

**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.    | : AC2596005                                                            | A.R. No.         | : KAPL/FP/26/AC2596005 |
| Batch Size   | : 2300 Ltr                                                             | Quantity sampled | : 25 Nos               |
| Fill Volume  | : 100 ml                                                               | Received Date    | : 15/06/2026           |
| Mfg. Date    | : 01/05/2026                                                           | Testing Date     | : 17/06/2026           |
| Exp. Date    | : 30/04/2028                                                           | Completion Date  | : 15/07/2026           |

| 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                     | 5.56                                                                                        | Between 4.50 to 6.50                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | IP Monograph             |
| 4.0     | Light asorption        | 0.006                                                                                       | Not more than 0.04                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | IP Monograph             |
| 5.0     | Related Substances     | 4- aminophenol : 0.0007 %<br>4-chloroacetanilide : Not Detected<br>Any other Imp : 0.0111 % | 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     | 0.0 particles per container<br>0.0 particles per container                                  | Not more than 6000 particles per container<br>Not more than 600 particles per container                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | IP Monograph             |

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|---------|----------------------|-------------------------|---------------------------------------------------------|--------------------------|
| 8.0     | Assay of Paracetamol | 1.0069 %w/v<br>100.69 % | Between 98.0% and 110.0% w/v<br>(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               | 15/07/2026             | 15/07/2026            | 15/07/2026  |
| Name               | Jinal Patel            | Baldev Makwana        | Kirit Patel |
| Designation        | OFFICER                | QC Executive          | QA Manager  |
| Revision No.: 1.00 | Issue Date: 27/11/2025 | Eff. Date: 28/11/2025 | Page 2 of 2 |

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