



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)

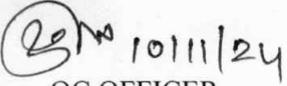
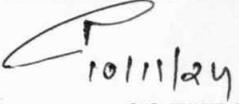
CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

| | | | |
|------------------------|--|-------------------------|------------|
| Name of Product | Sodium Bicarbonate Injection 84mg/ml (SODICAN) | | |
| Batch No. | BJ24015 | A.R. No. | FP/24/0113 |
| Mfg. Date | 10/24 | Exp. Date | 09/26 |
| Sampled Qty. | 36 Nos. | Date of Analysis | 19/10/24 |
| Batch Size | 400Ltr. | Date of Release | 10/11/24 |
| Container Type | Clear Glass Ampoules | Fill volume | 25.0 ml |
| Mfg. Lic. No. | 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 | 25.1 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 A dense white precipitate is formed | A White precipitated should be formed A dense White precipitate should be formed |
| 4 | pH | 7.94 | 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 | ≥ 10 microns= 18.33 /Container ≥ 25 Microns= 0.00/Container | Sub visible particle by LPC ≥ 10 microns=NMT 6000/Container ≥ 25 Microns=NMT 600/Container |
| 7 | Sterility test | Sterile | Should be sterile |
| 8 | Assay | | |
| 8.1 | Each ml Contains: Sodium Bicarbonate IP | 101.3 % | 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 | Checked By | Approved By |
|---|---|---|
|  QC OFFICER |  QC EXECUTIVE |  QA MANAGER |

