

“Crédit d’Impôt Recherche” (C.I.R.) Certification

C.I.R. certification, released to NiKem Research by the French Ministry of Research (FMR), entitles any French private company to claim significant tax credit (“Crédit d’Impôt Recherche”, C.I.R.) for R&D activities executed by NiKem Research on their behalf.

GLP Certification

GLP certification, released to NiKem Research by the Italian Ministry of Health for Pharmacokinetic and Metabolism allows NiKem to analyse biological samples from all preclinical species; in particular we can:

- Provide GLP method development by HPLC or UPLC/MS/MS;
- Resolve clients analytical bottlenecks by providing GLP bioanalytical support for GLP samples sent by the client;
- Provide, in partnership with EU based companies, specialized in GLP animal dosing, a complete preclinical PK and Toxicokinetic GLP service with NiKem providing the GLP bioanalysis and project co-ordination.

Qualification for Bioanalysis of Clinical Samples

Clinical samples bioanalysis qualification, released to NiKem Research by the regional authority ASL Milano 1 of Regione Lombardia, allows NiKem to perform Pharmacokinetic, Metabolism and Bioequivalence analyses for clinical trials on healthy volunteers, according to Italian D.M. 19 March 1998.

Our new capability allows us to analyse biological samples from clinical studies to supply certified bioanalyses for:

- Method development and validation by HPLC-UV or UPLC/MS/MS;
- New Chemical Entity (NCE) Phase I studies on healthy volunteers;
- Clinical bioequivalence studies.

[AIFA \(Italian Medicines Agency\) has recorded NiKem Research qualification.](#)

Authorization for Rodent Toxicology

Rodent toxicology authorization, released to NiKem Research by the Italian Ministry of Health allows NiKem to perform non-GLP acute and sub-chronic toxicology in rodents (e.g. MTD, 2- and 4-weeks treatment) for preliminary safety evaluation of novel chemical entities (NCEs) before entering formal pre-clinical development phase. Toxicokinetic (TK) studies are also allowed for correlation of plasma and/or organs exposure of NCEs (and potential metabolites) vs. the tolerated doses in toxicological experiments.