



Venkata Narayana Active Ingredients Private Limited

F&A PHARMA

CERTIFICATE OF ANALYSIS

Product : Tetracaine Hydrochloride
Batch No. : TH0180823
Reference : Ph.Eur 11.0
Dispatch Qty.: 25.000 Kg

CAS No. : [136-47-0]
Date of Mfg : August-2023
Retest Date : July -2028

Storage condition: In an air tight container, protected from light.

S.No	TEST	SPECIFICATION	RESULT
1.0	Appearance	White or almost white, slightly hygroscopic, crystalline powder	White, Slightly hygroscopic, crystalline powder
2.0	Solubility	Freely soluble in water, soluble in ethanol (96%), practically insoluble in heptane.	Complies
3.0	Melting range (°C)	134 to 150	147.3 -148.4
4.0	First Identification-Test:		
4.1	Infrared absorption spectrophotometry(Test-A)	The IR spectrum of the test sample should be concordant with the spectrum obtained from Tetracaine Hydrochloride working /RS standard.	Complies
4.2	Reaction of chlorides(Test-D)	Should respond to the test for chlorides	complies
5.0	Second Identification Test:		
5.1	Chemical test -B	Should respond to the test	complies
5.2	Chemical test -C	Should develop a violet colour	complies
6.0	Appearance of solution	Solution should be clear and colour less	Complies
7.0	pH	Between 4.5 and 6.5	5.61
8.0	Related substances by HPLC (in %)		
8.1	Impurity-A	Not more than 0.05	Not detected
8.2	Impurity-B	Not more than 0.15	Below quantitation limit(0.015)
8.3	Impurity-C	Not more than 0.15	Not detected
8.4	Maximum unspecified impurities	Not more than 0.10	Below disregard limit(0.05)
8.5	Total impurities	Not more than 0.5	Below disregard limit(0.05)
9.0	Loss on drying (% w/w)	Not more than 1.0	0.28
10.0	Sulphated ash (% w/w)	Not more than 0.1	0.07
11.0	Assay by Potentiometry (on dried basis) (% w/w)	Not less than 99.0 and not more than 101.0	99.5

Prepared By:

Date:

Checked By:

Date:

Approved By:

Date:

Regd. Office : Venkata Narayana Towers, 3rd Floor, New No.60, Old No.35, Venkatanarayana Road, T.Nagar, Chennai - 600017, Tamil Nadu. Phone : +91-44-42984141.

Factory : Sy. No.69, Chandrapadiya Village, Vinjamur Mandal, S.P.S.R. Nellore District - 524 228. Andhra Pradesh. Phone : +91-93840 98801 / 02 / 03 / 04

METAPHARMACEUTICAL

Web: www.vnai.in / CIN: U24231TN2005PTC057504

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27/02/2024



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S.No	TEST	SPECIFICATION	RESULT
12.0	Assay by HPLC (on dried basis) (% w/w)	Not less than 99.0 and not more than 101.0	100.0
13.0	Residual solvents by GC (in ppm)		
13.1	Methanol	Not more than 3000	Below detection limit(150)
13.2	Acetone	Not more than 5000	Below detection limit(250)
13.3	Hexanes	Not more than 290	Not detected
13.4	Toluene	Not more than 890	Not detected

Remarks: The product **Complies** as per the above specification.

Prepared By:
Date:

[Signature]
25/01/2024

Checked By:
Date:

[Signature]
25/01/24

Approved By:
Date:

[Signature]
25/01/2024



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