

Name: Shanghai Institute for Food and Drug Control

Address: Building 7, No.479, Fute Xiyi Road, Shanghai, China

Registration No. CNAS L0004

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

Effective Date: 2025-05-12 Expiry Date: 2029-03-04

SCHEDULE 3 ACCREDITED TESTING SCOPE

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
1	Drugs	1	Weight variation	ChP2020 Vol IV General chapter0101		2025-05-12
				ChP2020 Vol IV General chapter0107		2025-05-12
				ChP2020 Vol IV General chapte0108		2025-05-12
				ChP2020 Vol IV General chapter0121		2025-05-12
				ChP2020 Vol IV General chapte0125		2025-05-12
				ChP2020 Vol IV General chapter0126		2025-05-12
				ChP2020 Vol IV General chapter0182		2025-05-12
				ChP2020 Vol IV General chapter0186		2025-05-12
				ChP2020 Vol IV General chapter0188		2025-05-12



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		2	Filling variation	ChP2020 Vol IV General chapter0102		2025-05-12
				ChP2020 Vol IV General chapter0103		2025-05-12
				ChP2020 Vol IV General chapter (0104)		2025-05-12
				ChP2020 Vol IV General chapter0105		2025-05-12
				ChP2020 Vol IV General chapter0106		2025-05-12
				ChP2020 Vol IV General chapter0108		2025-05-12
				ChP2020 Vol IV General chapter0112		2025-05-12
				ChP2020 Vol IV General chapter0115		2025-05-12
				ChP2020 Vol IV General chapter0123		2025-05-12
				ChP2020 Vol IV General chapter0124		2025-05-12
				ChP2020 Vol IV General chapter0126		2025-05-12
				ChP2020 Vol IV General chapter0188		2025-05-12
		3	Filling variation (Weight variation)	EP11th 2.9.40		2025-05-12
		4	Filling	ChP2020 Vol IV General chapter0102		2025-05-12
				ChP2020 Vol IV General chapter0105		2025-05-12



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				ChP2020 Vol IV General chapter0106		2025-05-12
				ChP2020 Vol IV General chapter0116		2025-05-12
				ChP2020 Vol IV General chapter0123		2025-05-12
				ChP2020 Vol IV General chapter0181		2025-05-12
		5	Visible Particles	ChP2020 Vol IV General chapter0904		2025-05-12
		6	Metal particles	ChP2015 Vol IV General chapter0105		2025-05-12
		7	Ratio of sedimental volume	ChP2020 Vol IV General chapter0105		2025-05-12
				ChP2020 Vol IV General chapter0106		2025-05-12
				ChP2020 Vol IV General chapter0123		2025-05-12
				ChP2020 Vol IV General chapter0126		2025-05-12
		8	Uniformity of appearance	ChP2015 Vol IV General chapter0115		2025-05-12
		9	Solubility	ChP2020 Vol IV General Notices		2025-05-12
		10	uniformity of dispersion	ChP2020 Vol IV General chapter0101		2025-05-12
		11	Determination of Relative Density	ChP2020 Vol IV General chapter0601		2025-05-12
		12	Determination of Distilling Range	ChP2020 Vol IV General chapter0611		2025-05-12
		13	Determination of Melting Point	ChP2020 Vol IV General chapter0612		2025-05-12



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		14	Determination of Optical Rotation	ChP2020 Vol IV General chapter0621		2025-05-12
		15	Determination of Refractive Index	ChP2020 Vol IV General chapter0622		2025-05-12
		16	Determination of Viscosity	ChP2020 Vol IV General chapter0633		2025-05-12
		17	Determination of pH Value	ChP2020 Vol IV General chapter0631		2025-05-12
		18	Determination of Nitrogen	ChP2020 Vol IV General chapter0704		2025-05-12
		19	Determination of Ethanol	ChP2020 Vol IV General chapter0711		2025-05-12
		20	Determination of Acid Value	ChP2020 Vol IV General chapter0713		2025-05-12
		21	Determination of Saponification Value	ChP2020 Vol IV General chapter0713		2025-05-12
		22	Determination of Hydroxyl Value	ChP2020 Vol IV General chapter0713		2025-05-12
		23	Peroxide Value	ChP2020 Vol IV General chapter0713		2025-05-12
		24	Determination of Iodine Value	ChP2020 Vol IV General chapter0713		2025-05-12
		25	Limit Test for Chlorides	ChP2020 Vol IV General chapter0801		2025-05-12
		26	Limit Test for Sulfates	ChP2020 Vol IV General chapter0802		2025-05-12
		27	Limit Test for Iron	ChP2020 Vol IV General chapter0807		2025-05-12
		28	Limit Test for	ChP2020 Vol IV General chapter0821		2025-05-12

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
			Heavy Metals			
		29	Limit Test for Arsenic	ChP2020 Vol IV General chapter0822		2025-05-12
		30	Limit Test for Ammonium	ChP2020 Vol IV General chapter0808		2025-05-12
		31	Determination of Loss on Drying	ChP2015 Vol IV General chapter0831		2025-05-12
		32	Determination of Water	ChP2020 Vol IV General chapter0832		2025-05-12
				USP-NF General Chapters 921(Official as of 01-May-2022)		2025-05-12
		33	Determination of Residue on Ignition	ChP2020 Vol IV General chapter0841		2025-05-12
		34	Determination of Organic Solvent Residue	ChP2020 Vol IV General chapter0861	Except for Carbon tetrachloride, 1,1-Dichloroethene, 1,1,1-Trichloroethane, 1,2-Dichloroethene, 2-Ethoxyethanol, 2-Methoxyethanol, Methylbutyl ketone,	2025-05-12



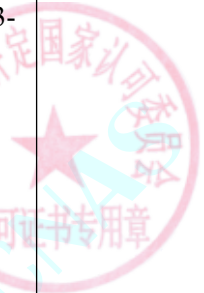
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		№	Item/ Parameter			
					Methylcyclohexane, Nitromethane, Sulfolane, Tetralin, Isopropylbenzene, 2-Butanol, Butyl acetate, Ethyl formate, Formic acid, Isobutyl acetate, 3-Methyl-1-butanol, 2-Methyl-1-propanol, Pentane, 1-Pentanol, Propyl	

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					acetate, 1,1-Diethoxypropane, 1,1-Dimethoxyethane, 2,2-Dimethoxypropane, Isooctane , Isopropyl ether, Methylisopropyl ketone, Methyltetrahydrofuran , Trichloroacetic acid	
				USP-NF General Chapters 467(Official as of 1-Sep-2022)	Except for Carbon tetrachloride, 1,1-Dichloroethene, 1,1,1-Trichloroet	2025-05-12



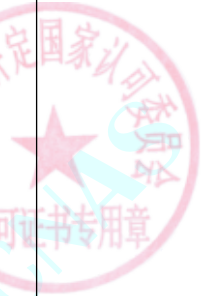
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		№	Item/ Parameter			
					hane, 1,2-Dichloroethene, 2-Ethoxyethanol, 2-Methoxyethanol, Methylbutyl ketone, Methylcyclohexane, Nitromethane, Sulfolane, Tetralin, Isopropyl, benzene, 2-Butanol, Butyl acetate, Ethyl formate, Formic acid, Isobutyl acetate, 3-	

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					Methyl-1-butanol, 2-Methyl-1-propanol, Pentane, 1-Pentanol, Propyl acetate, 1,1-Diethoxypropane, 1,1-Dimethoxyethane, 2,2-Dimethoxypropane, Isooctane , Isopropyl ether, Methylisopropyl ketone, Methyltetrahydrofuran ,	

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		№	Item/ Parameter			
					Trichloroacetic acid	
		35	Colour of Solution	ChP2020 Vol IV General chapter0901 EP11th edition 2.2.2 BP2025 Appendix IV B		2025-05-12
		36	Clarity of Solution	ChP2020 Vol IV General chapter0902 EP11th edition 2.2.1		2025-05-12
		37	Test for Particulate Matter in Injection	ChP2020 Vol IV General chapter0903		2025-05-12
		38	Crystallinity	ChP2020 Vol IV General chapter0981	Accredited only for method I	2025-05-12
		39	Determination of Particle Size and Distribution of Particle Size	ChP2020 Vol IV General chapter0982		2025-05-12
		40	Determination of Particle Size	ChP2020 Vol IV General chapter0105 ChP2020 Vol IV General chapter0109 ChP2020 Vol IV General chapter0113 ChP2020 Vol IV General chapter0115		2025-05-12
		41	Determination of Osmolality	ChP2020 Vol IV General chapter0632		2025-05-12



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		42	Determination of Disintegration	ChP2020 Vol IV General chapter0921		2025-05-12
		43	Disintegration Test for Suppositories and Vaginal Tablets	ChP2020 Vol IV General chapter0922		2025-05-12
		44	Dissolution Test, Drug Release Test	ChP2020 Vol IV General chapter0931	Except for method VI and method VII	2025-05-12
				USP-NF General Chapters 711(Official as of 1-May-2023)		2025-05-12
				EP11th edition 2.9.3		2025-05-12
		45	Test for Content Uniformity	ChP2020 Vol IV General chapter0941		2025-05-12
				JPXVIII General Tests 6.02		2025-05-12
				EP11th edition 2.9.6、2.9.40		2025-05-12
				USP-NF General Chapters 905(Official as of 1-Aug-2023)		2025-05-12
		46	Minimum Fill	ChP2020 Vol IV General chapter0942		2025-05-12
		47	Test for Tablet Friability	ChP2020 Vol IV General chapter0923		2025-05-12
		48	Description	ChP2020 Vol I 、 II 、 IV General chapter monographs		2025-05-12
		49	Volumetric Analysis	ChP2020 vol I 、 II 、 IV(Volumetric Analysis)		2025-05-12



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		50	Gravimetric Analysis	ChP2020 vol I 、 II 、 IV(Gravimetric Analysis)		2025-05-12
		51	Testing for inorganic ion	ChP2020 Vol I 、 II		2025-05-12
		52	Delivery amount in a dose	ChP2020 Vol IV General chapter0112		2025-05-12
		53	Content of active ingredient in an actuation、 Content of active ingredient in a dose、 Content of active ingredient in a Unit Spray	ChP2020 Vol IV General chapter0111		2025-05-12
				ChP2020 Vol IV General chapter0112		2025-05-12
				ChP2020 Vol IV General chapter0113		2025-05-12
		54	Adhesion test	ChP2020 Vol IV General chapter 0122	Accredited only for method I and method II	2025-05-12
				ChP2020 Vol IV General chapter 0952	Accredited only for method I and method II	2025-05-12
		55	Adhesion test	SoID JX20170061		2025-05-12
				SoID JX20160171		2025-05-12
		56	Test for excipient property	ChP2020 Vol IV General chapter 0122		2025-05-12



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
		57	Weight of cataplasms	ChP2020 Vol IV General chapter 0122		2025-05-12
		58	Test for Sterility	ChP2020 Vol IV General chapter 1101		2025-05-12
				EP11th edition 2.6.1		2025-05-12
				USP-NF General Chapters 71(Official Prior to 2013)		2025-05-12
		59	Microbial Limit tests	ChP2020 Vol IV General chapter 1105		2025-05-12
				ChP2020 Vol IV General chapter 1106		2025-05-12
				EP11th edition 2.6.12		2025-05-12
				EP11th edition 2.6.13		2025-05-12
				USP-NF General Chapters <61>(Official Prior to 2013)		2025-05-12
				USP-NF General Chapters <62> (Official Prior to 2013)		2025-05-12
		60	Test for Bacterial Endotoxin	ChP2020 Vol IV General chapter 1143		2025-05-12
		61	identification	ChP2020 Vol IV General chapter 0301 (General identification)		2025-05-12
				ChP2020 Vol IV General chapter 0401 (Ultraviolet-Visible Spectrophotometry)		2025-05-12
				ChP2020 Vol IV General chapter 0402 (Infrared Spectrophotometry)		2025-05-12
				ChP2020 Vol IV General chapter 0502 (Thin-layer Chromatography)		2025-05-12



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				ChP2020 Vol IV General chapter0512 (High Performance Liquid Chromatography)	Except for CAD detector and multidimensional HPLC	2025-05-12
				ChP2020 Vol IV General chapter0521 (Gas Chromatography)		2025-05-12
				ChP2020 Vol IV General chapter0703 (Oxygen Flask Combustion)		2025-05-12
				ChP2020 Vol IV General chapter0514 (Size-Exclusion Chromatography)		2025-05-12
				ChP2020 Vol IV General chapter0406 (Atomic Absorption Spectrophotometry)		2025-05-12
		62	related substances	ChP2020 Vol IV General chapter0401 (Ultraviolet-Visible Spectrophotometry)		2025-05-12
				ChP2020 Vol IV General chapter0502 (Thin-layer Chromatography)		2025-05-12
				ChP2020 Vol IV General chapter0512 (High Performance Liquid Chromatography)	Except for CAD detector and multidimensional HPLC	2025-05-12
				ChP2020 Vol IV General chapter0521 (Gas Chromatography)		2025-05-12
		63	assay	ChP2020 Vol IV General chapter0401 (Ultraviolet-Visible		2025-05-12



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				Spectrophotometry)		
				ChP2020 Vol IV General chapter0406 (Atomic Absorption Spectrophotometry)		2025-05-12
				ChP2020 Vol IV General chapter0512 (High Performance Liquid Chromatography)	Except for CAD detector and multidimensional HPLC	2025-05-12
				ChP2020 Vol IV General chapter0521 (Gas Chromatography)		2025-05-12
				ChP2020 Vol IV General chapter0513 (Ion Chromatography)		2025-05-12
				ChP2020 Vol IV General chapter0621 (Determination of Optical Rotation)		2025-05-12
				ChP2020 Vol IV General chapter0701 (Potentiometric Titration and Dead-stop Titration)		2025-05-12
				ChP2020 Vol IV General chapter0702 (Non-aqueous Titration)		2025-05-12
				ChP2020 Vol IV General chapter0704 (Determination of Nitrogen)		2025-05-12
				ChP2020 vol I 、 II 、 IV (Volumetric Analysis)		2025-05-12
				ChP2020 vol I 、 II 、 IV (Gravimetric Analysis)		2025-05-12
				ChP2020 Vol IV General chapter0514 (Size-Exclusion Chromatography)		2025-05-12



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				ChP2020 Vol IV General chapter0402 (Infrared Spectrophotometry)		2025-05-12
		64	Resistance to crushing of tablets	EP11th edition 2.9.8		2025-05-12
		65	Determination of Conductivity	ChP2020 Vol IV General chapter0681		2025-05-12
		66	Total number of discharges per container	ChP2020 Vol IV General chapter0111		2025-05-12
				ChP2020 Vol IV General chapter0112		2025-05-12
		67	Uniformity of delivered dose	ChP2020 Vol IV General chapter0106		2025-05-12
				ChP2020 Vol IV General chapter0112		2025-05-12
		68	Absorptivity	ChP2020 Vol IV General chapter0401 (Ultraviolet-Visible Spectrophotometry)		2025-05-12
		69	Transmittance of solution	ChP2020 Vol IV General chapter0401 (Ultraviolet-Visible Spectrophotometry)		2025-05-12
		70	Determination of Water	USP-NF General Chapters 921(Official as of 01-May-2022)		2025-05-12
		71	Turbidity	USP-NF General Chapters 855(Official as of 01-May-2019)		2025-05-12
		72	Measurement of consistency by penetrometry	ChP2020 Vol IV General chapter0983		2025-05-12
		73	Potassium(Kalium)	ChP2020 Vol IV General chapter0406		2025-05-12
				ChP2020 Vol IV General chapter0411		2025-05-12
		74	Calcium	ChP2020 Vol IV General chapter0406		2025-05-12

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				ChP2020 Vol IV General chapter0411		2025-05-12
		75	Sodium(Natrium)	ChP2020 Vol IV General chapter0406		2025-05-12
				ChP2020 Vol IV General chapter0411		2025-05-12
		76	Magnesium	ChP2020 Vol IV General chapter0406		2025-05-12
				ChP2020 Vol IV General chapter0411		2025-05-12
		77	Phosphorus	ChP2020 Vol IV General chapter0406		2025-05-12
				ChP2020 Vol IV General chapter0411		2025-05-12
		78	Zinc	ChP2020 Vol IV General chapter0406		2025-05-12
				ChP2020 Vol IV General chapter0411		2025-05-12
		79	Lead(Plumbum)	ChP2020 Vol IV General chapter0406		2025-05-12
				ChP2020 Vol IV General chapter0411		2025-05-12
		80	Arsenic	ChP2020 Vol IV General chapter0406		2025-05-12
				ChP2020 Vol IV General chapter0411		2025-05-12
		81	Mercury(Hydrargyrum)	ChP2020 Vol IV General chapter0406		2025-05-12
				ChP2020 Vol IV General chapter0411		2025-05-12
		82	Cadmium	ChP2020 Vol IV General chapter0406		2025-05-12



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		№	Item/ Parameter			
				ChP2020 Vol IV General chapter0411		2025-05-12
		83	Aluminium	ChP2020 Vol IV General chapter0406		2025-05-12
				ChP2020 Vol IV General chapter0411		2025-05-12
		84	Nickel	ChP2020 Vol IV General chapter0406		2025-05-12
				ChP2020 Vol IV General chapter0411		2025-05-12
		85	Chromium	ChP2020 Vol IV General chapter0406		2025-05-12
				ChP2020 Vol IV General chapter0411		2025-05-12
		86	Antimony (Stibium)	ChP2020 Vol IV General chapter0406		2025-05-12
				ChP2020 Vol IV General chapter0411		2025-05-12
		87	Palladium	ChP2020 Vol IV General chapter0406		2025-05-12
				ChP2020 Vol IV General chapter0411		2025-05-12
		88	Tests for Burkholderia cepacia complex	USP-NF General Chapters 60(Official as of 01-Dec-2019)		2025-05-12



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