

Sample Name	COMPOUND SODIUM LACTATE INJECTION-IP.	Mfg Lic No	[REDACTED]
Submitted By	Quality Control Advisor. (MMDSL) Shillong.	Report No	[REDACTED]
Address	DHS LaitumkhranhNM, EastKhasi Hills Meghalaya.	Receipt Date	22-Jun-24
Mfg By	N.S.	Report Date	13-Jul-24
Supplied By	N.S.	Ref No	N.S.
Batch No	Mfg. Date	Exp Date	Batch Size
MMDSL/QC-0319	01/2024	12/2025	N.S.
			Sample Qty
			12 BOTTLES.

TEST RESULTS

Date / Period of Performance of test 22/06/2024 to 13/07/2024.

Reference to protocol :- I.P-2022. (RINGER-LACTATE INJECTION-IP.)

Description :- Clear colourless solution filled in transparent plastic bottles.

Identification (A,B,C) :- Complies.

		LIMIT	
pH	:- 6.11	Lower	Upper
Bacterial Endotoxins	:- Less than 0.5EU/ml	5.0	7.0
		-	0.5 EU/ml.

Sterility :- Complies with the test for sterility.

Particulate contamination :- Complies.

Nominal volume :- 500ml.

Extractable volume :- 510ml NLT 500ml.

Assay :-

		LIMIT	
Content of	Obtained	Lower	Upper
Sodium	:- 0.305%w/v	0.27%w/v	0.32%w/v
Potassium	:- 0.0206%w/v	0.019%w/v	0.022%w/v
Total Chloride	:- 0.398%w/v	0.37%w/v	0.42%w/v
Calcium Chloride	:- 0.0267%w/v	0.025%w/v	0.029%w/v
Lactate cal. as Lactic Acid	:- 0.2611%w/v	0.23%w/v	0.28%w/v
(by HPLC)			Method
			IP.
			IP.
			IP.
			IP.
			IP.

NOTE:- SAMPLE CONSUMED IN TESTING.

Report: In Opinion of the undersigned, The sample re
as defined in the Act and the rules made there un
per IP.