.R. No.	: KAPL/FP/26/AC2656001
Batch Size	: 170 Ltr	Quantity sampled	: 4 Nos
Fill Volume	: 100 ml	Received Date	: 29/09/2026
Mfg. Date	: 01/09/2026	Testing Date	: 30/09/2026
Exp. Date	: 31/08/2028	Completion Date	: 15/10/2026

Sr. No.	Tests	Observation	Specifications	Reference to Test Method
1.0	Description	A clear and colourless solution.	A clear, colourless solution.	IP Monograph
2.0	Identification by HPLC	Confirms	The retention time of the principal peak obtained in the chromatogram of the assay preparation corresponding to that the retention time of the principal peak obtained in the chromatogram of the standard preparation, as obtained in the Assay.	IP Monograph
3.0	pH	5.85	Between 4.50 to 6.50	IP Monograph
4.0	Light asorption	0.002	Not more than 0.04	IP Monograph
5.0	Related Substances	4-Aminophenol : Not Detected 4-Chloroacetanilide : Not Detected Any other Impurity : 0.0173%	In chromatogram obtained with test solution area of any peak corresponding to 4-aminophenol should not more than 0.1 times area of principal peak in chromatogram obtained with reference solution (a) (0.1%), area of any peak corresponding to 4-chloroacetanilide should not more than 0.001 times area of the principle peak in chromatogram obtained with Reference solution (a) (10 ppm) and area of any other secondary peak should not more than 0.25 times area of principal peak in chromatogram obtained with reference solution (a) (0.25%)	IP Monograph
6.0	Extractable Volume	102 ml	The contents of each container should not less than the nominal volume.	IP Monograph
7.0	Particulate Matter	26.7 particles per container 0.0 particles per container	Not more than 6000 particles per container Not more than 600 particles per container	IP Monograph

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Sr. No.	Tests	Observation	Specifications	Reference to Test Method
8.0	Assay of Paracetamol	1.0280% w/v 102.80%	Between 98.0% and 110.0% w/v (Label Claim: 1.0% w/v)	IP Monograph
9.0	Bacterial Endotoxins	<1.0 EU/ml	Not more than 2.0 EU/ml	IP Monograph
10.0	Sterility	Sterile	It must be sterile	IP Monograph

Remarks : The finish product confirms with the defined specifications.

	Analysed by	Checked by	Verified by
Date	15/10/2026	15/10/2026	15/10/2026
Name	Jagriti Singh	Jaypal Vaghela	Vijay Prajapati
Designation	OFFICER	QC Executive	QA Manager

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