

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

Format No : ██████████
Mfg. Lic.No. : ██████████

Report No. : ██████████
Date of Receipt : 18/04/2024
Report Date : 22/04/2024
Period of Analysis : 18/04/2024-22/04/2024
Stability Condition :

| | | | | |
|------------------|------------------|------------------|-------------------|--------------------|
| Batch No. | Mfg. Date | Exp. Date | Batch Size | Sample Qty. |
| MMDSL/QC-0190 | 02/2024 | 01/2026 | NS | 20 Bottle |

RESULTS OF ANALYSIS

| | | | | | |
|--|---|--------------|--------------|--------------|---------------|
| Reference to Protocol | I.P.-2022 | | | | |
| Description | Orange coloured suspension filled in amber coloured plastic bottle. | | | | |
| Test Parameters | Results | Limit | | | |
| Identification : | | | | | |
| (A) by UV | Complies | | | | |
| (B) by UV | Complies | | | | |
| (C) by HPLC | Complies | | | | |
| Nominal Volume | 10.0 ml | | | | |
| Average fill Volume | 10.05 ml | | | | |
| Uniformity of fill Volume | Within limit | | | | |
| pH | 5.16 | 4.5 to 5.5 | | | |
| Related Substances (by HPLC) | | | | | |
| Any secondary impurity | 0.1473% | NMT 1.0% | | | |
| The sum of all secondary impurities | 0.2708% | NMT 2.0% | | | |
| Weight/ml | 1.1134 gm | | | | |
| Assay (by HPLC) | Each 5 ml contains: | | | | |
| <u>Particulars</u> | <u>Result</u> | <u>Claim</u> | <u>Lower</u> | <u>Upper</u> | <u>Method</u> |
| Albendazole | 197.14 mg | 200.0 mg | 180.0 mg | 220.0 mg | IP |

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 Laitumkrah, 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

Format No : [REDACTED]

Mfg. Lic.No. : [REDACTED]

Report No. : [REDACTED]

Date of Receipt : 18/04/2024

Report Date : 22/04/2024

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

Stability Condition :

| Batch No. | Mfg. Date | Exp. Date | Batch Size | Sample Qty. |
|---------------|-----------|-----------|------------|-------------|
| MMDSL/QC-0190 | 02/2024 | 01/2026 | NS | 20 Bottle |

RESULTS OF ANALYSIS

End of Report

Remark: In the opinion of the undersigned the sample referred to above is of standard quality as defined in the Act