

# GLP (Good Laboratory Practice) System

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## Introduction of GLP system into Occupational Toxicology Research

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Good Laboratory Practice (GLP) is a quality system concerned with the organizational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported. To avoid different scheme of implementation that could impede international trade in chemicals. OECD member countries have pursued international harmonization of test methods and GLP. The introduction of GLP principles into occupational toxicology

research could help to assure reliability of industrial chemical hazard data, and to avoid repeating of toxicity testing, and further improve the reliability of MSDS. In addition, GLP would be helpful to establish industrial chemical policy based on risk assessment, and prepare the global harmonization of classification and labelling of chemicals.

Key Words : GLP, , , Lab accreditation  
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3 3 system  
가 GLP ,  
OECD 가  
, ,  
가 6  
GLP (Yu et al., 2001).  
GLP (Good Laboratory Practice)  
GLP (Good Laboratory Practice;  
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GLP  
1996  
OECD  
GLP  
, 1999  
GLP system  
2000  
GLP , , ,

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1 3 가 GLP

표 1. 우리나라 부처별 GLP 제도

				GLP			
				2, 3, 4, 5, 6	. 1995		
( 2000-63)				17	10		
( 1999-61)				6	24		
( 1998-41)				15	72		
( 2000-17)				가 test guideline (TG)			
				(			
(Yu et al., 2000), OECD				(OECD, 1995).			
OECD Principles of Good Laboratory Practice,				1978 12 22	GLP 가		
FDA				1979 6 20	(		
Good Laboratory Practice for non-clinical Laboratory studies (FIFRA)				1999).			
OECD				. GLP			
(TSCA)				GLP			
(PMN)				, , , , ,			
GLP				1981 OECD GLP	([C(81)20		
(Stimson et al., 1993).				(final))	.		
				가 , 가 ,	, , (OECD, 1992).		
				1.			
				(OECD, 1992).			
GLP				1996	, ,		
The				OECD 가 GLP			
Good Laboratory Practice Regulations				OECD GLP			
( , 1999).				OECD 가	(Quality Assurance Unit; QAU)		
				. GLP			
				(			
				)			
Thalidomide				OECD	, GLP		
가							
(Phocomelia)							

표 2. 물리화학적 성상 (17개 시험)

				101 UV-Vis absorption spectra
				102 Melting Point/melting range
				103 Boiling point
				104 Vapour pressure
				105 Water solubility
				106 Absorption/desorption
				107 Partition coefficient (n-octanol/water: shake Flask method)
				108 Complex formation ability in water
				109 Density of liquids and solids
				110 Particle size distribution/fibre length and diameter distribution
				111 Hydrolysis as a function of pH
				112 Dissociation constants in water
				113 Screening test for thermal stability and stability in air
				114 Viscosity of liquids
				115 Surface tension of Aqueous solutions
				116 Fat solubility of solid and liquid substances
				117 Partition coefficient (n-octanol/water), HPLC method

## 표 3 환경독성시험 (10개 시험)

201	Alga, growth inhibition test
202	Daphnia sp. Acute immobilization test and reproduction test
203	Fish Acute toxicity test
204	Fish prolonged toxicity test: 14-day study
205	Avian Dietary toxicity test
206	Avian Reproduction test
207	Earthworm, acute toxicity tests
208	terrestrial plants, growth test
209	Activated sludges, respiration inhibition test
210	Fish, early-life stage toxicity test

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(Standard Operation Procedure; SOP)

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## 표 4 분해 축적성 시험 (6개 시험)

301	Ready biodegradability (6 )
302	Inherent biodegradability(3 )
303	Simulation test-aerobic sewage treatment: coupled units test
304	Inherent biodegradability in soil
305	Bioaccumulation (5 )
306	Biodegradability in seawater

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## 표 5 건강영향 시험 (24 개 시험)

401	Acute oral toxicity
402	Acute dermal toxicity
403	Acute inhalation toxicity
404	Acute dermal irritation/corrosion
405	Acute eye irritation/corrosion
406	Skin sensitisation
407	Repeated dose 28-day oral toxicity study in rodents
408	Subchronic oral toxicity- rodent: 90-day
409	Subchronic oral toxicity - non rodent : 90 day
410	Repeated dose dermal toxicity 21/28-day
411	Subchronic dermal toxicity : 90 day
412	Repeated dose inhalation toxicity 28/14-day
413	Subchronic inhalation toxicity: 90-day
414	Teratogenicity
415	One-generation reproduction toxicity
416	Two-generation Reproduction toxicity
417	Toxicokinetics
418	Delayed Neurotoxicity of organophosphorus substances following acute exposure
419	Delayed Neurotoxicity of organophosphorus substances; 29-day repeated dose study
420	Acute oral toxicity-fixed dose method
421	Reproduction/developmental toxicity screening test
451	Carcinogenicity studies
452	Chronic toxicity studies
453	Combined chronic toxicity/carcinogenicity studies

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Lab accreditation ( ) GLP

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Laboratory Quality Assurance

Program Lab Accreditation

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표 6. 유전독성시험 (15개 시험)

471 Genetic toxicology: Samonella typhimurium, reverse mutation assay	4	, LG	,
472 genetic toxicology: Escherichia coli, Reverse Mutation Assay		,	.
473 Genetic toxicology: In vitro mammalian cytogenetic test		5	GLP
474 Genetic toxicology: Micronucleus test			
475 Genetic toxicology: in vivo mammalian bone marrow cytogenetic test- chromosomal analysis	(2001. 9	),	GLP OECD (Mutual Acceptance of Data)
476 Genetic toxicology: In vitro mammalian cell gene mutation tests			GLP
477 Genetic toxicology: Sex-linked recessive lethal test in Drosophila melanogaster			(Yu et al., 2001).
478 Genetic toxicology: Rodent dominant lethalk test			
479 Generic toxicology: In vitro sister chromaid exchange assay in mammalian cells			
480 Genetic toxicology: Saccharomyces cerevisiae, gene mutation assay			
481 Generic toxicology: Saccharomyces cerevisiae, mitotic recombination assay			
482 Generic toxicology: DNA damage and repair, unscheduled DNA synthesis in mammalian cells in vitro			GLP
483 Genetic toxicology: Mammalian germ cell cytogenetic assay			
484 Genetic toxicology: Mouse spot test			
485 Genetic toxicology: Mouse heritable translocation assay			

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(KFDA) GLP 가 .

표 7. 실험실인증과 GLP의 차이

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, (QAC) , , (QA)
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(SOP) (SOP) ,
, , kV

표 8 국내 GLP 시험기관 현황

가				
	( , )	- ( , )	- (1999. 1. 23)	2000.3.4
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	-	-	-	
	(3 )			1988.7.22*
			-	1988.8.11*
				1988.8.11*
LG	-			1995.5.24
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	(3 )			
* 1980	GLP	OECD	GLP	.
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OECD	가			가
SIDS (Screening Inforamtion Data Set)			, 가,	
가	(		, MSDS,	
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ILO, UNCETDG (

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(IFCS, 2001),

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## 5. MSDS

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