

Name: Guangdong Institute for Drug Control

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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 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		



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
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7	Assay		ChP 2020 Vol IV 1205 Biological Assay of Vasopressin			2024-06-04
			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			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 降钙素生物效价			2024-06-04
			ChP 2020 Vol II P207 Iron Dextran Injection			2024-06-04
			SoID JX20010153 注射部位未吸收 Fe 含量			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

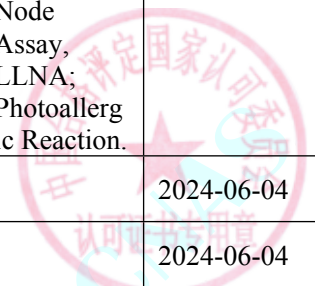


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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
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		10	Sensitization test	SFDA Technical Guidelines for Irritation ,Sensitization and Hemolysis Research of Human Pharmaceuticals 2014	Active Systemic Anaphylaxis, ASA; Passive Cutaneous Anaphylaxis, PCA; Active Cutaneous Anaphylaxis, ACA; Guinea-Pig Maximization Test, GPMT; Buehler Test; Murine Local Lymph Node Assay, LLNA; Photoallergic Reaction.	2024-06-04
		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) 2014		2024-06-04

CHINA NATIONAL ACCREDITATION SERVICE FOR CONFORMITY ASSESSMENT
SCHEDULE OF ACCREDITATION CERTIFICATE



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
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				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) 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	ChP 2020 Vol II P1029		2024-06-04
		20	estrogen activity	USP-NF Official Prior to 1-Jul-2018		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		2024-06-04



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				ChP 2020 Vol III 3508		2024-06-04
				ChP 2020 Vol III 3512		2024-06-04
CHINA NATIONAL ACCREDITATION SERVICE FOR CONFORMITY ASSESSMENT SCHEDULE OF ACCREDITATION CERTIFICATE						
Cosmetics						
1	Cosmetics	1	Acute oral toxicity test	《Safety and Technical Standards for Cosmetics》 2015 Chapter Six Toxicological testing methods 2		2024-06-04
		2	Acute dermal toxicity test	《Safety and Technical Standards for Cosmetics》 2015 Chapter Six Toxicological testing methods 3		2024-06-04
		3	Dermal irritation/corrosion test	《Safety and Technical Standards for Cosmetics》 2015 Chapter Six Toxicological testing methods 4		2024-06-04
		4	Acute eye irritation/corrosion test	《Safety and Technical Standards for Cosmetics》 2015 Chapter Six Toxicological testing methods 5		2024-06-04
		5	Skin sensitisation test	《Safety and Technical Standards for Cosmetics》 2015 Chapter Six Toxicological testing methods 6		2024-06-04
		6	Skin phototoxicity test	《Safety and Technical Standards for Cosmetics》 2015 Chapter Six Toxicological testing methods 7		2024-06-04
		7	Salmonella typhimurium / reverse mutation assay	Circular No. 12 of 2019 on the inclusion of nine test methods, including methods for the detection of free formaldehyde in cosmetics, in the technical specifications for the safety of cosmetics 2015 Edition 2019 No.12 appendix 9		2024-06-04
		8	In Vitro Mammalian Cells Chromosome Aberration Test	《Safety and Technical Standards for Cosmetics》 2015 Chapter Six Toxicological testing methods 9		2024-06-04
		9	In Vitro Mammalian Cells Gene	《Safety and Technical Standards for Cosmetics》 2015 Chapter Six Toxicological testing methods 10		2024-06-04



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			Mutation Test			
		10	Mammalian Erythrocyte Micronucleus Test	《Safety and Technical Standards for Cosmetics》 2015 Chapter Six Toxicological testing methods 12		2024-06-04
		11	Testicle Cells Chromosome Aberration Test	《Safety and Technical Standards for Cosmetics》 2015 Chapter Six Toxicological testing methods 13		2024-06-04
		12	Test method for 3T3 neutral red uptake of cosmetics chemical raw materials in vitro	《Safety and Technical Standards for Cosmetics》 2015 Chapter Six Toxicological testing methods 18		2024-06-04
		13	In Vitro Skin Corrosion:Transcutaneous Electrical Resistance Test(TER)	《Safety and Technical Standards for Cosmetics》 2015 Chapter Six Toxicological testing methods 19		2024-06-04
		14	Skin Photoallergy Tset	《Safety and Technical Standards for Cosmetics》 2015 Chapter Six Toxicological testing methods 20		2024-06-04
		15	Short-term exposure of rabbit corneal epithelial cells to cosmetic chemicals in vitro	《Safety and Technical Standards for Cosmetics》 2015 Chapter Six Toxicological testing methods 21		2024-06-04
		16	The Murine Local Lymph Node Assay: DA	《Safety and Technical Standards for Cosmetics》 2015 Chapter Six Toxicological testing methods 22 (2019 No.12)		2024-06-04
		17	The Murine Local Lymph Node Assay:	《Safety and Technical Standards for Cosmetics》 2015 Chapter Six Toxicological testing methods 23 (2019 No.12)		2024-06-04



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			BrdU-ELISA			
Drug packaging material						
1	Part Parameters	1	Undue Toxicity	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



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