



OM BIOMEDIC PVT LTD

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	: SOLINEX EAR DROPS 10 ML	A.R. No.	: OMFPOP241247
Packing	: 10 ML	Rel. Dt.	: 25-10-2024
Generic Name	: TURPENTINE OIL, CHLOR BUTOL, BENZOCAINE & PARADICHLOROBENZENE EAR DROPS	T.R. Slip No.	: FTREED0019
Product Code	: SOLI01	Exp. Dt.	: 08/2026
Batch No.	: EI24-05	Test Packing	: 1 DROPS
Actual Batch Size	: 263 LTR (26300 DROP)	Mfg. Lic No.	: 138/UA/SC/P2007
Packing Batch Size	: 263 LTR	Test As Per	: IH
Sample Size	: 20.000 DROPS		
Released Qty	: 263.000 LTR (26300 DROPS)		

Remarks :

Location : HARIDWAR
Make : OMBPL

Sr.	Test	Result	Specification
1	DESCRIPTION	Clear, yellow colour viscous solution filled in White colour LDPE bottle with Green Cap. Properly sealed & labeled.	Clear, yellow colour viscous solution filled in White colour LDPE bottle with Green Cap. Properly sealed & labeled.
2	IDENTIFICATION	Positive for: Turpentine Oil, Chlorbutol, Benzocaine & Paradichlorobenzene.	Positive for: Turpentine Oil, Chlorbutol, Benzocaine & Paradichlorobenzene.
3	NOMINAL VOLUME	10.0ml	10.0ml
4	EXTRACTABLE VOLUME	10.1ml	NLT 10.0ml
5	PARTICULATE MATTER	No any particle observed by unaided eye.	No any particle observed by unaided eye.
6	STERILITY	Complies.	Should Comply.
7	ASSAY	1) 14.88%w/v (99.18%) 2) 5.05%w/v (100.95%) 3) 2.66%w/v (98.72%) 4) 2.04%w/v (102.10%)	Composition: 1) Turpentine Oil BP 15.0%w/v [Limit: 13.50%w/v - 16.50%w/v][90.0% - 110.0%] 2) Chlorbutol IP 5.0%w/v [Limit: 4.50%w/v - 5.50%w/v][90.0% - 110.0%] 3) Benzocaine IP 2.70%w/v [Limit: 2.43%w/v - 2.97%w/v][90.0% - 110.0%] 4) Paradichlorobenzene 2.0%w/v [Limit: 1.80%w/v - 2.20%w/v][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