

Draft Guidance Document for GLP certification scope of National GLP Compliance Monitoring Authority (NGCMA)

The GLP certification scope of NGCMA is as per the Document No. 2 of OECD Principles of GLP, wherein 9 broad areas of expertise are defined. However, further sub-classifications in the GLP certification scope of NGCMA are covered in this document.

A. The necessary sub-classifications under major Areas of Expertise are as under:

1. Physical Chemical Testing including Five Batch Analysis:

- a) The TFs performing at least 14 out of the 21 Physical Chemical tests/studies as per OECD Test Guidelines, will be certified for “Physical Chemical Testing”, after successful validation of such studies during the GLP inspection(s).
- b) The Five Batch Analysis is part of the Physical Chemical Testing, however, the TFs found competent to perform Five Batch Analysis along with Physical Chemical Testing will be provided GLP scope for “Physical Chemical Testing including Five Batch Analysis” while the TFs not possessing the competency to perform the Five Batch Analysis will be provided GLP certification for “Physical Chemical Testing” only.

2. Toxicity Studies:

- a) **Acute Toxicity** includes all studies with all the routes of administration except inhalation. Inhalation toxicity is already covered as a separate study under toxicity scope.
- b) **Cytotoxicity** includes MTT Assay and Neutral Red Uptake Assay.
- c) **Eye irritation/ Serious eye damage (*ex vivo*)** includes Bovine Corneal Opacity Test and Hen’s Egg Chorioallantoic Membrane (HET CAM) Test.
- d) **Immunogenicity** includes local tolerance Studies.
- e) **Maximum Tolerated Dose (MTD) study** is included as part of Acute toxicity study irrespective of the routes of administration except inhalation.
- f) **Repeated Dose Toxicity** includes three sub-classifications in the GLP certification scope i.e. Sub-Acute, Sub-chronic, Chronic. The basic differentiation for the above such sub-classification is as follows:

Repeat Dose Sub-classification	Period of Studies
Sub-acute	≤28 days
Sub-chronic	≤90 days
Chronic	>90 days

- a) **Skin Sensitization (*in vivo*)** includes Guinea Pig Maximization Test (GPMT), Local Lymph Node Assay (LLNA) and Buehler test.

3. Mutagenicity studies:

- a) **Mutagenicity** includes the genotoxicity studies.
b) **Cell Gene Mutation Test** includes Mouse Lymphoma Assay.

4. Environmental Toxicity Studies on Aquatic and Terrestrial Organisms includes Fish Short-Term Reproduction Test, Fish Screening Assay, Fish Sexual Development Test, Amphibian Metamorphosis Assay, Larval Amphibian Growth and Development Assay

5. Residue Studies:

- a) The Test Facilities performing both field studies and residue analysis will be provided the GLP scope for “Residue Studies”, while the TFs performing only Residue analysis will be provided the scope for “Residue Analysis” only, under the “Others” category of the areas of expertise.

6. Studies on Effects on Mesocosms and Natural Ecosystems include-Soil Microorganisms: Nitrogen & Carbon Transformation Test.

7. Others

- a) **Toxicokinetic** studies include ADME/DMPK studies.

B. The necessary sub-classification under major Test Items is as under:

The **Nutraceuticals** will be covered under Pharmaceuticals (Human) & Pharmaceuticals (Veterinary) as applicable.

C. The necessary sub-classification under major Test Systems are as under:

- a) **3D culture** includes Episkin, RhE, RhCE, Synthetic Membrane.
b) **Aquatic Plants** include Lemna.
c) **Bird** includes Mallard Duck, Japanese Quail, Pigeon, Chicken.
d) **Body Fluids** include Cerebrospinal Fluid, Blood, Plasma, Serum, Urine, Semen and Bone Marrow.

- e) **Body Organs/Tissues** include Cryopreserved Liver, Cornea, Skin, Cavader Skin and Bovine eyes.
- f) **Insects** include Wasp, Mosquito, Honey Bee, Chironomus, Cockroach and Collembolan, Crustaceans, Bed bug and Housefly.
- g) **Phytoplankton** includes Diatoms.
- h) **Primary Cell Culture** includes the cultivation and application of cells derived from the tissues of Human and Animals such as Human Peripheral Blood Lymphocytes, Inducible hepatocytes
- i) **Sub-cellular Fractions** includes Cryopreserved liver microsomes, Cryopreserved Liver S9 Fraction
- j) **Worms** include Earthworm and Silkworm.

Note: This document will be a dynamic document. Test facilities seeking any additional scope other than mentioned in the GLP certification scope or this document will be dealt on case-to-case basis and after necessary deliberations and recommendations of the Technical Committee on GLP, suitable additions or deletions will be made.
