



OM BIOMEDIC PVT LTD

QUALITY CONTROL DEPARTMENT

Page 1 of 1

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
Packing : 10 ML
Generic Name : TURPENTINE OIL, CHLORBUTOL, BENZOCAINE & PARADICHLOROBENZENE BP EAR DROPS
Product Code : SOLI01
Batch No. : EF24-03
Actual Batch Size : 263 LTR (26300 DROP)
Packing Batch Size : 263 LTR
Sample Size : 15.000 DROPS
Released Qty : 263.000 LTR (26300 DROPS)

Mfg. Dt. : 06/2024
Exp. Dt. : 05/2026
Test Packing : 1 DROPS

Mfg. Lic No. : 138/UA/SC/P2007

Test As Per : BP 154

A.R. No. : OMFPOP240773

Rel. Dt. : 03-08-2024

T.R. Slip No. : FTREED0012

T.R. Slip Dt. : 20-07-2024

Analysis Date : 20-07-2024

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	10.5ml	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) 15.021%w/v (100.14%) 2) 5.1215%w/v (102.79%) 3) 2.7651%w/v (102.43%) 4) 2.0308%w/v (101.54%)	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 BP 154

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