

Annual overview of test facilities inspected

Country: Chinese Taipei

Name of monitoring authority: Taiwan Accreditation Foundation (TAF)

Date of submission: 13 May 2021

Legends: See last page

TEST FACILITY	DATE OF INSPECTION	STATUS	NATURE OF INSPECTION	AREA OF EXPERTISE	REMARKS
[Name (bold type) and full address of test facility]	[mm.yyyy]	[ic/nic/pen/rfp]	[full/re-i/ fac/sa]	[1-8, 9: specify]	(for example: refer to nic notification)
Level Biotechnology Inc. CRO - Preclinical Testing Center Level Biotechnology Inc. No.80, Lane 169, Kangning St., Hsi-Chih Dist., New Taipei City 221, Taiwan R.O.C GLP002	01.2017 06.2018 01.2019 09.2019	ic ic ic ic	full sa full full	2,3 2,3 2,3,8 2,3,9(Biocompatibility Studies)	*(1)
GLP Bioanalytical Laboratory Virginia Contract Research Organization Co., Ltd. 3F, No.2, Lane 258, Ruiguang Rd., Neihu District, Taipei 11491, Taiwan GLP003	02.2017 01.2018 07.2018 04.2019 08.2020	ic nic ic ic rfp	sa full re-i sa	8 8 8 8	rfp: (Registration expired)
Department of Medical Research and Development, Laboratory Animal Center of Good Laboratory Practice, Chang Gung Medical Foundation Linko Branch No.5, Fuxing St., Guishan Dist., Taoyuan City 33305, Taiwan (R.O.C.) GLP004	08.2017	ic rfp	sa	2,8	rfp: 12.2018 (TF voluntary withdraw)

TEST FACILITY	DATE OF INSPECTION	STATUS	NATURE OF INSPECTION	AREA OF EXPERTISE	REMARKS
Biosafety Testing Laboratory Agricultural Technology Research Institute No. 52, Kedung 2nd Rd., Chunan Township, Miaoli County 350, Taiwan, R.O.C. GLP005	10.2017	ic	sa	9(biosafety testing)	*(1)
	01.2019	ic	full	9(biosafety testing)	
	02.2020	ic	full	9(biosafety testing)	
	12.2020	ic	full	9(biosafety testing)	
TACTRI GLP Test Facility Taiwan Agricultural Chemicals and Toxic Substances Research Institute, Council of Agriculture, Executive Yuan. No.11, Guangming Rd., Wufong, Taichung 41358, Taiwan (R.O.C.) GLP006	10.2017	ic	sa	1,2,3,4,6	
	06.2018	ic	full	1,2,3,4,6	
	06.2019	ic	sa	1,2,3,4,6	
	04.2020	ic	full	1,2,3,4,6	
Sinon Central Laboratory SINON CORPORATION No.101, Nanrong Road, Dadu District, Taichung City 43245, Taiwan (R.O.C) GLP008	06.2018	ic	sa	1	
	12.2018	ic	full	1	
	12.2020	ic	full	1	
MedGaea Life Sciences Institute MedGaea Life Sciences, Ltd. 7F., No.45, Lane3, Sec.1, Zhongzheng E. Rd., Tamsui Dist., New Taipei City 25147, Taiwan GLP010	01.2017	ic	sa	2,3,9(biocompatibility studies)	*(1)
	06.2017	ic	full	2,3,9(biocompatibility studies)	
	06.2018	ic	sa	2,3,9(biocompatibility studies)	
	06.2019	ic	full	2,3,9(biocompatibility studies)	
	02.2020	ic	full	2,3,4,9(biocompatibility studies) 2,3,4,9(biocompatibility studies)	

TEST FACILITY	DATE OF INSPECTION	STATUS	NATURE OF INSPECTION	AREA OF EXPERTISE	REMARKS
Center of Toxicology and Preclinical Sciences QPS Taiwan No. 103, Lane 169, Kangning St., Xizhi Dist., New Taipei City 22180, Taiwan GLP011	02.2017	ic	sa	2,3,9(Irritation studies, sensitization studies, pharmacokinetics studies, biocompatibility studies) 2,3,9(Irritation studies, sensitization studies, biocompatibility studies) 2,3,9(Irritation studies, sensitization studies, biocompatibility studies) 2,3	*(1)
	09.2017	ic	full		
	11.2018	ic	sa		
	11.2019	ic	full		
Demeter Laboratory Huikwang Corporation 17-10 Ling Tzzy Lin, Matou, Tainan 72152, Taiwan GLP012	05.2017	ic	sa	1	
	12.2017	ic	full	1	
	05.2019	ic	sa	1	
	01.2020	ic	full	1	
Rotam Biotechnology Limited Laboratory Rotam Biotechnology Limited. No. 566, Longpu St., Yongkang Dist., Tainan City 71090, Taiwan (R.O.C.) GLP013	06.2017	ic	full	1	
	07.2018	ic	sa	1	
	03.2019	ic	full	1	
Tai Yeh Industry Co. LTD. Department of Quality Assurance Tai Yeh Industry Co. LTD. No.68-1, Baujhanz Vil., Guanyin Dist., Taoyuan City 32851, Taiwan (R.O.C.) GLP014	07.2017	ic	full	1	
	09.2018	ic	sa	1	
	05.2019	ic	full	1	

TEST FACILITY	DATE OF INSPECTION	STATUS	NATURE OF INSPECTION	AREA OF EXPERTISE	REMARKS
Contract Research Organization (CRO) Super Laboratory Co., Ltd. No.21, Wugong 5th Rd., Xinzhuang Dist., New Taipei City 24890, Taiwan(R.O.C.) GLP015	08.2017	nic	full	2,3,4,9(biocompatibility studies,	*(1) Special study audit requested by domestic RA
	11.2017	ic	re-i	biodegradation studies)	
	08.2018	ic	full	2,3,4,9(biocompatibility studies,	
	06.2019	ic	full	biodegradation studies)	
	02.2020	ic	sa	2,3,4,9(biocompatibility studies, biodegradation studies) 1,2,3,4,5,9(biocompatibility studies, endotoxin studies) 1,2,3,4,5,9(biocompatibility studies, endotoxin studies)	
Sunstar Laboratory Taiwan Nissan Chemical Industries Corporation No.15, Siangong N. 1st Rd., Shengang Township, Changhua County 50953, Taiwan GLP016	07.2017	ic	full	1	
	07.2018	ic	sa	1	
	06.2019	ic	full	1	
Pharmaceutical Analysis Center Mithra Biotechnology Inc. 7F., No.104, Sec. 1, Xintai 5th Rd., Xizhi Dist., New Taipei City, Taiwan GLP017	08.2017	ic	sa	9(preclinical drug concentration analysis of biological specimen)	*(1)
	06.2018	ic	full	8	
	07.2019	ic	sa	8	
	09.2019	ic	full	8,9(biosafety testing)	
	04.2020	ic	full		
Biocompatibility Laboratory LEON Biotech. Co., Ltd. 4F-2, No.288-8, Xinya Rd., Qianzhen Dist., Kaohsiung City 80673, Taiwan GLP018	09.2017	ic	sa	2,9(biocompatibility test)	
	05.2018	ic	full	2,9(biocompatibility test)	
	02.2020	ic	sa	2,9(biocompatibility test)	
	05.2020	ic	full	2,9(biocompatibility test) 2,3,4,9(biocompatibility test)	

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Lih-Nung Laboratory LIH-NUNG CHEMICAL CO.,LTD. No. 48-1, Zungtsun Putzu Tzutung, Yunlin City 64747, Taiwan (R.O.C.) GLP019	11.2017	ic	sa	1	
	10.2018	ic	full	1	
	12.2019	ic	sa	1	
	01.2021	ic	full	1	
Great Victory Physical-chemical Character Studying Lab. GREAT VICTORY CHEMICAL INDUSTRY CO., LTD. No.3, Nongsiao Rd., Cihong Township, Yunlin County 647, Taiwan GLP020	09.2017	ic	sa	1	
	10.2018	ic	full	1	
	10.2019	ic	sa	1	
	05.2020	ic	full	1	

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Ultra Trace & Industrial Safety SGS Taiwan Ltd. No. 38, Wu Chyuan 7th Rd., New Taipei Industrial Park, Wu Ku Dist., New Taipei City 24890, Taiwan (R.O.C.) GLP021	02.2017	ic	full	3,9(endotoxin test, biocompatibility)	
	08.2018	ic	full		
	02.2019	ic	full	3,6,9(endotoxin test, biocompatibility)	
	03.2020	ic	sa	3,6,9(endotoxin test, biocompatibility)	*(1)
	04.2020	ic	sa	3,6,9(endotoxin test, biocompatibility)	*(1)(2)
	03.2020	ic	full	3(In vitro Mammalian Chromosomal Aberration Test, Salmonella Reverse Mutation Test), 6(Analytical phase), 9(Biocompatibility: In vitro Cytotoxicity Test, Hemolysis Test ,Endotoxin Test)	
01.2021	ic	full	3(In vitro Mammalian Chromosomal Aberration Test, Salmonella Reverse Mutation Test), 6(Analytical phase), 9(Biocompatibility: In vitro Cytotoxicity Test, Hemolysis Test ,Endotoxin Test)		
				3(In vitro Mammalian Chromosomal Aberration Test, Salmonella Reverse Mutation Test), 6(Analytical phase), 9(Biocompatibility: In vitro Cytotoxicity Test, Hemolysis Test ,Endotoxin Test)	
				3(In vitro Mammalian Chromosomal Aberration Test, Salmonella Reverse Mutation Test), 6(Analytical phase), 9(Biocompatibility: In vitro Cytotoxicity Test, Hemolysis Test ,Endotoxin Test)	
				3(In vitro Mammalian Chromosomal Aberration Test, Salmonella Reverse Mutation Test), 6(Analytical phase), 9(Biocompatibility: In vitro Cytotoxicity Test, Hemolysis Test ,Endotoxin Test)	
				3(In vitro Mammalian Chromosomal Aberration Test, Salmonella Reverse Mutation Test), 6(Analytical phase), 9(Biocompatibility: In vitro Cytotoxicity Test, Hemolysis Test ,Endotoxin Test)	
				3(In vitro Mammalian Chromosomal Aberration Test, Salmonella Reverse Mutation Test), 6(Analytical phase), 9(Biocompatibility: In vitro Cytotoxicity Test, Hemolysis Test ,Endotoxin Test)	
				3(In vitro Mammalian Chromosomal Aberration Test, Salmonella Reverse Mutation Test), 6(Analytical phase), 9(Biocompatibility: In vitro Cytotoxicity Test, Hemolysis Test ,Endotoxin Test)	
				3(In vitro Mammalian Chromosomal Aberration Test, Salmonella Reverse Mutation Test), 6(Analytical phase), 9(Biocompatibility: In vitro Cytotoxicity Test, Hemolysis Test ,Endotoxin Test)	
				3(In vitro Mammalian Chromosomal Aberration Test, Salmonella Reverse Mutation Test), 6(Analytical phase), 9(Biocompatibility: In vitro Cytotoxicity Test, Hemolysis Test ,Endotoxin Test)	
				3(In vitro Mammalian Chromosomal Aberration Test, Salmonella Reverse Mutation Test), 6(Analytical phase), 9(Biocompatibility: In vitro Cytotoxicity Test, Hemolysis Test ,Endotoxin Test)	
				3(In vitro Mammalian Chromosomal Aberration Test, Salmonella Reverse Mutation Test), 6(Analytical phase), 9(Biocompatibility: In vitro Cytotoxicity Test, Hemolysis Test ,Endotoxin Test)	
				3(In vitro Mammalian Chromosomal Aberration Test, Salmonella Reverse Mutation Test), 6(Analytical phase), 9(Biocompatibility: In vitro Cytotoxicity Test, Hemolysis Test ,Endotoxin Test)	
				3(In vitro Mammalian Chromosomal Aberration Test, Salmonella Reverse Mutation Test), 6(Analytical phase), 9(Biocompatibility: In vitro Cytotoxicity Test, Hemolysis Test ,Endotoxin Test)	
				3(In vitro Mammalian Chromosomal Aberration Test, Salmonella Reverse Mutation Test), 6(Analytical phase), 9(Biocompatibility: In vitro Cytotoxicity Test, Hemolysis Test ,Endotoxin Test)	
				3(In vitro Mammalian Chromosomal Aberration Test, Salmonella Reverse Mutation Test), 6(Analytical phase), 9(Biocompatibility: In vitro Cytotoxicity Test, Hemolysis Test ,Endotoxin Test)	
				3(In vitro Mammalian Chromosomal Aberration Test, Salmonella Reverse Mutation Test), 6(Analytical phase), 9(Biocompatibility: In vitro Cytotoxicity Test, Hemolysis Test ,Endotoxin Test)	
				3(In vitro Mammalian Chromosomal Aberration Test, Salmonella Reverse Mutation Test), 6(Analytical phase), 9(Biocompatibility: In vitro Cytotoxicity Test, Hemolysis Test ,Endotoxin Test)	

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Chung Hsi Chemical Plant, Ltd. GLP Laboratory Chung Hsi Chemical Plant, Ltd. No. 33, Lane 376, Kuan Tung Rd., Hsinchu City 30074, Taiwan GLP022	04.2017	ic	full	1	
	06.2018	ic	sa	1	
	05.2019	ic	full	1	
CH Biotech GLP Department CH BIOTECH R&D CO., LTD. No.89, Wenxian Rd., Nantou City, Nantou County 540, Taiwan (R.O.C.) GLP023	01.2017	ic	sa	1	
	07.2017	ic	full	1	
	08.2018	nic	sa	1	
	11.2018	ic	re-i	1	
	04.2019	ic	full	1	
	06.2020	ic	sa	1	
Bioanalytical Laboratory(GLP) Protech Pharmservices Corporation 11F., No.3, Park St., Nangang District, Taipei City 11503, Taiwan GLP024	02.2017	ic	sa	8	
	12.2017	ic	full	8	
	07.2019	ic	full	8	
Animal Toxicology Laboratory Agricultural Technology Research Institute No. 52, Kedung 2nd Rd., Chunan Township., Miaoli County 35053, Taiwan (R.O.C.) GLP025	09.2017	ic	sa	2	*(1)
	07.2018	ic	full	2	
	07.2019	ic	full	1,2	
	05.2020	ic	full	1,2	
Cell Culture Laboratory TCI Gene Co., Ltd. 10F, No.185, Kang Chien., Nei Hu Dist., Taipei 11494, Taiwan (R.O.C.) GLP026	03.2017	ic	full	2	
	04.2018	ic	sa	2	
	03.2019	ic	full	2	

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Testing Facility for Biological Safety TFBS Bioscience, Inc. 3F., No.103, Lane 169, Kangning St., Xizhi Dist., New Taipei City 22180,Taiwan(R.O.C) GLP027	09.2017 12.2018 07.2019	ic ic ic	full sa full	2,8,9(Biosafety Testing) 2,8,9(Biosafety Testing) 2,8,9(Biosafety Testing)	
Biomedical Verification Laboratory Plastics Industry Development Center No.193, 38th Road, Taichung Industrial Park, Taichung City 40768, Taiwan (R.O.C) GLP028	10.2017 07.2018 10.2019	ic ic ic	full sa full	9(biocompatibility studies) 9(biocompatibility studies) 9(biocompatibility studies)	
Formosa Laboratory LANLIX CROP SCIENCE CO.,LTD. No.79, Xiangyang Rd., Changzhi Township, Pingtung County 908, Taiwan (R.O.C.) GLP029	10.2017 12.2017 08.2018 09.2019	nic ic ic ic	full re-i sa full	1 1 1 1	
Fulon GLP Laboratory Fulon Chemical Industrial Co., Ltd. No.51-10, 9th Neighborhood, Caota, Bao Jhang Village, Guanyin Dist., Taoyuan City 32851, Taiwan(R.O.C) GLP030	09.2018 05.2020	ic nic rfp	full sa	1 1	rfp: 06.2020

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Preclinical Testing Laboratory TRINEO BIOTECHNOLOGY CO., LTD. 20F., No.81, Sec.1, Xintai 5th Rd., Xizhi Dist., New Taipei City 22101, Taiwan (R.O.C) GLP031	09.2018 01.2020 09.2020	ic ic ic	full sa full	2,3,9(Safety pharmacology studies) 2,3,9(Safety pharmacology studies) 2,3,9(Safety pharmacology studies, In vitro tumorigenicity test, Biodistribution studies)	
Biocompatibility Testing Laboratory National Laboratory Animal Center, National Applied Research Laboratories Building G, No. 99, Ln, 130, Sec. 1, Academia Rd., Nangang Dist., Taipei City 115, Taiwan (R.O.C) GLP032	12.2018 02.2020 08.2020	ic ic ic	full sa full	9(biocompatibility studies) 9(biocompatibility studies) 9(biocompatibility testing)	
Drug Analysis Laboratory isRed Pharma & Biotech Research Co., Ltd. 5F., No. 32, Keya Rd., Daya Dist., Taichung City 42881, Taiwan (R.O.C) GLP033	02.2020	nic rfp	full	8	rfp: 05.2020 (TF voluntary withdraw)
Genetic Toxicology Testing Laboratory Master Laboratory Co., Ltd. Rm.A209, 2F., No.2, Sec.2, Shengyi Rd., Zhubei City, Hsinchu County 302, Taiwan (R.O.C.) GLP034	12.2019 05.2020	pen ic	full re-i	2,3 2,3	

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TAIWAN IHARA Laboratory IHARA CHEMICAL CO., (TAIWAN) LTD. No.111, Dingxi, Huwei Township, Yunlin Country 632, Taiwan (R.O.C) GLP035	03.2019	ic	full	1	
	05.2020	ic	sa	1	
Pesticide Residue Analysis Center National Chung Hsing University 145 Xingda Rd., South Dist., Taichung City 402, Taiwan(R.O.C) GLP036	04.2019	ic	full	6	
	07.2020	ic	sa	6	
CHARVEST ANALYTICS CHIA YI CHEMICAL INDUSTRY CO., LTD. No.165, Changrong, Jiangjun Dist., Tainan City 72541, Taiwan (R.O.C) GLP037	04.2019	ic	full	1	
	05.2020	ic	sa	1	
Three Sigma Lab Three Sigma Chemical Co., Ltd. No.22, Xiangong N. 3rd Rd., Xianxi Township, Changhua County 50741 GLP038	04.2019	ic	full	1	
	03.2020	ic	sa	1	
	01.2021	ic	full	1	
GLP residue field trial department Taiwan Agriculture and Food Health Testing, Co., Ltd. No. 101, Nanrong Road, Dadu District, Taichung City 43245, Taiwan (R.O.C.) GLP039	02.2020	ic	full	6	

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IWANTCHEM GLP Laboratory IWANTCHEM Co., Ltd. No.61, Yingshan St., Xihu Township, Changhua County 51449, Taiwan(R.O.C) GLP040	03.2020	ic	full	1	
YIH FONG CHEMICAL COPORATION GLP LAB YIH FONG CHEMICAL COPORATION No.60, Lane 597, Kuang Hsing Rd., Taiping, Taichung 41148, Taiwan GLP041	07.2019	ic	full	1	
Phesol Testing Laboratory PHESOL INDUSTRIAL CO.,LTD No.64,Chung-Hsiao Road, Hsin-Ying District, Tainan City 73054, Taiwan R.O.C GLP042	08.2019	ic	full	1	
NKSP Bioanalytical Laboratory QPS Taiwan 12F., No.3, Park St., Nangang Dist., Taipei City 115, Taiwan GLP043	04.2020	ic	full	8	
Taiwan Agrochemical GLP Laboratory TAIWAN AGROCHEMICAL INDUSTRIES INC. No. 13, Xiangong N. 1st Rd., Shengang Township, Changhua County 50953, Taiwan (R.O.C) GLP044	03.2020	ic	full	1	

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Aquatic Core Technology Laboratory (ACTL) Agricultural Technology Research Institute No. 1, Ln. 51, Dahu Rd., Xiangshan Dist., Hsinchu City 30093, Taiwan, R.O.C. GLP045	08.2019	ic	full	2	
Animal Experiment Laboratory Master Laboratory Co., Ltd. 3F., No.221, Sec.1,Zhongxing Rd., Zhudong Township, Hsinchu County 31053, Taiwan (R.O.C.) GLP047	07.2020	ic	full	2,9	*(1)
Agricultural Biotechnology Test Center Hyper Quantum Technologies, Ltd. 7F-1, No.286-8, Xinya Rd., Qianzhen District., Kaohsiung City 80673, Taiwan (R.O.C) GLP048	07.2020	ic	full	1	
Bayer Taiwan Crop Science Pesticide Field Trial Station Bayer Taiwan Company Ltd. Rm. 840, 8F., International Agricultural Research Center, No. 145, Xingda Rd., South Dist., Taichung City 40227, Taiwan (R.O.C.) GLP049	09.2020	ic	full	6	*(2)

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Precision Laboratory JIH NONG SCIENCE CO., LTD. 3-28 Teh An Liaw Hsien Chia Dist. Tainan 72647, Taiwan (R.O.C) GLP050	10.2019	ic	full	1	
HWA SHIAH Laboratory HWA SHIAH SCIENTIFIC AGROCHEMICAL CO., LTD No.12, Zhongcun, Ganxi, Citong Township, Yunlin Country647, Taiwan (R.O.C) GLP051	09.2019 03.2020	pen ic	full re-i	1 1	
Department of Drug Metabolism and Pharmacokinetics Development Center for Biotechnology No. 101, Lane 169, Kangning St. Xizhi Dist., New Taipei City 22180, Taiwan GLP052	09.2020	ic	full	8	*(1)
Chia Tai GLP Laboratory Chia Tai Enterprise Co., Ltd. No.457, Sec.7, Jin-Ling Rd., Ping-Zhen Dist., Tao-Yuan City, Taiwan GLP053	08.2020	ic	full	1	

Legends to the abbreviations used:

Areas of expertise of the inspected test facility:

- 1 Physical-Chemical testing.
- 2 Toxicity studies.
- 3 Mutagenicity studies.
- 4 Environmental toxicity studies on aquatic and terrestrial organism.
- 5 Studies on behaviour in water, soil and air; bioaccumulation.
- 6 Residue studies.
- 7 Studies on effects on mesocosms and natural ecosystems.
- 8 Analytical and clinical chemistry.

9 Other: specified.

Status of test facilities:

ic In compliance with GLP.

nic Not in compliance: Major deviations from the GLP principles have been observed. Procedures in the test facility are such that the reliability of data cannot be ensured.

pen Pending: GLP compliance status not yet decided on.

rfp Removed from inspection program.

Nature of Inspection:

full Full routine GLP inspection including study audit.

re-i Re-inspection following first or routine GLP inspection.

sa Study audit on request of other authorities.

faci Facility inspection.

Remarks:

*(1) The Program for Food and Drug Administration, Ministry of Health and Welfare Non-clinical Good Laboratory Practice Test Facility Registration. (A program with few extra requirements apart from OECD GLP Principle that are specifically required by domestic RA).

*(2) The Program for Bureau of Animal and Plant Health Inspection and Quarantine, COA, Good Laboratory Practice for Pesticide Residue Study Test Facility