

Nutra Specialities Private Limited

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

Andhra Pradesh. Phone : +91-8627-300100

NUTRA

CERTIFICATE OF ANALYSIS

Product : Tetracaine Hydrochloride
Batch No. : TH0010118
Dispatch Qty : 100.0 Kg
Reference : EP 9

CAS No. : [136-47-0]
Date of Mfg : January-2018
Expiry Date : December 2022

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%)	Complies
3.0	Melting range (°C)	It melts at about 148	148.4 -149.3
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	Should respond to the test	complies
4.3	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	5.41
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	Not detected
7.3	Impurity-C	Not more than 0.1	Not detected
7.4	Maximum unspecified impurities	Not more than 0.10	Not detected
7.5	Total impurities	Not more than 0.5	Not detected
8.0	Loss on drying (% w/w)	Not more than 1.0	0.46
9.0	Sulphated ash (% w/w)	Not more than 0.1	0.08
10.0	Assay (on dried basis) (% w/w)	Not less than 99.0 and not more than 101.0	99.5

Prepared By: *[Signature]*
Date: 21/01/2018

Checked By: *[Signature]*
Date: 21/01/2018

Approved By: *[Signature]*
Date: 21/01/2018

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S.No	TEST	SPECIFICATION	RESULT
11.0	Residual solvents by GC (in ppm)		
11.1	Methanol	Not more than 3000	Not detected
11.2	Acetone	Not more than 5000	400
11.3	Hexanes	Not more than 290	Not detected
11.4	Toluene	Not more than 890	Not detected

Remarks: The product confirms as per the above specification.

Prepared By : *[Signature]*
Date: 31/01/2018

Checked By : *[Signature]*
Date: 31/01/2018

Approved By: *[Signature]*
Date: 31/01/2018