



NABL

National Accreditation Board for Testing and Calibration Laboratories

(An Autonomous Body under Department of Science & Technology, Govt. of India)

CERTIFICATE OF ACCREDITATION

TEENA BIOLABS PVT. LTD.

has been assessed and accredited in accordance with the standard

ISO/IEC 17025:2005

"General Requirements for the Competence of Testing & Calibration Laboratories"

for its facilities at

Plot No. 41, S. V. Co-Operative Industrial Estate, Bachupally (V), Quthbullapur (M), R. R. Dist., Telangana

in the discipline of

BIOLOGICAL TESTING

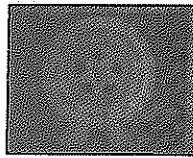
(To see the scope of accreditation of this laboratory, you may also visit NABL website www.nabl-india.org)

Certificate Number

T-2852

Issue Date

20/10/2016



Valid Until

19/10/2018

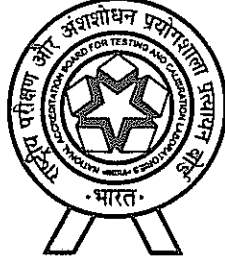
This certificate remains valid for the Scope of Accreditation as specified in the annexure subject to continued satisfactory compliance to the above standard & the additional requirements of NABL.

Signed for and on behalf of NABL

N. Venkateswaran
Program Manager

Anil Relia
Director

Prof. S. K. Joshi
Chairman



रा.प्र.प्र.बो.

राष्ट्रीय परीक्षण और अंशशोधन प्रयोगशाला प्रत्यायन बोर्ड

(विज्ञान एवं प्रौद्योगिकी विभाग, भारत सरकार के अधीन स्वायत्तशासी निकाय)

प्रत्यायन प्रमाण-पत्र

टीना बायोलैब्स प्रा. लि.

का मूल्यांकन और प्रत्यायन निम्न मानक के अनुसार

आई.एस.ओ./आई.ई.सी. 17025:2005

“परीक्षण एवं अंशशोधन प्रयोगशालाओं की सक्षमता की सामान्य अपेक्षाएँ”

कुतबुल्लापुर, तेलंगाना

में स्थित इसकी सुविधाओं के लिए

जैविक परीक्षण

के विषय क्षेत्र में किया गया।

(इस प्रयोगशाला के प्रत्यायन के विषय क्षेत्र की जानकारी एन ए बी एल वेबसाइट www.nabl-india.org से भी प्राप्त कर सकते हैं)

प्रमाण-पत्र संख्या

प-2852

जारी करने की तिथि

20/10/2016

वैधता की तिथि

19/10/2018

यह प्रमाण-पत्र उपर्युक्त मानक तथा राष्ट्रीय परीक्षण और अंशशोधन प्रयोगशाला प्रत्यायन बोर्ड की अतिरिक्त अपेक्षाओं का निरंतर संतोषप्रद अनुपालन किए जाने पर अनुबंध में निर्दिष्टानुसार प्रत्यायन के क्षेत्र के लिए वैध रहेगा।

रा.प्र.प्र.बो. की ओर से हस्ताक्षरित

एन. वेंकटेश्वरन

कार्यक्रम प्रबन्धक

अनिल रेलिया

निदेशक

प्रो. श्रीकृष्ण जोशी

अध्यक्ष



NABL

SCOPE OF ACCREDITATION

Laboratory	Teena Biolabs Pvt. Ltd., Plot No. 41, S. V. Co-Operative Industrial Estate, Bachupally (V), Quthbullapur (M), R. R. Dist., Telangana		
Accreditation Standard	ISO/IEC 17025: 2005		
Discipline	Biological Testing	Issue Date	20.10.2016
Certificate Number	T-2852	Valid Until	19.10.2018
Last Amended on	-	Page	1 of 3

S. No.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
I.	DRUGS AND PHARMACEUTICALS			
1.	Dried Aluminium Hydroxide gel	Escherichia coli/g	IP 2014, Vol. II, App 2.2.9, Page. 1022	Qualitative (Present or Absent)/g
2.	Starch	Escherichia coli/g	IP 2014, Vol. III, App 2.2.9, Page. 3270	Qualitative (Present or Absent)/g
		Salmonella species/10g	IP 2014, Vol. II, App 2.2.9, Page. 3270	Qualitative (Present or Absent)/g
3.	Gelatin	Microbial limit test		
		Total aerobic microbial count cfu/g	IP 2014, Vol. II, App 2.2.9, Page. 1848	Not More Than 1000 cfu/g
		Escherichia coli/g	IP 2014, Vol. II, App 2.2.9, Page. 1848	Qualitative (Present or Absent)/g
		Salmonella species/10g	IP 2014, Vol. II, App 2.2.9, Page. 1848	Qualitative (Present or Absent)/10g
4.	Hard gelatin capsules	Microbial limit test		
		Total aerobic microbial count cfu/g	IP 2014, Vol. II, App . 2.2.9, Page. 1849	Not More Than 1000 cfu/g
		Escherichia coli/g	IP 2014, Vol. II, App 2.2.9, Page. 1849	Qualitative (Present or Absent)/g
		Salmonella species/10g	IP 2014, Vol. III, App 2.2.9, Page. 1849	Qualitative (Present or Absent)/10g

Bhumi Rajyaguru
Convenor

N. Venkateswaran
Program Manager



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S. No.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
5.	Purified water	Microbial limit test Total aerobic microbial count cfu/ml	IP 2014, Vol. III, App 2.2.9, Page. 2988	Not More Than 100 cfu/ml
6.	Water for injection	Microbial limit test Total aerobic microbial count cfu/g Bacterial endotoxins test Method A. Gel-clot	IP 2014, Vol. III, App 2.2.9, Page. 2989 IP 2014, Vol. III, App 2.2.3, Page. 2989	Not More Than 10 cfu/ml Not More Than 0.25 EU/ml
7.	Sodium chloride injection	Sterility test by membrane filtration	IP 2014, Vol. III, App 2.2.11, Page. 2744	Qualitative test
8.	Enoxoparin injection	Sterility test by membrane filtration Bacterial endotoxins test Method A. Gel-clot	IP 2014, Vol. II, App 2.2.11, Page. 1661 IP 2014 Vol. II App , 2.2.3, Page. 1661	Qualitative test Not More Than 0.01EU/Unit of Anti factor Xa
9.	Heparin injection	Sterility test by membrane filtration Bacterial endotoxins test Method A. Gel-clot	IP 2014, Vol. II, App 2.2.11, Page. 1888 IP 2014, Vol. II, App 2.2.3, Page. 1888	Qualitative test Not More Than 0.03 EU/Unit of Heparin
10.	Medical device Intravenous set	Sterility test by membrane filtration	IP 2014, Vol. I, App 2.2.11, Page. 59	Qualitative test
11.	Medical device Syringes	Sterility test by membrane filtration	IP 2014, Vol. I, App 2.2.11, Page. 59	Qualitative test

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S. No.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
12.	Blood bags	Sterility test by direct inoculation	IP 2014, Vol. I, App 2.2.11, Page. 59	Qualitative test
		Intracutaneous test	IP 2014, Vol. I, App 6.2.3.2, Page. 895	Qualitative test
13.	Rabis vaccine, human	Pyrogen test	IP 2014, Vol. III, App 2.2.8, Page. 3135	Qualitative test
II. TOXICOLOGY				
1.	Protamine sulphate injection	Abnormal toxicity	IP 2014, Vol. III, App 2.2.1, Page. 2589	Qualitative test
2.	Polypropylene granules for plastic closures and containers	Systemic injection test	IP 2014, Vol. I, App 6.2.3.2, Page. 894	Qualitative test
		Intracutaneous test	IP 2014, Vol. I, App 6.2.3.2, Page. 895	Qualitative test

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