

# ZEE LABORATORIES

47, Industrial Area, Gondpur Paonta Sahib Sirmour HP INDIA 173025

## CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

(The Drugs & Cosmetics Act 1940 at the under form 39)

Work Order No. : 252618193

Document No. : 252625921

Ref. STS No.	APNL -18A	Product Code	FG04714
Product Name	SUP. ZEECAINE GEL		
Generic Name	OXETACAINE DRIED ALUMINIUM HYDROXIDE & MAGNESIUM HYDROXIDE GEL		
Batch No.	625-796	Date Of Sampling	04/12/2025
Batch Size	4000.000 Bott.	Sample Quantity	10.000 Bott.
Mfg. Date	11/2025	Exp. Date	10/2027
		Date Of Analysis	04/12/2025
A. R. No.	ZL25FG05447	Date Of Release	09/12/2025

S NO.	Tests	Specification	Results
1	Description	A pink colour thick suspension filled in amber colour pet bottle.	Complies
2	Identification	Positive for Oxetacaine, Dried Aluminium Hydroxide Gel & Magnesium Hydroxide.	Complies
3	Av. vol. Contains	200 ml $\pm$ 4.5%	200 ml
4	pH	7.0 to 9.0	8.57
5	Uniformity of volume	Within Limits	Complies
6	Assay: Each 5 ml contains: Oxetacaine B.P. 10 mg	NLT 90.0% and NMT 110.0% of labelled amount	109.99 %
7	Assay: Each 5 ml contains: Dried Aluminum Hydroxide Gel I.P. 291 mg	NLT 90.0% and NMT 110.0% of labelled amount	98.52 %
8	Assay: Each 5 ml contains: Magnesium Hydroxide I.P. 98 mg	NLT 90.0% and NMT 110.0% of labelled amount	99.74 %
9	Microbial Limit Test:	-	
10	Total Aerobic microbial count	NMT 100 Cfugm	10 Cfugm
11	Total fungal count	NMT 10 Cfugm	Nil
12	Escherichia Coli	Should be absent/gm	Absent

**Remarks** The above sample complies/does not comply with prescribed standards of Quality with respect to above tests as per IP/BP/USP/In house specification.

Particulars	Prepared / Analysed by	Reviewed By	Approved / Authorized By
Signature:	<i>Amarjeet</i>	<i>Sunil Kotech</i>	<i>Amit Kumar</i>
Name:	Amarjeet Kumar	Sunil Kotech	Amit Kumar
Designation:	QC Executive	Astt. QCM	QCM
Date	09/12/2025	09/12/2025	09/12/2025

