भारत सरकार
विज्ञान और प्रौद्योगिकी विभाग
राष्ट्रीय उत्तम प्रयोगशाला पद्धति (जी एल पी) अनुपालन निगरानी प्राधिकरण (एन जी सी एम ए)

जी एल पी अनुपालन प्रमाण-पत्र

निरीक्षण और तत्पश्चात अनुवर्ती कार्रवाईयों के आधार पर

सीएसआईआर–सेंट्रल ड्रग रिसर्च इंस्टिट्यूट
सेक्टर 10, जानकीपुरम एक्सटेंशन
लखनऊ–226031 (उत्तर प्रदेश)

को जीएलपी के आर्थिक सहयोग एवं विकास संगठन (ओईसीडी) सिद्धांतों के अनुपालन में निम्नलिखित जांच/अध्ययन करने में सक्षम होने के लिए प्रमाणित किया जाता है

- विषैलापन अध्ययन
- अन्य

विशेषज्ञता के विशिष्ट क्षेत्र, रसायनों के प्रकार और जांच प्रणालियों की सूची अनुलग्नक में दी गई है।

वैधता की अवधि : 18 अक्टूबर, 2017 – 17 अक्टूबर, 2020

यह प्रमाण पत्र इस शर्त के अध्यधीन है कि जांच सुविधा एनजीसीएमए के प्रबंधन संबंधी जीएलपी–101 "जांच सुविधा द्वारा जीएलपी प्रमाणीकरण की प्राप्ति और अनुरक्षण के लिए एनजीसीएमए की निबंधन एवं शर्तों" तथा जीएलपी के ओईसीडी सिद्धांतों का अनुपालन करती है।

प्रमाण पत्र सं. : जी एल पी/सी–108/2017
जारी करने की तारीख : 18–10–2017

(डॉ नीरज शर्मा)
प्रमुख, राष्ट्रीय जी एल पी
अनुपालन निगरानी प्राधिकरण

GOVERNMENT OF INDIA
Department of Science and Technology
National Good Laboratory Practice (GLP) Compliance Monitoring Authority (NGCMA)

Certificate of GLP Compliance

Based on the Inspection and the subsequent follow-up actions

CSIR-Central Drug Research Institute
Sector 10, Jankipuram Extension
Lucknow – 226031 (Uttar Pradesh)

is certified capable of conducting the below-mentioned tests/studies in compliance with Organization for Economic Co-operation & Development (OECD) Principles of GLP:

- **Toxicity Studies**
- **Others**

The specific areas of expertise, types of chemicals and test systems are listed in annexure overleaf.

Validity: October 18, 2017 – October 17, 2020

This certificate is subject to the condition that the test facility complies with the NGCMA's Document No. GLP-101 "Terms & Conditions of NGCMA for obtaining and maintaining GLP certification by a test facility" and OECD Principles of GLP.

Certificate No.: GLP/C-108/2017
Issue Date : 18-10-2017

(Dr. Neeraj Sharma)
Head, NGCMA

जीएलपी प्रमाणित जॉच सुविधा
GLP Certified Test Facility

सूचनाकेलिए, कृपयासंपर्ककरें:

निदेशक
सीएसआईआर-केन्द्रीयऔषधिअनुसंधानसंस्थान
सेक्टर 10, जानकीपुरमविस्तार, सीतापुररोड
लखनऊ - 226031, उप्र, भारत
दूरभाष: 091-522-2771940;
ईमेल: director@cdri.res.in

परीक्षण सुविधा प्रबंधन
सीएसआईआर-केन्द्रीयऔषधि अनुसंधान संस्थान
सेक्टर 10, जानकीपुरम विस्तार, सीतापुर रोड
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For information, please contact:

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Test Facility Management
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CSIR-Central Drug Research Institute

जीएलपी प्रमाणित जॉच सुविधा
GLP Certified Test Facility

GLP
Test Facility
For Pharmaceuticals

सीएसआईआर-केन्द्रीय औषधि अनुसंधान संस्थान
CSIR-CENTRAL DRUG RESEARCH INSTITUTE
www.cdri.res.in

GLP Test Facility for Pharmaceuticals

(CSIR-CDRI), a constituent laboratory of the Council of Scientific & Industrial Research, India, received certificate of GLP compliance from NGCMA in November 2017 for safety pharmacology and acute toxicity studies. It is the second laboratory of the CSIR family to receive this international accreditation. The GLP certification is the testimony of the high quality research work that has been carried out in the Institute.

CSIR-CDRI has successfully delivered several drugs and technologies leading to affordability of drugs in India and also the developing world. About two-thirds of all drugs developed in independent India are from this Institute. The Indian pharmaceutical industry is richly dotted with CDRI alumni who have made invaluable contributions to the sector. CDRI is the only public funded institute that has strong teams of researchers with capabilities extending from disease biology to pre-clinical development.

CSIR-CDRI GLP facility leverages in vivo rodent models to enable safety of suitable products in pharma, and biotech sectors. Our experienced team with vast knowledge in the domain of regulatory toxicology and safety pharmacology and advanced biotechnologies at the GLP Test Facility is committed to realize its mission towards serving national as well as global needs in the area of toxicology and safety. This facility has the distinction of being the only government laboratory with all knowledge of drug discovery and development.

India has a full adherence member status of OECD's Working Group on GLP. Hence, the toxicity and safety pharmacology data generated for variety of pharmaceutical molecules/ NCEs /formulations, from this test facility will be accepted regulatory authorities in 100 countries including all OECD member countries & all associated non-member countries.

GLP certified studies

The following studies are conducted under certificate of GLP compliance for various sponsors to meet the regulatory requirements:

- Acute toxicity study
- Oxygen Saturation study
- Respiratory Safety study
- CNS Safety Pharmacology
- CVS Safety Pharmacology

Types of Chemicals/Materials for Toxicity Studies:

- New chemical entities (NCE)
- Pharmaceuticals (Small molecules, Biosimilars, Biotherapeutics, Vaccines, etc.)
- Veterinary drugs
- Nutraceuticals
- Phytopharmaceuticals
- Plant extracts in Ayush mode

Test Systems for the Studies:

- Rat (Wistar, SD, CF)
- Mouse (Swiss albino; C57BL/6; BALB/C)
- Rabbit (New Zealand White, Belgium)

Studies under GLP Compliant Conditions:

- AMES assay
- In vivo micronucleus assay
- In vitro micronucleus assay
- In vivo chromosomal aberration assay
- In vitro chromosomal assay
- Repeat dose toxicity studies in rodents (28, 90 and 180 days)
- Repeat dose toxicity study in non-human primates
- Male fertility study
- Female fertility study
- Teratogenicity study
- One generation reproductive toxicity
- Two generation reproductive toxicity

Test Systems for the Studies:

- Rat (Wistar, SD, CF)
- Mouse (Swiss albino; C57BL/6; BALB/C)
- Rabbit (New Zealand White, belgium)
- Monkeys (Macacamulata)
- Guinea Pig (Hartley)