Phototoxicity

Light is an inevitable resource in human life, but it also has the potential to be toxic when human skin comes in contact with substances which are phototoxic in nature. Phototoxic substances cause damage to human cells. After exposure to phototoxic chemicals, skin response such as sunburn, visible redness, and swelling may occur. Therefore, phototoxicity testing plays a pivotal role in the safety evaluation of products which are likely to be applied to human skin.

JRF Global offers comprehensive non-clinical GLP research services for regulatory Submissions, worldwide.

JRF Global is constantly dedicated to optimizing its services in the field of regulatory toxicology and has taken the lead in developing alternatives to animal testing to rationalize the use of animals. In this context, we are happy to announce that JRF had validated and implemented the testing protocol of phototoxicity Test, using OECD 432 with a test system (Balb/c 3T3 cell line) a few years ago, and has been conducting this test for several chemicals.

Our scientists had validated this study a few years ago by using seven different reference substances, recommended by OECD 432, such as Amiodarone HCL, Norfloxacin, Protoporphyrin IX Disodium, Anthracene, L-Histidine Monohydrochloride Monohydrate, Hexachlorophene, and Sodium Lauryl Sulfate.

Phototoxicity assay work on the principle of evaluating the cell viability of Balb/c 3T3 cell, after the exposure to the test chemicals, with and without exposure to UVA. Generally, a set of two 96-Well plates with a monolayer of Balb/c 3T3 cell line are treated with eight different concentrations of the chemical. One plate is kept in the dark and other is kept for exposure to the UVA. Following the exposure to different concentrations, cells are incubated for 24 hours and further proceeded to check cell viability, by using neutral red uptake.

Based on the following criteria, the results were evaluated.

01 **IC_{50}**

02 **PIF** *(Photo-Irritation-Factor)*

03 **MPE** *(Mean Photo Effect)*

For calculating IC_{50}, PIF, and MPE (Mean Photo Effect), OECD provided software package was used. The result was interpreted using the OECD TG 432 Criteria:

PIF	MPE	Prediction
< 2	< 0.1	No Phototoxicity
≥ 2 and < 5	≥ 0.1 and < 0.15	Probable Phototoxicity
≥ 5	≥ 0.15	Phototoxicity

JRF GLOBAL

Pioneering Solutions since 1977 - Responsibly

Details of reference substances and there IC_{50}, PIF AND MPE

JRF Global has successfully validated the method, using different phototoxic chemicals to evaluate the phototoxic potential of the test items.

Sr. No.	Name of Reference Substance	Light	IC_{50}	PIF	MPE
1	Amiodarone HCL	-	29.525	2.630	0.380
		+	11.272		
2	Norfloxacin	-	633.795	17.103	0.730
		+	45.618		
3	Anthracene	-	-	70.093	0.687
		+	1.429		
4	Protoporphyrin IX Disodium	-	68.600	33.844	0.718
		+	3.472		
5	L-Histidine monohydrochloride monohydrate	-	-	1.000	-0.003
		+	-		
6	Hexachlorophene	-	15.526	1.559	-0.004
		+	9.995		
7	Sodium Lauryl Sulfate	-	14.489	0.74	0.038
		+	20.232		

Bindi S. Patel, M.Sc.

She has over three years of experience in performing various in vivo and *in vitro* studies in compliance with OECD Principle of GLP. She is also actively involved in different *in vitro* skin sensitization assays, *in vitro* skin corrosion and skin irritation assays, and other Mutagenicity assays.

Founded in 1977, JRF Global is one of the most experienced and respected non-clinical Contract Research Organizations in Asia.

JRF's capabilities spanning from Discovery to Development phase provide integrated services to both innovator and generic companies belonging to Pharmaceuticals, Agrochemicals, Cosmetics, Specialty chemicals, and Biological Industries.

Salient Features:

- GLP and AAALAC accredited
- 300+ Employees, 700+ Clients across 60+ Countries
- Spread across 6 locations worldwide (USA, Canada, Spain, UK, India, Japan)
- 33500+ GLP Studies across all industries and have been well received by US FDA, EMA, USEPA, ECHA, MHRA, ANVISA, and other regulatory agencies
- State-of-the-art animal house facility which is one of the best facilities in Asia

Services at a Glance:

- P-C Chemistry, Analytical/Bioanalytical Chemistry
- Med-Chem & Custom Synthesis
- *In vitro* DMPK and *In vivo* Pharmacokinetics
- Mammalian Toxicity
- Alternative Methods
- Safety Pharmacology
- Environmental Fate and Metabolism
- Genotoxicity
- DART - Segment I, II, III
- Residue Analysis
- Ecotoxicity

JRF GLOBAL

Pioneering Solutions since 1977 - Responsibly