



Nutra Specialities Private Limited

Survey No. 69, Chandrapadiya Village, Vinjamur Mandal, Nellore District - 524 228,
Andhra Pradesh India. Tel: 08627-300100 Fax: 08627-300111

CERTIFICATE OF ANALYSIS

Product : Tetracaine Hydrochloride
Batch No. : TH0020215
Dispatch Qty : 150.0 Kg
Reference : EP 8.0
No. R0-CEP 2010-256-Rev 00

CAS No. : [136-47-0]
Date of Mfg : February-2015
Expiry Date : January- 2020

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	145.5 – 146.7
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	131.5
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	5.93
7.0	Related substances by HPLC (in %)		
7.1	Impurity-A	Not more than 0.05	Below LOD (0.0116)
7.2	Impurity-B	Not more than 0.1	Below LOD (0.0072)
7.3	Impurity-C	Not more than 0.1	Below LOD (0.0273)
7.4	Maximum unspecified impurities	Not more than 0.10	0.03
7.5	Total impurities	Not more than 0.5	0.08
8.0	Heavy metals (ppm)	Not more than 10	Less than 10
9.0	Loss on drying (% w/w)	Not more than 1.0	0.35
10.0	Sulphated ash (% w/w)	Not more than 0.1	0.06
11.0	Assay by Potentiometry (on dried basis) (% w/w)	Not less than 99.0 and not more than 101.0	99.76

Prepared By: P. P. K. —
Date: 20.02.2015

Checked By: *[Signature]*
Date: 20/02/2015

Approved By: *[Signature]*
Date: 20/02/2015



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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	99.9
13.0	Residual solvents by GC (in ppm)		
13.1	Methanol	Not more than 3000	Below LOD (9)
13.2	Acetone	Not more than 5000	112
13.3	Hexanes	Not more than 290	Below LOD (5)
13.4	Toluene	Not more than 890	Below LOD (7)
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 : P.P. K. _____
Date: 20.02.2015

Checked By : B. S. _____
Date: 20/02/2015

Approved By: _____
Date: 20/02/2015

