Sample Name FLUOXETINE CAPSULES-IP. 20mg

Submitted By Quality Control Advisor. (MMDSL) Shillong.

DHS LaitumkhrahNHM, EastKhasi Hills Meghalaya. Receipt Date 29-Apr-24

Mfg By N.S.

Supplied By N.S.

Batch No MMDSL/QC-0208 Mfg. Date 02/2024

Exp Date 01/2026

Ref No Batch Size N.S.

N.S. Sample Qty 60 CAPS.

Report Date 16-May-24

Mfg Lic No

Report No

TEST RESULTS

Date / Period of Performance of test 29/04/2024 to 16/05/2024.

Reference to protocol :- I.P.2022.

Description

:- Green & white hard gelatin capsules containing white powder.

Identification (A) (by I.R.) :- Complies.

(B) (by HPLC) :- Complies.

Average weight

:- 318.6mg.

Average fill

:- 255.4mg.

Uniformity of weight

:- Within limit.

Dissolution(by HPLC)

:- Complies(80.4% to 86.3%)

LIMIT NLT-70%+5%

Related substances(by HPLC) :- Complies.

Assay(by HPLC)

:- Each hard gelatin capsule contains:-

Contents of

Obtd./Av.fill

Claim Lower

Upper

Method

Fluoxetine Hydrochloride

calculated as Fluoxetine :- 19.81mg

20.0mg. 18.0mg.

22.0mg.

LIMIT

IP.

NOTE: - SAMPLE CONSUMED IN TESTING.

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