

08/06/2023

METAPHARMACEUTICAL

N DE LOTE:

0021123



Venkata Narayana Active Ingredients Private Limited
(Formerly Nutra Specialities Private Limited)

METAPHARMACEUTICAL

CERTIFICATE OF ANALYSIS

N DE LOTE:

0021123

Product : Tetracaine Hydrochloride
Batch No. : TH0080422
Dispatch Qty.: 100.0 Kg
Reference : EP10.7

CAS No. : [136-47-0]
Date of Mfg : April-2022
Retest Date : March-2027

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	147.1-148.3
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	5.68
8.0	Related substances by HPLC (in %)		
8.1	Impurity-A	Not more than 0.05	Below detection limit(0.007)
8.2	Impurity-B	Not more than 0.15	Below detection limit(0.005)
8.3	Impurity-C	Not more than 0.15	Below detection limit(0.005)
8.4	Maximum unspecified impurities	Not more than 0.10	0.09
8.5	Total impurities	Not more than 0.5	0.18
9.0	Loss on drying (% w/w)	Not more than 1.0	0.27
10.0	Sulphated ash (% w/w)	Not more than 0.1	0.05
11.0	Assay by Potentiometry (on dried basis) (% w/w)	Not less than 99.0 and not more than 101.0	100.3

Prepared By: Y

Date:

Checked By: Y

Date:

Approved By: Y

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.

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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	100.4
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 quantification limit (750)
13.3	Hexanes	Not more than 290	Below detection limit (14.5)
13.4	Toluene	Not more than 890	Below detection limit (44.5)

Remarks: The product Complies as per the above specification.

Prepared By : *[Signature]*
Date: 30.06.22

Checked By: *[Signature]*
Date: 30.06.2022

Approved By: *[Signature]*
Date: 30/06/2022



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