



Nutra Specialties Private Limited

Factory : Sy. No.69, Chandrapadiya Village, Vinjamur Mandal,
Nellore District - 524 228.

Andhra Pradesh. Phone : +91-8627-300100

NUTRA
FOR Niche Pharma Ingredients

CERTIFICATE OF ANALYSIS

Product : Tetracaine Hydrochloride

CAS No. : [136-47-0]

Batch No. : TH0081216

Date of Mfg : December-2016

Dispatch Qty : 50.0 Kg

Expiry Date : November- 2021

Reference : EP 8.0

No. R0-CEP 2010-256-Rev 00

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%)	Freely soluble in water, soluble in ethanol (96%)
3.0	Melting range (°C)	Between 134 and 147	144.3-145.4
4.0	Identification by		
4.1	IR	The IR spectrum of the test sample should be concordant with the spectrum obtained from working standard	The IR spectrum of the test sample was concordant with the spectrum obtained from working standard
4.2	Melting point (°C)	Should melt at about 131	131.7
4.3	Chemical test	Should develop a violet colour	Positive
4.4	Reaction of chlorides	Should respond to the test for chlorides	Positive
5.0	Appearance of solution	Solution should be clear and colour less	Solution was clear and colour less
6.0	pH	Between 4.5 and 6.5	5.32
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	0.01
7.3	Impurity-C	Not more than 0.1	Not detected
7.4	Maximum unspecified impurities	Not more than 0.10	0.03
7.5	Total impurities	Not more than 0.5	0.04
8.0	Heavy metals (ppm)	Not more than 10	Less than 10
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	100.5

Prepared By: [Signature]
Date: 28/02/2017

Checked By: [Signature]
Date: 28/02/2017

Approved By: [Signature]
Date: 28/02/2017



NUTRA
FOR MORE PHARMACEUTICALS

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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	100.5
13.0	Residual solvents by GC (in ppm)		
13.1	Methanol	Not more than 3000	130
13.2	Acetone	Not more than 5000	233
13.3	Hexanes	Not more than 290	1
13.4	Toluene	Not more than 890	43
14.0	Genotoxic Impurities content by GC (in ppm)		
14.1	N-Butyl bromide	Not more than 15 ppm	Not detected
14.2	N,N-dimethyl amino ethyl chloride HCl	Not more than 15 ppm	Not detected

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

Prepared By :
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