



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

Generic Name : Methylergometrine Injection IP
Sample Name : Methylergometrine Injection 0.2mg/ml

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 : 02/05/2024
Period of Analysis : 18/04/2024-02/05/2024
Stability Condition :

Batch No.	Mfg. Date	Exp. Date	Batch Size	Sample Qty.
MMDSL/QC-0194	02/2024	01/2026	NS	50 Ampoules

RESULTS OF ANALYSIS

Reference to Protocol : I.P.-2022
Description : Clear colourless liquid filled in amber coloured glass ampoules

Test Parameters	Results	Limit
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Identification :

(A) by TLC	Complies	-
(B) by Chemically	Complies	-
(C) by Chemically	Complies	-

Nominal Volume	1.0 ml	-
Average fill Volume	1.0 ml	-
Uniformity of Volume	Within limit	-

pH	2.86	2.7 to 3.5
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Related Substances (by TLC)	Complies	-
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Bacterial endotoxins	Less than 1.7 EU/mg	NMT 1.7 EU/mg
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Sterility	Complies	-
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Assay (by UV) : Each ml contains:

<u>Particulars</u>	<u>Result</u>	<u>Claim</u>	<u>Lower</u>	<u>Upper</u>	<u>Method</u>
Methylergometrine Maleate	0.198 mg	0.2 mg	0.18 mg	0.22 mg	IP-2022

End of Report

Remark: 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 reason given below ; Complies as per IP