



F. & A. PHARMA-Handels-GmbH
Bonhoeffering 41 • D - 46286 Dorsten • Germany
Phone: +49(0) 2369-9261947 • Fax: +49(0) 2369-9261950

Venkata Narayana Active Ingredients Private Limited

(Formerly Nutra Specialities Private Limited)

METAPHARMACEUTICAL

CERTIFICATE OF ANALYSIS

N DE LOTE:

0180921

Product : Tetracaine Hydrochloride
Batch No. : TH0060721
Dispatch Qty : 20.0 Kg
Reference : EP 10

CAS No. : [136-47-0]
Date of Mfg : July-2021
Retest Date : June-2026

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	Almost White, slightly hygroscopic, crystalline powder
2.0	Solubility	Freely soluble in water, soluble in ethanol (96%)	Complies
3.0	Melting range (°C)	It melts at about 148	148.3
4.0	Identification by		
4.1	IR	The IR spectrum of the test sample should be concordant with the spectrum obtained from working standard	Complies
4.2	Chemical test -A	Should respond to the test	complies
4.3	Chemical test -B	Should develop a violet colour	complies
4.4	Reaction of chlorides	Should respond to the test for chlorides	complies
5.0	Appearance of solution	Solution should be clear and colour less	Complies
6.0	pH	Between 4.5 and 6.5	4.91
7.0	Related substances by HPLC (in %)		
7.1	Impurity-A	Not more than 0.05	Not detected
7.2	Impurity-B	Not more than 0.1	Below Disregarded Limit(0.05)
7.3	Impurity-C	Not more than 0.1	Not detected
7.4	Maximum unspecified impurities	Not more than 0.10	Below Disregarded Limit(0.05)
7.5	Total impurities	Not more than 0.5	Below Disregarded Limit(0.05)
8.0	Loss on drying (% w/w)	Not more than 1.0	0.36
9.0	Sulphated ash (% w/w)	Not more than 0.1	0.05
10.0	Assay by Potentiometry (on dried basis) (% w/w)	Not less than 99.0 and not more than 101.0	100.1

Prepared By: *[Signature]*
Date: 20/08/2021

Checked By: *[Signature]*
Date: 20/08/2021

Approved By: *[Signature]*
Date: 20/08/2021

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
Web: www.vnai.in / CIN: U24231TN2005PTC057504



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S.No	TEST	SPECIFICATION	RESULT
11.0	Assay by HPLC (on dried basis) (% w/w)	Not less than 99.0 and not more than 101.0	100.0
12.0	Residual solvents by GC (in ppm)		
12.1	Methanol	Not more than 3000	Below Detection Limit (150)
12.2	Acetone	Not more than 5000	Below Detection Limit(250)
12.3	Hexanes	Not more than 290	Below Detection Limit(14.5)
12.4	Toluene	Not more than 890	Not detected

Remarks: The product confirms as per the above specification.

Prepared By : *Ty*
Date: 20/08/2021

Checked By : *fulp*
Date: 20/08/2021

Approved By: *A*
Date: 20/08/2021

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