

Tamman Titoe Pharma Pvt Ltd 56-57, Sidco Pharmaceutical Complex, Alathur-603 110, Tamilnadu.

QUALITY CONTROL DEPARTMENT

Certificate of Analysis of Finished Product

(Under Drug And Cosmetic Act. 1940 & The Rules There Under)

Report No: TT/FG/226/24-25 Report Date: 12-08-2024

Name of the product.

: NUMBON 2% w/v Injection 30ml

Generic Name

: Lignocaine Hydrochloride Injection I.P

Batch No.

: LH411

Batch Size

Mfg. Date.

: 14000

Exp. Date.

:JULY-2024

:JUNE-2026

Quantity of Sample

:25 Nos

Date of Sampling

:29-07-2024

Date of Commencement of analysis

:29-07-2024

Date of Completion of analysis

:12-08-2024

TEST NAME	SPECIFICATION	OBSERVATION
Description:	A clear, colourless solution.	A clear, colourless solution
Identification: A. Colour Reaction	A bluish-green precipitate is formed	Complies to IP specification
B. Melts at about 229°	To a volume containing 0.1g of Lignocaine Hydrochloride add 10ml of picric acid solution ;the precipitate, after washing with water and drying at 105°, melts at about 229°.	Complies to IP specification
C.Reaction of chloride: (A)	A Curdy white precipitate is formed	Complies to IP specification
рН	5.0 to 7.0	6.40
Extractable Volume	NLT- 30ml / Vial	31 ml
Particulate matter	No visible particles	Complies
Bacterial Endotoxins	NMT 1.1 EU/mg	LT 1.1 EU/mg
Sterility Test	To comply as per IP	Complies
Assay		
Each ml contains:	1.90% w/v to 2.1% w/v	2. 07% w/v
Lignocaine Hydrochloride I.P 2.0% w\v	(95.0 % - 105.0%)	(103.50%)

OBSERVATION:

In the opinion of the undersigned the sample referred to above is of Standard Quality/Not-Standard Quality as

in the act and the rules made there under for the reason given below.

REMARKS

COMPLIES AS PER IP WITH RESPECT TO THE ABOVE TESTS ONLY CARRIEDOUT.

Analysed By

Checked B Date:

Date:

Person/In