FORM 39A |(SEE RULE 150 E (f) UNDER THE DRUGS & COSMETICS ACT 1940 & RULES THEREUNDER)

Generic Name: Albendazole Oral Suspension IP

Sample Name : Albendazole Oral Liquid 200mg/5ml (Paed)

Submitted By : M/s Meghalayan Medical Drugs and Services Limited

New Colony Shillong, DHS Laitumkhrah, Office of the Managing Director, MMDSL East Khasi Hills District Meghalaya Shillong (Assam) 793003 District Meghalaya

Shillong (Assam) 793003

Mfd. By

: NS

Supplied By : NS

Ref.No.

: NS

Batch No.

02/2024

Mfg. Date

Exp. Date 01/2026

Format No

Mfg. Lic.No.

Report No.

Date of Receipt

Report Date

: 22/04/2024 Period of Analysis : 18/04/2024-22/04/2024

: 18/04/2024

Stability Condition:

Batch Size

Sample Qty.

20 Bottle

RESULTS OF ANALYSIS

Reference to Protocol

Description

MMDSL/QC-0191

Orange coloured suspension filled in amber coloured plastic bottle.

Test Parameters

Results

I.P.-2022

Limit

NS

Identification:

(A) by UV

(B) by UV

Complies

Complies

(C) by HPLC

Complies

Nominal Volume

10.0 ml

Average fill Volume

10.1 ml

5.08

Uniformity of fill Volume

Within limit

рΗ Related Substances (by HPLC)

The sum of all secondary impurities

Any secondary impurity

0.1602%

0.2830%

Weight/ml

1.1071 gm

Assay (by HPLC)

Each 5 ml contains:

Particulars Albendazole Result 195.77 mg

Claim 200.0 mg Lower

4.5 to 5.5

NMT 1.0%

NMT 2.0%

Upper

Method

180.0 mg

220.0 mg

IP

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RESULTS OF ANALYSIS

End of Report