FORM-39A (THE DRUGS & COSMETICS ACT 1940 & RULES THEREUNDER)

Sample Name METOCLOPRAMIDE HCL INJECTION-IP.5.0mg./ml Submitted By Quality Control Advisor. (MMDSL) Shillong. Address

DHS LaitumkhrahNHM, EastKhasi Hills Meghalaya.

Mfg By N.S.

Supplied By N.S.

Batch No MMDSL/QC-0100

Mfg. Date 12/2023

Exp Date 11/2025

Batch Size N.S.

Mfg Lic No

Report Date

Receipt Date 19-Mar-24

Report No

Ref No

N.S. Sample Qty 30 AMPOULES.

05-Apr-24

RESULT OF ANALYSIS

Date / Period of Performance of test 19/03/2024 to 05/04/2024.

Reference to protocol

:- I.P-2022.

:- Complies.

Description

:- Clear colourless solution filled in amber colour glass ampoules.

Identification A(by U.V)

B & C :- Complies.

рН

:- 4.21

Lower 3.0

Upper 5.0

Limit

Bacterial endotoxin

:- Less than NMT 2.5EU/mg of Metoclopramide

NMT 2.5EU/mg of Metoclopramide

Related substances (by HPLC) :- Complies.

Nominal volume Extractable volume

:- 2ml. :- 2.04ml

NLT 2ml.

Sterility

:- Complies with the test for sterility.

Particulate matter

:- Complies.

Assay (by U.V)

:- Each ml contains:-

Limit

Content of

Obtained

Claim

Lower

Upper

Method

Metoclopramide hydrochloride

eq. to Anhydrous

Metoclopramide hydrochloride: - 4.98mg

5.0mg

4.5mg

5.5mg

IP.

NOTE: - SAMPLE CONSUMED IN

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

NOTE: 1. The result listed refer only to the tested samples and applicable parameter. Endorsement of products is neither inferred nor implied.

2. Sample not drawn by us. Total liability of this laboratory limited to the invoice amount/

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