

**Department of Science & Technology**  
**National GLP Compliance Monitoring Authority/GLP Cell**

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The scope of GLP certification (Type of studies and Test systems) has been drafted based on the deliberations of the brainstorming meeting held on November 16, 2023 involving participants from Technical Committee on GLP, Experts from Industry, representatives from Regulatory Authorities (DCGI and CIBRC), Subject matter specialists as well as GLP inspectors.

The draft scope is attached herewith at Annexures I, II, III and IV. Stakeholders comments are invited latest by January 10, 2024.

The comments on the draft scope may be submitted using the following google spreadsheet link:

<https://docs.google.com/spreadsheets/d/1JyCQPNjlkEdl4DK4o-fF7tFB3Gh2ZGqLo0KsKM1BisY/edit?usp=sharing>

The comment could also be sent over email (*anurag.dbt@nic.in*), within the due date mentioned above.

<b>Sl. No.</b>	<b>Toxicity Studies</b>	<b>Toxicity Sub-studies</b>
<b>1</b>	Acute Toxicity	
<b>2</b>	Bacterial Endotoxin Test (BET)	
<b>3</b>	Bovine Corneal Opacity (BCO)	
<b>4</b>	Carcinogenicity	
<b>5</b>	Developmental and Reproductive Toxicity	
<b>6</b>	Endocrine Disruptor Assay ( <i>in vitro</i> )	
<b>7</b>	Endocrine Disruptor Assay ( <i>in vivo</i> )	
<b>8</b>	Eye Irritation/ Serious Eye Damage ( <i>in vitro</i> )	
<b>9</b>	Eye Irritation/ Serious Eye Damage ( <i>in vivo</i> )	
<b>10</b>	Hen's Egg Test Chorioallantoic Membrane (HET-CAM)	
<b>11</b>	<i>in vitro</i> Hematotoxicity Assay	
<b>12</b>	Inhalation Toxicity	
<b>13</b>	Immunogenicity	
<b>14</b>	Immunotoxicity	
<b>15</b>	Local Tolerance	
<b>16</b>	Neurotoxicity	
<b>17</b>	Phototoxicity ( <i>in vitro</i> )	
<b>18</b>	Pyrogen Test	
<b>19</b>	Repeated Dose Toxicity	
<b>20</b>	Skin Irritation/ Corrosion ( <i>in vitro</i> )	
<b>21</b>	Skin Irritation/ Corrosion ( <i>in vivo</i> )	
<b>22</b>	Skin Sensitization ( <i>in vitro</i> )	
<b>23</b>	Skin Sensitization ( <i>in vivo</i> )	
		Guinea Pig Maximization
		Local Lymph Node Assay (LLNA)
<b>24</b>	Others	

<b>Sl. No.</b>	<b>Mutagenicity Studies</b>
<b>1</b>	Minimum Inhibitory Concentration (MIC) Assay
<b>2</b>	Micronucleus Test ( <i>in vitro</i> )
<b>3</b>	Micronucleus Test ( <i>in vivo</i> )
<b>4</b>	Mouse Lymphoma Assay (MLA)
<b>5</b>	MTT Assay
<b>6</b>	Bacterial Reverse Mutation (AMES) Test
<b>7</b>	Cell Gene Mutation Test
<b>8</b>	Chromosomal Aberration Test ( <i>in vitro</i> )
<b>9</b>	Chromosomal Aberration Test ( <i>in vivo</i> )
<b>10</b>	Comet Assay
<b>11</b>	Others

<b>Sl. No.</b>	<b>Type of Studies</b>
<b>1</b>	ADME / DMPK Studies
<b>2</b>	Toxicokinetics
<b>3</b>	Bioanalysis
<b>4</b>	Bioassays
<b>5</b>	Biocompatibility Studies
<b>6</b>	Bioefficacy studies
<b>7</b>	Functional Safety Testing
<b>8</b>	Hemocompatibility Studies
<b>9</b>	Method Validation
<b>10</b>	Safety Pharmacology
<b>11</b>	Viral Clearance Studies
<b>12</b>	Neurovirulence Study
<b>13</b>	Histopathology Slide Evaluation and Peer Review
<b>14</b>	Statistical analysis
<b>15</b>	Toxicokinetic data analysis
<b>16</b>	Electrocardiography trace analysis and evaluation
<b>17</b>	Others

Sl. No.	Test System	Sub-group_Level_1	Sub-group_Level_2
1	Algae		
2	Aquatic Organisms		
		Mosquito Larvae	
		<i>Lemna</i>	
3	Aquatic Flora –		
		Zooplankton	
		Phytoplankton	
		<i>Daphnia Magna</i>	
4	Household pests		
		Bed Bug	
		Cockroach	
		Mosquito	
		Housefly	
		Dust mite	
5	Biological Matrices		
		Whole Blood	
		Plasma	
		Serum	
		CSF	
		Milk	
		Urine	
		Faeces	
		Tissues	
		Hepatocytes, Liver S9 Fraction and Liver Microsomes	
6	Birds		
7	Human Lymphocytes		
8	Fish		
		Warm Water Fish	
		Cold Water Fish	
9	Bovine Eyes		
10	Cell Lines		
11	Plants and Seeds		
12	Soil and Water		
13	Rodents		
		Mice	
		Rat	
		Hamster	
		Guinea Pig	
14	Non-rodents		
		Goat	
		Dog	
		Rabbit	
		Non-Human Primates	
		Pig	
15	Microbes		
		Bacteria	
			<i>E.coli.</i>
			<i>Salmonella typhimurium</i>
		Fungi	
		Virus	
16	Reconstructed Human Epidermis		
17	Fertile Chicken Eggs		
18	Hen's Egg Chorioallantoic Membrane		
19	Recombinant Enzymes		
20	Reconstructed Human Cornea Like Epithelium (RhCE)		
21	Earthworm		
22	Insects		
		Wasp	
		Silkworm	
		Honey Bee	