

ANURAG MISHRA
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National GLP Compliance
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भारत सरकार

विज्ञान और प्रौद्योगिकी मंत्रालय विज्ञान और प्रौद्योगिकी विभाग टेक्नोलॉजी भवन, नया महरौली मार्ग नई दिल्ली-110 016

GOVERNMENT OF INDIA

MINISTRY OF SCIENCE AND TECHNOLOGY DEPARTMENT OF SCIENCE AND TECHNOLOGY TECHNOLOGY BHAVAN, NEW MEHRAULI ROAD

NEW DELHI-110 016

Dated	

2.7.2024

D.O. No.

DST/GLP (APP)-320/23

Dear Dr. Rath,

Thanks for extending kind cooperation in facilitating re-certification inspection of your Test Facility (TF) for GLP certification by a Team of GLP Inspectors on October 16&17, 2023.

I am pleased to inform you that based on the inspection and recommendations of Technical Committee (TC) on GLP, CSIR-Central Drug Research Institute, Lucknow has been granted GLP compliance certification in the area(s) of expertise, test system(s) and test item(s), as mentioned in the attached GLP certificate.

Please acknowledge receipt of the GLP certificate attached herewith.

Please note that as per NGCMA's advisory dated February 16, 2021, your TF is required to publish factual information regarding GLP certification on your website. Further, the compliance of the said advisory will be checked by the inspection team during the next GLP inspection.

A copy of the report of re-certification inspection can be downloaded from the NGCMA portal.

This issues with the approval of the Competent Authority.

With kind regards,

Yours sincerely.

(Anurag Mishra)

Dr. S. K. Rath
Deputy Test Facility Management
CSIR-Central Drug Research Institute
Sector 10, Jankipuram Extension, Sitapur Road
Lucknow – 226031, Uttar Pradesh

National Good Laboratory Practice (GLP) Compliance Monitoring Authority (NGCMA)

Certificate of GLP Compliance



GOVERNMENT OF INDIA Department of Science and Technology

Technology Bhawan, New Mehrauli Road, New Delhi-110016 https://dst.gov.in/ngcma





राष्ट्रीय उत्तम प्रयोगशाला पद्धति (जीएलपी) अनुपालन निगरानी प्राधिकरण (एनजीसीएमए) विज्ञान और प्रौद्योगिकी विभाग

भारत सरकार

जी एल पी अनुपालन प्रमाण-पत्र

प्रमाणित किया जाता है कि

सीएसआईआर—केन्द्रीय औषधि अनुसंघान संस्थान सेक्टर 10, जानकीपुरम एक्सटेंशन, सीतापुर रोड लखनऊ—226031, उत्तर प्रदेश (भारत)

एनजीसीएमए की प्रलेख संख्या जीएलपी—101 "जाँच सुविधा केंद्र द्वारा जीएलपी प्रमाणीकरण की प्राप्ति एवं अनुरक्षण से संबंधित एनजीसीएमए के निबंधन एवं शर्ती" और जीएलपी के ओईसीडी के सिद्धांतों का अनुपालन करने वाला जीएलपी प्रमाणित जाँच सुविधा केंद्र है।

यह जाँच सुविधा केंद्र निम्नलिखित जाँच/अध्ययन संचालित करता है:

- विषाक्तता अध्ययन
- उत्परिवर्तजनीयता अध्ययन
- अन्य

विशेषज्ञता के विशिष्ट क्षेत्रों, जाँच मद और जाँच प्रणालियों की सूची अनुलग्नक में दी गई है।

वैधता की अवधिः 18 अक्टूबर, 2023 – 17 अक्टूबर, 2026

प्रमाण पत्र सं.ः जीएलपी / सी–230 / 2024

जारी करने की तारीखः 2-7-2024

राकाता कापूर

(डॉ. एकता कपूर) प्रमुख, एनजीसीएमए



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

Certificate of GLP Compliance

This is to certify that

CSIR—Central Drug Research Institute
Sector 10, Jankipuram Extension, Sitapur Road
Lucknow—226031, Uttar Pradesh (India)

is a GLP certified test facility in compliance 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.

The test facility conducts the below-mentioned tests/ studies:

- Toxicity Studies
- Mutagenicity Studies
- Others

The specific area(s) of expertise, test item(s) and test system(s) are listed in the annexure overleaf.

Validity: October 18, 2023 – October 17, 2026

Certificate No. : GLP/C-230/2024

Issue Date : 2-7-2024

(Dr. Ekta Kapoor) Head, NGCMA

National GLP Compliance Monitoring Authority (NGCMA)

Annexure to Certificate of GLP Compliance No. GLP/C-230/2024

Area(s) of Expertise:

Toxicity Studies

- o Acute Toxicity
- o Developmental and Reproductive Toxicity
- o Repeated Dose Toxicity

Mutagenicity Studies

- o Bacterial Reverse Mutation (AMES) Test
- o Chromosomal Aberration Test (in vitro)
- o Micronucleus Test (in vivo)

Others

o Safety Pharmacology

Test Item(s): Pharmaceuticals (Human)

Test System(s): Mice, Primary Cell Culture, Rabbit, Rat and Salmonella typhimurium

(Dr. Ekta Kapoor) Head, NGCMA

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