# BAJAJ HEALTHCARE LTD. [UNIT-II]

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FORMAT NO: QA030/F/06-07

## CERTIFICATE OF ANALYSIS

| | | | |
|---|---|---|---|
| Product | : Chlorhexidine Gluconate Solution USP | A.R. No. | : EFM252600491 |
| Batch No. | : CS-00510725 | Batch Size | : 4000kg |
| Mfg. Date | : JUL-2025 | Sampled on | : 21/07/2025 |
| ~~Retest~~ / Exp. Date | : JUN-2028 | Page No. | : 01 of 01 |

| TEST | LIMITS | RESULT |
|---|---|---|
| Description | Almost colorless or pale-yellow, Clear liquid | Clear colorless liquid |
| Solubility | Miscible with glacial acetic acid and with water, miscible with three parts its volume of acetone and with five times its volume of dehydrated alcohol, further addition of acetone or dehydrated alcohol yield a white turbidity. | Complies |
| Identification: | | |
| A. IR | IR spectrum of the test sample should be concordant with that of Chlorhexidine working standard. | Complies |
| B. TLC | The principal spot of the sample solution corresponds in color, size and Rf value to that of the standard solution. | Complies |
| C. By HPLC | The retention time of the major peak from the sample solution corresponds to that of the standard solutions obtained in the Assay. | Complies |
| Specific Gravity | 1.06 - 1.07 | 1.066 |
| pH | 5.5 - 7.0 | 6.17 |
| Limit of p-Chloroaniline | Not more than 500 ppm | 14ppm |
| Organic impurities (by HPLC): | | |
| Chlorhexidine oxazinone analog | Not more than 0.2 % | 0.169% |
| Specified unidentified impurity-1 | Not more than 0.2 % | 0.067% |
| Chlorhexidine Amine | Not more than 0.3 % | 0.003% |
| Chlorhexidine guanidine | Not more than 1.0 % | 0.181% |
| Chlorhexidine urea | Not more than 0.2 % | 0.027% |
| p-Chlorophenyl urea | Not more than 0.2 % | 0.011% |
| Chlorhexidine nitrile | Not more than 0.4 % | 0.022% |
| Chlorhexidine dimer | Not more than 0.5 % | 0.242% |
| o- Chlorhexidine and specified unidentified impurity-2 | Not more than 0.4 % | 0.042% |
| Chlorhexidine glucityl triazine | Not more than 0.4 % | 0.043% |
| Oxochlorhexidine | Not more than 0.4 % | 0.022% |
| Any individual Unspecified imp. | Not more than 0.10 % | 0.045% |
| Total impurities | Not more than 3.0 % | 0.977% |
| Assay (by HPLC) | Not less than 19.0 % and Not more than 21.0 % (w/v) | 20.0% w/v |
| Residual Solvent (By GC) : | | |
| Methanol | NMT 3000 ppm | 39ppm |
| n-Butanol | NMT 5000 ppm | 52ppm |

Conclusion: The sample complies / ~~Does not comply~~ with the standard of quality prescribed in specification as per USP 46.

| Sign/Date | 26/07/2025 | 26/07/2025 | 26/07/2025 |
|---|---|---|---|
| | **Prepared by QC** | **Checked by QC** | **Approved by QA** |