Sample Name SODIUM BICARBONATE INJECTION-IP. 7.5%w/v Submitted By Quality Control Advisor. (MMDSL) Shillong. Report No Address DHS LaitumkhrahNHM, EastKhasi Hills Meghalaya. Receipt Date 21-Aug-24

Mfg Lic No

Mfg By N.S. Report Date 09-Sep-24

Supplied By N.S.

Ref No

N.S.

Batch No MMDSL/QC-0422

Mfg. Date 02/2024

Exp Date 01/2027

Batch Size N.S.

Sample Qty 30 AMPOULES.

TEST RESULTS

Date / Period of Performance of test 21/08/2024 to 09/09/2024.

Reference to protocol :- I.P-2022.

Description

:- Clear colourless solution filled in colourless glass

ampoule.

Identification (A,B)

:- Complies.

Limit

Нq

Lower Upper :- 8.30 7.0 8.5

Nominal volume

:- 25ml

Extractable volume

:- 26ml

NLT 25ml.

Sterility

:- Complies with the test for sterility.

Particulate matter :- Complies.

Bacterial endotoxins :- Less than 1.7EU/ml

NMT- 1.7EU/ml

Assay

: -

Contents of

Obtained

LIMIT

Claim Lower

Upper

Method

Sodium Bicarbonate

: -7.442%w/v 7.5%w/v 7.05%w/v 7.95%w/v

IP.

NOTE: - SAMPLE CONSUMED IN TESTING.

Report: In Opinion of the undersigned, The sample referred to above is of Standard Quality as defined in the Act and the rules made there under for the reason given: Complies as per IP.