

Sample Name	TIOTROPIUM BROMIDE INHALER.	Mfg Lic No	[REDACTED]	
Submitted By	Quality Control Advisor. (MMDSL) Shillong.	Report No	[REDACTED]	
Address	DHS LaitumkhrahNHM, EastKhasi Hills Meghalaya.	Receipt Date	19-Sep-24	
Mfg. By	N.S.	Report Date	25-Sep-24	
Supplied By	N.S.	Ref No	N.S.	
Batch No.	Mfg. Date	Exp Date	Batch Size	Sample Qty
MMDSL/QC-0497	07/2024	06/2026	N.S.	12 PCS.

TEST RESULTS

Date / Period of Performance of test 19/09/2024 to 25/09/2024.

Reference to protocol :- In House Specification.

Description :- Clear colourless liquid filled in pressurized metallic container.

Identification :- Positive for Tiotropium Bromide.

Content of active ingredient delivered per spray :- Complies.

Uniformity of delivered dose :- Within limit.

Nominal delivered per container:- 200 metered doses.

Number of deliveries per container :- 204 metered doses.

Leak Test :- Passes the test.

Particle size :- Complies.
Deposition of the emitted dose:- Complies.

Assay :- Each actuation delivers:-

Content of Tiotropium Bromide Monohydrate eq. to Tiotropium	Obtained	Claim	LIMIT		Method
			Lower	Upper	
:- 8.92mcg	9.0mcg.	8.1mcg.	9.9mcg.	HPLC.	

Report: In 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 reason given: Complies with respect above test only.

