



## DERREN HEALTHCARE PVT. LTD.

Plot No. #33, 35/p & 36/p XCELON Industrial Park, Lane besides Chak-de-India  
Weighbridge, Sarkhej-Bavla Highway Village: Vasna-Chacharvadi,  
Ahmedabad-382 213, Gujarat (India)

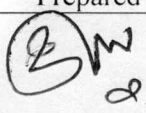
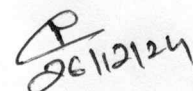
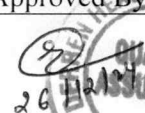
### CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

|                        |  |                         |            |
|------------------------|--|-------------------------|------------|
| <b>Name of Product</b> | Sodium Bicarbonate Injection 84mg/ml (SODICAN) |                         |            |
| <b>Batch No.</b>       | BJ24016  | <b>A.R. No.</b>         | FP/24/0144 |
| <b>Mfg. Date</b>       | 12/24  | <b>Exp. Date</b>        | 11/26      |
| <b>Sampled Qty.</b>    | 36 Nos.  | <b>Date of Analysis</b> | 09/12/24   |
| <b>Batch Size</b>      | 500Ltr.  | <b>Date of Release</b>  | 25/12/24   |
| <b>Container Type</b>  | Clear Glass Ampoules                           | <b>Fill volume</b>      | 25.0 ml    |
| <b>Mfg. Lic. No.</b>   | G/28/1862                                      |                         |            |

| Sr. No. | Test   | Result   | Specification  |
|---------|--|--|--|
| 1       | Description  | Clear, Colourless liquid free from visible particles and fibers.                         | Clear, Colourless liquid free from visible particles and fibers.   |
| 2       | Extractable volume   | 25.5 ml  | NLT 25.0 ml  |
| 3       | Identification   |  |  |
| 3.1     | Identification It Gives reaction (A) of sodium salts and the reaction of bicarbonate | A White Precipitated is formed<br>A dense white precipitate is formed                    | A White precipitated should be formed<br>A dense White precipitate should be formed                        |
| 4       | pH   | 7.99   | 7.0 to 8.5   |
| 5       | Bacterial endotoxin  | Less than 5.0 Eu/mg  | NMT 5.0 EU/mg of Sodium bicarbonate  |
| 6       | Particulate matter   |  |  |
| 6.1     | By Visual Inspection   | The solution is free from particles that is observed by inspection with the unaided eye. | The solution should be free from particles that can be observed by inspection with the unaided eye.        |
| 6.2     | By Light Obscuration Method  | $\geq 10$ microns= 253.33 /Container<br>$\geq 25$ Microns= 3.33/Container                | Sub visible particle by LPC<br>$\geq 10$ microns=NMT 6000/Container<br>$\geq 25$ Microns=NMT 600/Container |
| 7       | Sterility test   | Sterile  | Should be sterile  |
| 8       | Assay  |  |  |
| 8.1     | Each ml Contains: Sodium Bicarbonate IP  | 105.9 %  | 94.0% to 106.0% of the labelled amount of Sodium Bicarbonate   |

Conclusion: The above sample complies as per **IP** specification.

In the opinion of the undersigned the sample referred to above is of **standard** / ~~not of standard~~ quality as defined in the act and the rules made there under for the reasons given above.

|  |   |  |
|--|---|--|
| Prepared By<br><br>25/12/24<br>QC OFFICER | Checked By<br><br>26/12/24<br>QC EXECUTIVE | Approved By<br>H Fo<br><br>26/12/24<br>QA MANAGER |
|--|---|--|

