

Name: Guangdong Institute for Drug Control

Address: No.2, Jinbuli, Huifu West Road, Yuexiu District, Guangzhou, Guangdong, China

Registration No. CNAS L2000

Accreditation Criteria: ISO/IEC 17025:2017 and relevant requirements of CNAS

Effective Date: 2024-06-04 Expiry Date: 2028-04-19

SCHEDULE 3 ACCREDITED TESTING SCOPE

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
Drug						
1	Drug	1	Undue Toxicity	ChP 2020 Vol IV 1141		2024-06-04
		2	Pyrogens	ChP 2020 Vol IV 1142		2024-06-04
		3	Bacterial Endotoxin	ChP 2020 Vol IV 1143		2024-06-04
				ChP 2020 Vol IV Guidelines 9251		2024-06-04
		4	Vasopressor Substances	ChP 2020 Vol IV 1144		2024-06-04
		5	Depressor Substances	ChP 2020 Vol IV 1145		2024-06-04
		6	Sensitization tests	ChP 2020 Vol IV 1147		2024-06-04
7	Assay	ChP 2020 Vol IV 1205(Biological Assay of Vasopressin)		2024-06-04		



No. CNAS L2000

The scope of the accreditation in Chinese remains the definitive version.

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				ChP 2020 Vol IV 1208(Biological Assay of Heparin)	Only Clotting time assay	2024-06-04
				ChP 2020 Vol IV 1209 (Biological Assay of Chorionic Gonadotrophin)		2024-06-04
				ChP 2020 Vol IV 1210(Biological Assay of Oxytocin)		2024-06-04
				ChP 2020 Vol IV 1211(Biological Assay of Insulin)		2024-06-04
				ChP 2020 Vol IV 1212(Test for the Prolongation Effect of Protamine Zinc Insulin)		2024-06-04
				ChP 2020 Vol IV 1213(Biological Assay of Protamine Sulfate)		2024-06-04
				ChP 2020 Vol IV 1216(Biological Assay of Follicle Stimulating)		2024-06-04
				ChP 2020 Vol IV 1217(Biological Assay of Luteinising Hormone)		2024-06-04
				ChP 2020 Vol IV 1218(Biological Assay of Calcitonin)		2024-06-04
				SoID JX20000036		2024-06-04
				SoID JX20010153		2024-06-04
				ChP 2020 Vol II P207 Iron Dextran Injection		2024-06-04
		8	Muscular Irritation	SFDA Technical Guidelines for Irritation 、Sensitization and Hemolysis Research of Human Pharmaceuticals (2014)		2024-06-04
		9	Skin Irritation test	SFDA Technical Guidelines for Irritation 、Sensitization and Hemolysis Research of Human Pharmaceuticals (2014)		2024-06-04
		10	Sensitization test	SFDA Technical Guidelines for Irritation 、Sensitization and	Active	2024-06-04

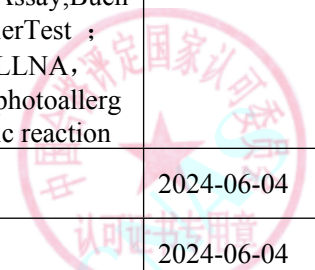


No. CNAS L2000

The scope of the accreditation in Chinese remains the definitive version.

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				Hemolysis Research of Human Pharmaceuticals (2014)	Systemic Anaphylaxis, ASA, Passive Cutaneous Anaphylaxis, PCA, Active Cutaneous Anaphylaxis, ACA; Guinea-Pig Maximization Test, GPMT; Murine Local Lymph Node Assay, Buehler Test; LLNA, photoallergic reaction	
		11	Intravascular Irritation test	SFDA Technical Guidelines for Irritation 、Sensitization and Hemolysis Research of Human Pharmaceuticals (2014)		2024-06-04
		12	Hemolysis test	SFDA Technical Guidelines for Irritation 、Sensitization and Hemolysis Research of Human Pharmaceuticals (2014)		2024-06-04
		13	Acute toxicity test	SFDA Technical Guidelines for Single dose toxicity study of Human Pharmaceuticals (2014)		2024-06-04

CHINA NATIONAL ACCREDITATION SERVICE FOR CONFORMITY ASSESSMENT  
SCHEDULE OF ACCREDITATION CERTIFICATE



No. CNAS L2000

第 3 页 共 6 页

The scope of the accreditation in Chinese remains the definitive version.

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				Hong Kong Registration Technical Guidelines for Chinese Traditional Patent Medicine (2004)		2024-06-04
		14	Long term toxicity test	SFDA Technical Guidelines for Repeated dose toxicity study of Human Pharmaceuticals (2014) Hong Kong Registration Technical Guidelines for Chinese Traditional Patent Medicine (2004)		2024-06-04
		15	Hydroxy-propoxy	ChP 2020 Vol IV 1148		2024-06-04
		16	Mammalian chromosome mutation test in vitro	Technical research guidelines for drug genotoxicity (2018)		2024-06-04
		17	Mammalian micronucleus test in vivo	Technical research guidelines for drug genotoxicity (2018)		2024-06-04
		18	Substance of histamine	ChP 2020 Vol IV 1146		2024-06-04
		19	Substance of estrogen	ChP2020 Vol II 1029		2024-06-04
		20	estrogen activity	USP43-NF38 Estrogenic Activity (Official as of 1-Aug-2020)		2024-06-04
Biological products						
1	Biological products	1	Pyrogen	ChP 2020 Vol III 1142		2024-06-04
		2	Bacterial Endotoxin	ChP 2020 Vol III 1143		2024-06-04
		3	Undue Toxicity	ChP 2020 Vol III 1141		2024-06-04
		4	Assay	ChP 2020 Vol III 3503	Accredited only for	2024-06-04



No. CNAS L2000

The scope of the accreditation in Chinese remains the definitive version.

在线扫码获取验证

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					method 1	
				ChP 2020 Vol III 3508		2024-06-04
				ChP 2020 Vol III 3512		2024-06-04
Cosmetic						
1	Cosmetics	1	Acute oral toxicity test	《Safety and Technical Standards for Cosmetics》 2015 Edition Chapter Six Toxicological testing methods /2		2024-06-04
		2	Acute dermal toxicity test	《Safety and Technical Standards for Cosmetics》 2015 Edition Chapter Six Toxicological testing methods /3		2024-06-04
		3	Dermal irritation/corrosion test	《Safety and Technical Standards for Cosmetics》 2015 Edition Chapter Six Toxicological testing methods /4		2024-06-04
		4	Acute eye irritation/corrosion test	《Safety and Technical Standards for Cosmetics》 2015 Edition Chapter Six Toxicological testing methods /5		2024-06-04
		5	Skin sensitisation test	《Safety and Technical Standards for Cosmetics》 2015 Edition Chapter Six Toxicological testing methods /6		2024-06-04
		6	Skin phototoxicity test	《Safety and Technical Standards for Cosmetics》 2015 Edition Chapter Six Toxicological testing methods /7		2024-06-04
		7	Bacterial reverse mutation assay	《Safety and Technical Standards for Cosmetics》 2015 Edition Chapter Six Toxicological testing methods /9 (NMPA 2019 No.12 appendix 9)		2024-06-04
		8	In Vitro Mammalian Cells Chromosome Aberration Test	《Safety and Technical Standards for Cosmetics》 2015 Edition Chapter Six Toxicological testing methods /9		2024-06-04



No. CNAS L2000

The scope of the accreditation in Chinese remains the definitive version.

在线扫码获取验证

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		9	In Vitro Mammalian Cells Gene Mutation Test	《Safety and Technical Standards for Cosmetics》 2015 Edition Chapter Six Toxicological testing methods /10		2024-06-04
		10	Mammalian Erythrocyte Micronucleus Test	《Safety and Technical Standards for Cosmetics》 2015 Edition Chapter Six Toxicological testing methods /12		2024-06-04
		11	Testicle Cells Chromosome Aberration Test	《Safety and Technical Standards for Cosmetics》 2015 Edition Chapter Six Toxicological testing methods /13		2024-06-04
		12	Skin Sensitization: Local Lymph Node Assay: DA (LLNA:DA)	《Safety and Technical Standards for Cosmetics》 2015 Edition Chapter Six Toxicological testing methods /22 (NMPA 2019 No.12 appendix 4)		2024-06-04
		13	The Murine Local Lymph Node Assay: BrdU-ELISA	《Safety and Technical Standards for Cosmetics》 2015 Edition Chapter Six Toxicological testing methods /23 (NMPA 2019 No.12 appendix 5)		2024-06-04
5、 Drug packaging material						
1	Pharmaceutical packaging materials	1	Undue Toxity	Drug packaging material (HDPE Bottles for Oral Solid Preparation) YBB00122002-2015		2024-06-04
				General Rule for Laminated Films and Pouches for Pharmaceutical Packaging YBB00132002-2015		2024-06-04



No. CNAS L2000

The scope of the accreditation in Chinese remains the definitive version.

在线扫码获取验证