



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	: PYRIBROOK 10 ML EYE DROP	A.R. No.	: OMFPO240903
Packing	: 10 ML	Rel. Dt.	: 24-08-2024
Generic Name	: CHLORAMPHENICOL AND BETAMETHASONE SODIUM PHOSPHATE EYE/EAR DROPS	T.R. Slip No.	: FTREED0017
Product Code	: PYRI10	T.R. Slip Dt.	: 10-08-2024
Batch No.	: EH24-03	Analysis Date	: 10-08-2024
Actual Batch Size	: 212LTR(20990 VIAL)		
Packing Batch Size	: 212 LTR		
Sample Size	: 15.000 VIAL		
Released Qty	: 212.000LTR(20990 VIAL)		
Mfg. Dt.	: 08/2024		
Exp. Dt.	: 07/2026		
Test Packing	: 10 ML		
Mfg. Lic No.	: 138/UA/SC/P2007		
Test As Per	: IH		
Remarks		Location	: HARIDWAR
		Make	: OMBPL

Sr.	Test	Result	Specification
1	DESCRIPTION	Clear, colourless liquid filled in white colour LDPE bottle. Properly sealed & labeled.	Clear, colourless liquid filled in white colour LDPE bottle. Properly sealed & labeled.
2	IDENTIFICATION	Positive for: Chloramphenicol & Betamethasone Sodium Phosphate.	Positive for: Chloramphenicol & Betamethasone Sodium Phosphate.
3	PH	7.90	6.50 - 8.50
4	NOMINAL VOLUME	10.00ml	10.00ml
5	EXTRACTABLE VOLUME	10.3ml	NLT 10.0ml
6	PARTICULATE MATTER	No any particle observed by unaided eye.	No any particle observed by unaided eye.
7	STERILITY	Complies.	Should Comply.
8	ASSAY	1) 1.00%w/v (99.80%) 2) 0.01%w/v (100.82%)	Composition: 1) Chloramphenicol IP 1.0%w/v [Limit: 0.90%w/v - 1.10%w/v][90.0% - 110.0%] 2) Betamethasone Sodium Phosphate IP 0.01%w/v [Limit: 0.009%w/v - 0.011%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