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

(MMDSL)

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. MMDSL/QC-0189 Mfg. Date

02/2024

Exp. Date 01/2026

Format No

Mfg. Lic.No.

Report No.

Date of Receipt

Report Date

: 18/04/2024 : 22/04/2024

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

Stability Condition:

Batch Size

Sample Qty.

NS

20 Bottle

RESULTS OF ANALYSIS

Reference to Protocol

Description

Orange coloured suspension filled in amber coloured plastic bottle.

Test Parameters

Results

I.P.-2022

Complies Complies

Complies 10.0 ml

10.0 ml

5.09

Within limit

0.1337%

0.2571%

1.1082 gm

196.62 mg

Limit

Identification:

(A) by UV

(B) by UV

(C) by HPLC

Nominal Volume

Average fill Volume

Uniformity of fill Volume

pH

Related Substances (by HPLC)

Any secondary impurity

The sum of all secondary impurities

Weight/ml

Assay (by HPLC)

Each 5 ml contains:

Particulars

Albendazole

Result

Claim

200.0 mg

Lower

4.5 to 5.5

NMT 1.0%

NMT 2.0%

Upper

Method

180.0 mg

220.0 mg

ΙP

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Meghalaya Shillong (Assam) 793003 District Meghalaya

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RESULTS OF ANALYSIS

End of Report