



**R. N. LABORATORIES PVT. LTD.**  
Plot No.1 & 86, Sursez, Diamond Park, Sachin, Surat, Gujarat, India.

### Certificate of Analysis

|              |  |            |               |
|--------------|--|------------|---------------|
| Product Name | Chlorhexidine Gluconate 20 % Solution (Pharma Grade) |            |               |
| Reference    | USP/EP/BP –  | AR. No.    | FP/1/22/03 77 |
| Batch No.    | CGP2022251 –   | Batch Size | 8000 Kg.      |
| Mfg. Date    | 30/09/2022 –   | Exp. Date  | 29/09/2025 –  |
| Release Date | 06/10/2022   |            |               |

### Section-A: Chemical testing

| Sr. No. | Tests                              | Specification   | Reference | Results                   |
|---------|------------------------------------|---|-----------|---------------------------|
| 1.      | Description                        | Almost colorless or pale yellowish, clear liquid.   | USP/EP/BP | A clear colorless liquid. |
| 2.      | Solubility                         | Miscible with glacial acetic acid and with water; miscible with three times its volume of acetone and with five times its volume of dehydrated alcohol; further addition of acetone or dehydrated alcohol yields a white turbidity. | USP       | Complies                  |
|         |                                    | Miscible with water, with not more than 3 parts of acetone and with not more than 5 parts of ethanol (96%).   | EP/BP     | Complies                  |
| 3.      | IDENTIFICATION:                    |   |           |                           |
|         | A. IR                              | The IR Spectrum obtained with sample should correspond with that of standard.   | USP/EP/BP | Complies                  |
|         | B. Thin Layer Chromatography       | The principal spot in the chromatogram obtained with the test solution should be similar in position, colour and size to the principal spot in the chromatogram obtained with the reference solution.                               | USP/EP/BP | Complies                  |
|         | C. Residual melting point          | 132°C to 136°C.   | EP/BP     | 134.3°C                   |
|         | D. Chemical Test                   | A deep red color should be produced.  | EP/BP     | Complies                  |
| 4.      | Specific gravity/ Relative density | 1.06 to 1.07  | USP/EP/BP | 1.064                     |
| 5.      | pH(5% v/v)                         | 5.5 to 7.0  | USP/EP/BP | 6.37                      |

|             | PREPARED BY       | CHECKED BY      | APPROVED BY       |
|-------------|-------------------|-----------------|-------------------|
| NAME        | Mr. Bhargav Patel | Mr. Vimal Patel | Mr. Sohail Shaikh |
| DESIGNATION | Officer QC        | Manager QC      | Manager QA        |
| SIGNATURE   |                   |                 |                   |
| DATE        | 06/10/2022        | 06/10/2022      | 06/10/2022        |





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| Reference    | USP/EP/BP  | AR. No.    | FP/I/22/03 77 |
| Batch No.    | CGP2022251   | Batch Size | 8000 Kg.      |
| Mfg. Date    | 30/09/2022   | Exp. Date  | 29/09/2025    |
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| Sr. No. | Tests   | Specification | Reference | Results |
|---------|---|---------------|-----------|---------|
| 6.      | <b>Organic impurities (Related substances)</b>                            |               |           |         |
|         | Chlorhexidineoxazinoneanalog (Impurity L)                                 | NMT 0.2 %     | USP/EP/BP | BDL     |
|         | Specified unidentifiedimpurity 1 (Impurity Q)                             | NMT 0.2 %     | USP/EP/BP | 0.08 %  |
|         | Chlorhexidine amine (Impurity G)  | NMT 0.3 %     | USP/EP/BP | BDL     |
|         | Chlorhexidine guanidine (Impurity N)                                      | NMT 1.0 %     | USP/EP/BP | 0.11 %  |
|         | Chlorhexidine urea (Impurity B)   | NMT 0.2 %     | USP/EP/BP | 0.05 %  |
|         | p-Chlorophenyl urea (Impurity F)  | NMT 0.2 %     | USP/EP/BP | BDL     |
|         | Chlorhexidine nitrile (Impurity A)  | NMT 0.4 %     | USP/EP/BP | BDL     |
|         | Chlorhexidine dimer (Impurity H)  | NMT 0.5 %     | USP/EP/BP | 0.17 %  |
|         | o-Chlorhexidineandspecifiedunidentifiedimpurity 2 (Sum of Impurity I & O) | NMT 0.4 %     | USP/EP/BP | 0.08 %  |
|         | Chlorhexidineglucityl Triazine (Impurity J)                               | NMT 0.4 %     | USP/EP/BP | BDL     |
|         | Chlorhexidine   | -             | USP/EP/BP | -       |
|         | Oxochlorhexidine (Impurity K)   | NMT 0.4 %     | USP/EP/BP | 0.05 %  |
|         | Any individual unspecified impurity                                       | NMT 0.10 %    | USP/EP/BP | 0.06 %  |
|         | Total impurities  | NMT 3.0 %     | USP/EP/BP | 0.60 %  |

|             | PREPARED BY       | CHECKED BY      | APPROVED BY       |
|-------------|-------------------|-----------------|-------------------|
| NAME        | Mr. Bhargav Patel | Mr. Vimal Patel | Mr. Sohail Shaikh |
| DESIGNATION | Officer QC        | Manager QC      | Manager QA        |
| SIGNATURE   |                   |                 |                   |
| DATE        | 06/10/2022        | 06/10/2022      | 06/10/2022        |





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### Certificate of Analysis

|              |  |            |              |
|--------------|--|------------|--------------|
| Product Name | Chlorhexidine Gluconate 20 % Solution (Pharma Grade) |            |              |
| Reference    | USP/EP/BP  | AR. No.    | FP/I/22/0377 |
| Batch No.    | CGP2022251   | Batch Size | 8000 Kg.     |
| Mfg. Date    | 30/09/2022   | Exp. Date  | 29/09/2025   |
| Release Date | 06/10/2022   |            |              |

| Sr. No.          | Tests                                 | Specification                            | Reference | Results     |
|------------------|---------------------------------------|--|-----------|-------------|
| 7.               | p –Chloroaniline                      | Not more than 500 ppm                    | USP       | 10.87 ppm   |
| 8.               | Assay                                 | NLT 19.0 % (w/v) and<br>NMT 21.0 % (w/v) | USP       | 20.33 % w/v |
|                  |                                       | NLT 190 g/L and<br>NMT 210 g/L           | EP/BP     | 200.2 g/L   |
| Residual Solvent |                                       |  |           |             |
| 9.               | Methanol                              | Not more than 3000 ppm                   | Inhouse   | 283 ppm     |
| 10.              | Butanol                               | Not more than 5000 ppm                   | Inhouse   | 31 ppm      |
| 11.              | Colour absorbance test by UV at 480nm | NMT 0.05                                 | Inhouse   | 0.013       |

BDL= below disregard limit; ND= Not detected

If present, o-chlorhexidine and specified unidentified impurity 2 may not be completely resolved by the method. These peaks are integrated together to determine conformance.

**Report:** In the opinion of the undersigned, the above batch complies with the standards of specifications Mentioned under current monographs of USP/EP/BP

|             | PREPARED BY       | CHECKED BY      | APPROVED BY       |
|-------------|-------------------|-----------------|-------------------|
| NAME        | Mr. Bhargav Patel | Mr. Vimal Patel | Mr. Sohail Shaikh |
| DESIGNATION | Officer QC        | Manager QC      | Manager QA        |
| SIGNATURE   |                   |                 |                   |
| DATE        | 06/10/2022        | 06/10/2022      | 06/10/2022        |



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### Certificate of Analysis

|                     |                                       |                   |              |
|---------------------|---------------------------------------|-------------------|--------------|
| <b>Product Name</b> | Chlorhexidine Gluconate 20 % Solution |                   |              |
| <b>Reference</b>    | In house                              | <b>AR. No.</b>    | MT/I/22/0379 |
| <b>Batch No.</b>    | CGP2022251                            | <b>Batch Size</b> | 8000.00 Kg   |
| <b>Mfg. Date</b>    | 30/09/2022                            | <b>Exp. Date</b>  | 29/09/2025   |
| <b>Release Date</b> | 08/10/2022                            |                   |              |

### Section-B: Microbial testing

| Sr. No. | Tests   | Specification          | Reference | Results      |
|---------|---|------------------------|-----------|--------------|
| 1.      | Microbial Enumeration Test  |                        |           |              |
|         | A. Total aerobic microbial count                                    | NMT $10^2$ CFU/mL      | In house  | Nil          |
|         | B. Total yeasts and molds count                                     | NMT $10^2$ CFU/mL      | In house  | Nil          |
|         | C. Other specific micro Organisms<br>( <i>Serratia marcescens</i> ) | Should be Absent/10 mL | In house  | Absent/10 mL |

**Note:** The batch is released based on chemical analysis reported in Section - A, on completion of microbial tests results are reported in this Section -B.

**Report:** In the opinion of the undersigned, the above batch complies with the Current In house Specification.

|                    | PREPARED BY       | CHECKED BY      | APPROVED BY       |
|--------------------|-------------------|-----------------|-------------------|
| <b>NAME</b>        | Mr. Akash Dhangar | Mr. Vimal Patel | Mr. Sohail Shaikh |
| <b>DESIGNATION</b> | Sr. Executive MB  | Manager QC      | Manager QA        |
| <b>SIGNATURE</b>   |                   |                 |                   |
| <b>DATE</b>        | 08/10/2022        | 08/10/2022      | 08/10/2022        |