

SELVOK PHARMACEUTICAL CO.

147, G.I.D.C., Antalia, Bilimora – 396 325

QUALITY CONTROL DEPARTMENT

CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT

LIGNOCAINE HYDROCHLORIDE GEL IP 2% w/v

Name of Product : Numbon 2% Gel	A.R.No. : UFP/24/SG/064
Specification No. : SPC/FPS/STE.GEL/IP/01	Protocol No. : SPC/FPP/STE.GEL/IP/01

Batch No.	: MA 002	Mfg. Date	: 2/2024
Batch size	: 302 Lits	Exp. Date	: 1/2026
Sampled Quantity	: 21 x 30 gm	Testing Date	: 02/02/2024
Received Date	: 02/02/2024	Release Date	: 16/02/2024

Result of Analysis As Per Specification

(Under the Drugs & Cosmetics Act 1940 and the Drugs & Cosmetics Rules 1945 thereunder)

Sr. No.	Test Parameters	Results	Specifications
1.0	Description	Clear, colourless viscous gel	Clear, Colourless viscous gel.
2.0	Identification	# by IR – Complies Bluish green ppts is produced Yellow coloured is produced	The residue complies with the following tests, A. Determine by infrared absorption spectrophotometry. B. a bluish green precipitate is produced. C. a yellow colour is produced
3.0	Uniformity of weight	30.0398 gm	Not Less than Labelled amount 30.0 gm
4.0	pH	6.633	Limit : 6.0 to 7.0
5.0	Weight per Millilitre	1.0203 gm/ml	1.0000 gm/ ml to 1.1000 gm/ml at 25° C
6.0	2,6-Dimethylaniline	Less than 400 ppm	Not more than 400 ppm
7.0	Assay (by Titration)	Estimated amount : 2.0035 % w/v (100.18 %)	Not less than 95.0% and Not more than 105.0 % of the Labelled amount of Lignocaine Hydrochloride IP equivalent to Lignocaine Hydrochloride Anhydrous 2.000% w/v
8.0	Sterility	Complies	By membrane filtration method No evidence of Microbial growth is found in 14 days

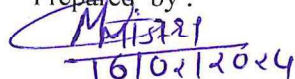
Tests complies with

Royal Research centre Navsari . COA No : RRC/COA/FP/2442/23-24

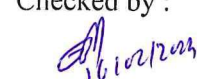
Date : 08/02/2024

Opinion : In the opinion of the undersigned, the sample referred to above is OF STANDARD QUALITY / NOT OF STANDARD QUALITY as defined in the Act and the rules made there under for reason given Below. The sample COMPLIES / DOES NOT COMPLY with the prescribed above standard as per I.P./B.P./U.S.P./IN-HOUSE-SPECIFICATION.


Prepared by :


16/02/2024
(Q. C. Chemist)

Checked by :


16/02/2024
(Q. C. Head)

Approved by :


16/02/2024
(Q. A. Head)