MEGHALAYAN MEDICAL DRUGS & SERVICES LIMITED

सत्यमेव जयते
Government of Meghalaya

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No. MMDSL/CT/8/2023(1) Dated: 06/12/2023

PRESS RELEASE

This is for the clarification on Albendazole Tablets being of substandard quality in the recent coverage on some media outlets.

Initial Quality Assurance Measures: Upon receipt at the State warehouse, Albendazole tablets batch no. MS4AI2301 (Manufacturing Date: Jan-2023, Expiry Date: Dec-2025) were distributed to respective districts based on allocations. Certified quality tests were conducted in February 2023, including the manufacturer's in-house quality test report and the National Accreditation Board for Testing and Calibration Laboratories (NABL) quality test report. Both reports affirmed that the tablets meet standard quality requirements.

However, upon receiving a quality report from the Regional Drug Testing Lab (RDTL), Assam, in October 2023, indicating the tablets as "not of standard quality," an immediate directive was issued to halt the distribution of the specific batch.

Response taken: A Comprehensive Quality Reassessment was again conducted in November 2023 by the Quality Control division of Meghalayan Medical Drugs & Services Ltd which drew samples from the warehouses. These samples were sent to NABL-accredited lab in Kolkata, while the manufacturer's identity and batch number was kept confidential. The batch number generated by the quality Assurance department was MMDSL QC 0022. The subsequent quality test report confirmed that the Albendazole tablets with batch no. MS4AI2301 (Manufacturing Date: Jan-2023, Expiry Date: Dec-2025) meets standard quality criteria.

The comprehensive testing procedures involved tests in two NABL labs and one manufacturer's in-house lab. All these labs confirmed that the drugs met the quality, efficacy, and safety standards with Meghalayan Medical Drugs & Services Ltd taking immediate action to verify the quality of the drugs, addressing the concerns raised. Also, no adverse effect has been reported so far as a resultant of this batch.

The Government takes utmost seriousness on quality of medicines to ensure proper services to people in a timely manner.

Shri Ramkumar S
Managing Director

Approved By Shri Ramkumar S(Managing Director) on 06/12/2023 02:51 PM
(The document is digitally approved and does not require any Seal or Signature in original)

QA.15.0.0.3

FORM 39

[RULE 150 - E(F)] APPROVAL NUMBER: T-22/DC

TEST REPORT

ISSUED TO :		**REPORT NO**	:
Meghalayan Medical Drugs And Services Limited New colony shillong, DHS, laitumkhrah, Office of the mission director,NHM, Shillong, East Khasi Hills Meghalaya, 793003 Shillong - 793003		**ISSUE DATE**	: 22/11/2023
		CUSTOMER REFERENCE	: TRF
		DATE	: 17/11/2023
MFG. LICENCE No :		**PAGE NO**	: 3 of 3

Date : **22/11/2023**

UOM : **Unit of Measurement**

REMARKS : **The sample is tested as per test procedure shared by client and Opinion on Quality is drawn against the result obtained for tested parameter only.**

Note :

-END OF THE TEST REPORT-

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ISSUE DATE : 22/11/2023
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DATE : 17/11/2023
PAGE NO : 2 of 3

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TEST RESULT

SL No.	TEST PARAMETER	TESTING / REF. PROCEDURE	LABEL CLAIM	UOM	ACCEPTANCE LIMIT	RESULTS
2	Identification A	Indian Pharmacopoeia 2022	-	—	The principal spot in the chromatogram obtained with the test solution should correspond to that in the chromatogram obtained with the reference solution.	The principal spot in the chromatogram obtained with the test solution corresponds to that in the chromatogram obtained with the reference solution.
3	Identification B	Indian Pharmacopoeia 2022	-	—	Should Comply	Complies
4	Disintegration test	Indian Pharmacopoeia 2022	-	Min./Sec.	NMT 15 Mins	Min : 04 Min 26 Sec , Max : 05 Min30 Sec
5	Dissolution	Indian Pharmacopoeia 2022	400 mg/Tab	% of L.C.	NLT 85.0	Avg :95.98 , Min :95.67 , Max : 96.29
6	Uniformity of the weight	Indian Pharmacopoeia 2022	-	%	(±)5.0	Avg wt :705.27 mg , (-) Dev :0.61, (+) Dev : 1.45
7	Assay	Indian Pharmacopoeia 2022	400 mg/Tab	% of L.C.	370.0 - 430.0 mg/Tab i.e. 92.5 - 107.5	395.36 mg/Tab i.e. 98.84

In the opinion of the undersigned, the Sample referred to above is of Standard Quality / ~~is not of Standard Quality as defined in the Act or the Rules madethere under for the reasons given below~~:

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New colony shillong, DHS, laitumkhrah, Office of the mission director,NHM, Shillong, East Khasi Hills Meghalaya, 793003
Shillong - 793003
MFG. LICENCE No :

REPORT NO : EFRAC/2023/DRG/RG/03650
ISSUE DATE : 22/11/2023
CUSTOMER REFERENCE : TRF
DATE : 17/11/2023
PAGE NO : 1 of 3

SAMPLE DETAILS

SAMPLE REGISTRATION DETAILS

Sample Name : Albendazole
Sample Receipt Date : 17/11/2023
Registration No : EFRAC/2023/DRG/RG/03650
Name of Manufacturer : N/A
Batch No. : MMDSL QC-0022
Date of Mfg. : Jul-2023

Sample Quantity Received : 60.00 Tablets
Sample Registration Date : 20/11/2023
Sample Submitted/Drawn by : Client
Batch Size : N/A
Date of Expiry : Dec-2025

SAMPLE ANALYSIS DETAILS

Analysis Starting Date : 20/11/2023
Analysis Completion Date : 21/11/2023

TEST RESULT

SL No.	TEST PARAMETER	TESTING / REF. PROCEDURE	LABEL CLAIM	UOM	ACCEPTANCE LIMIT	RESULTS
1	Description	Indian Pharmacopoeia 2022	-	—	Light orange colour biconvex oval shaped uncoated tablet having red specs on whole body , one side plain and other side breakline chewable tablet.	Light orange colour biconvex oval shaped uncoated tablet having red specs on whole body , one side plainand other sidebreakline chewable tablet.

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[redacted]

Sample	: Albendazole Tablet IP		**Report No.**	: [redacted]
Supplied by	[redacted]		**Your Ref**	: 04/02/2023
Mfd. by			**Mfg. Lic. No.**	: Ns
Submitted by			**Date of Receipt:**	04/02/2023
Location				

Batch No.	**Mfg. Date**	**Exp. Date**	**Batch Size**	**Sample Qty.**
MS4AI2301	01/2023	12/2025	9.74 Lac	100 Tablets

Date of Start of Analysis: 04/02/2023 Date of Completion of Analysis: 06/02/2023

RESULTS OF ANALYSIS

Reference Protocol	:	AS PER IP
Description	:	Pinkish color elongated shaped biconvex uncoated chewable tablets having central break line on one side and plain on othe side of each tablet.
Identification (By TLC)	:	Complies
(By UV)	:	Complies
Average Weight	:	695.83 mg
Uniformity of weight	:	Within Limit
Dissolution	:	Min. 89.5%, Max. 93.5%, [NLT 80.0% (Q)] Avg. 90.9%
Assay	:	Each uncoated chewable tablet contains

Ingredients	Claim	Observation	Limit
Albendazole IP	400.0 mg	397.62 mg	[370.0 mg to 430.0 mg]

In the opinion of the undersigned, the sample referred to above is **of Standard quality** as defined in the Act and the Rules made there under for the reasons given below. **As per IP** w.r.t above tests.

[redacted]

06/02/2023

DATE OF COMPLETION

NOTE :
1) Sample(s) not drawn by us unless otherwise stated.
2) Total liability of our analytical division is limited to the invoiced amount.
3) Test certificate in full or parts shall not be used for promotional pe publicity purposes.
4) Result given in report are related to sample tested

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[redacted]

CERTIFICATE OF ANALYSIS
FINISHED PRODUCT

Product Name	Albendazole Tablets IP		
Generic Name	Albendazole Tablets IP 400 mg		
Batch No.	MS4AI2301	**A.R. No.**	MG/FG0087/23
Manufacturing date	JAN.2023	**Sampling date**	04/02/2023
Expiry date	DEC.2025	**Date of analysis**	04/02/2023
Batch size	9.74 Lac	**Date of release**	04/02/2023
Sample quantity	100 Tablets	**Tested As per**	IP

Sr. No.	TEST	SPECIFICATION	OBSERVATION
01	Description	Pinkish color elongated shaped biconvex uncoated chewable tablet having central break line on one side and plain on other side of each tablet.	Pinkish color elongated shaped biconvex uncoated chewable tablet having central break line on one side and plain on other side of each tablet.
02	Identification By TLC By UV	The principal spot of chromatogram in the test preparation corresponds to that in the chromatogram obtained with standard preparation. The absorbance of the solution at the maximum 309 nm, about 0.74.	Complies Complies
03	Average Weight	679 mg to 721mg	696.03 mg
04	Uniformity of Weight	Not more than 2 tablets in 20 deviate from the average weight of 20 tablets by more than 5.0 %. No tablet deviates from the average weight of 20 tablets by more than 10.0 %.	-1.84 % to + 3.05 % of Average Weight.
05	Friability	NMT 1.0%	0.20%
06	Dissolution	D.NLT 80%	Min.89.5%,Max. 93.5%, Avg. 90.9%
07	Assay: Each uncoated chewable Tablet contains: Albendazole IP 400 mg	370.0 mg to 430.0 mg (92.5 % to 107.5% of Labeled Amount)	396.9647 mg 99.2 %

Conclusion: The above sample of finished product **complies/~~does not comply~~** as per IP.

[redacted]