



OM BIOMEDIC PVT LTD

PLOT NO : 68,69,82 & 83,SECTOR 6A,IIE,SIDCUL,HARIDWAR-249403
REG.OFF.: 134/5 H.T.M ROAD NEAR SECTOR 1&4,RAIPUR LANE-HISAR HARYANA PIN-125001,HISAR-
C.I.No. : U85110HR2005PTC040863

QUALITY CONTROL DEPARTMENT

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THE DRUG & COSMETIC ACT. 1940 & THE RULES THERE UNDER FORM-39(RULE 150-E(F))

FINISHED PRODUCT CERTIFICATE OF ANALYSIS

Product Name : DROTACAN INJECTION 2 ML	A.R. No. : OMFPLI240876
Packing : 2 ML	Rel. Dt. : 16-08-2024
Generic Name : DROTAVERINE HYDROCHLORIDE INJECTION.	T.R. Slip No. : FTRLIQ4211
Product Code : DROT18	T.R. Slip Dt. : 02-08-2024
Batch No. : IH24-36	Analysis Date : 02-08-2024
Actual Batch Size : 221 LTR (105238 AMP)	Mfg. Dt. : 08/2024
Packing Batch Size : 221 LTR	Exp. Dt. : 07/2026
Sample Size : 50.000 ML	Test Packing : 2 ML
Released Qty : 221.000 LTR (105238 AMP)	Mfg. Lic No. : 138/UA/SC/P2007
Remarks :	Test As Per : IH
	Location : HARIDWAR
	Make : OMBPL

Sr.	Test	Result	Specification
1	DESCRIPTION	Clear, light yellow colour solution filled in amber colour glass ampoules. Properly sealed & labeled.	Clear, light yellow colour solution filled in amber colour glass ampoules. Properly sealed & labeled.
2	IDENTIFICATION	Positive for: Drotaverine HCl.	Positive for: Drotaverine HCl.
3	PH	4.56	2.00 - 5.00
4	NOMINAL VOLUME	2.0ml	2.0ml
5	EXTRACTABLE VOLUME	2.12ml.	NLT 2.00ml.
6	PARTICULATE MATTER	No any particle observed by unaided eye.	No any particle observed by unaided eye.
7	STERILITY	Complies.	Should Comply.
8	ASSAY	19.94mg (99.68%)	Each ml Contains: Drotaverine Hydrochloride IP 20.0mg [Limit: 18.0mg - 22.0mg][90.0% - 110.0%]

Conclusion : The above sample complies as per IH
In the Opinion of the undersigned the sample referred to above is of Standard quality as defined in the Act and the Rules made thereunder for the result given above. "This computer generated certificate of analysis is valid without signature"

Analysed By

Approved By