

**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.	: AC2595008	A.R. No.	: KAPL/FP/25/AC2595008
Batch Size	: 3500 Ltr	Quantity sampled	: 25 Nos
Fill Volume	: 100 ml	Received Date	: 11/12/2025
Mfg. Date	: 01/12/2025	Testing Date	: 12/12/2025
Exp. Date	: 30/11/2027	Completion Date	: 27/12/2025

Sr. No.	Tests	Observation	Specifications	Reference to Test Method
1.0	Description	A clear & 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	5.96	Between 4.50 to 6.50	IP Monograph
4.0	Light asorption	0.005	Not more than 0.04	IP Monograph
5.0	Related Substances	4-aminophenol : 0.0093% 4-chloroacetanilide: not detected any other impurity: 0.0264%	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	0.00 Particle Per Container 0.00 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	1.0196 % w/v 101.96 %	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 Confirm with the defined specification

	Analysed by	Checked by	Verified by
Date	27/12/2025	27/12/2025	27/12/2025
Name	Jinal Patel	Kuldeep Nai	Kirit Patel
Designation	OFFICER	QC Executive	QA Manager

Revision No.: 1.00

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