

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: 2023-06-06 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		2023-06-06
				ChP2020 Vol IV General chapter0107		2023-06-06
				ChP2020 Vol IV General chapte0108		2023-06-06
				ChP2020 Vol IV General chapter0121		2023-06-06
				ChP2020 Vol IV General chapte0125		2023-06-06
				ChP2020 Vol IV General chapter0126		2023-06-06
				ChP2020 Vol IV General chapter0182		2023-06-06
				ChP2020 Vol IV General chapter0186		2023-06-06
				ChP2020 Vol IV General chapter0188		2023-06-06



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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
2			Filling variation	ChP2020 Vol IV General chapter0102		2023-06-06
				ChP2020 Vol IV General chapter0103		2023-06-06
				ChP2020 Vol IV General chapter0104		2023-06-06
				ChP2020 Vol IV General chapter0105		2023-06-06
				ChP2020 Vol IV General chapter0106		2023-06-06
				ChP2020 Vol IV General chapter0108		2023-06-06
				ChP2020 Vol IV General chapter0112		2023-06-06
				ChP2020 Vol IV General chapter0115		2023-06-06
				ChP2020 Vol IV General chapter0123		2023-06-06
				ChP2020 Vol IV General chapter0124		2023-06-06
				ChP2020 Vol IV General chapter0126		2023-06-06
				ChP2020 Vol IV General chapter0188		2023-06-06
				3		Filling variation (Weight variation)
4		Filling	ChP2020 Vol IV General chapter0102		2023-06-06	
			ChP2020 Vol IV General chapter0105		2023-06-06	



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		№	Item/ Parameter			
				ChP2020 Vol IV General chapter0106		2023-06-06
				ChP2020 Vol IV General chapter0116		2023-06-06
				ChP2020 Vol IV General chapter0123		2023-06-06
				ChP2020 Vol IV General chapter0181		2023-06-06
		5	Visible Particles	ChP2020 Vol IV General chapter0904		2023-06-06
		6	Metal particles	ChP2015 Vol IV General chapter0105		2023-06-06
		7	Ratio of sedimental volume	ChP2020 Vol IV General chapter0105		2023-06-06
				ChP2020 Vol IV General chapter0106		2023-06-06
				ChP2020 Vol IV General chapter0123		2023-06-06
				ChP2020 Vol IV General chapter0126		2023-06-06
		8	Uniformity of appearance	ChP2015 Vol IV General chapter0115		2023-06-06
		9	Solubility	ChP2020 Vol IV General Notices		2023-06-06
		10	uniformity of dispersion	ChP2020 Vol IV General chapter0101		2023-06-06
		11	Determination of Relative Density	ChP2020 Vol IV General chapter0601		2023-06-06
		12	Determination of Distilling Range	ChP2020 Vol IV General chapter0611		2023-06-06
		13	Determination of Melting Point	ChP2020 Vol IV General chapter0612		2023-06-06



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		14	Determination of Optical Rotation	ChP2020 Vol IV General chapter0621		2023-06-06
		15	Determination of Refractive Index	ChP2020 Vol IV General chapter0622		2023-06-06
		16	Determination of Viscosity	ChP2020 Vol IV General chapter0633		2023-06-06
		17	Determination of pH Value	ChP2020 Vol IV General chapter0631		2023-06-06
		18	Determination of Nitrogen	ChP2020 Vol IV General chapter0704		2023-06-06
		19	Determination of Ethanol	ChP2020 Vol IV General chapter0711		2023-06-06
		20	Determination of Acid Value	ChP2020 Vol IV General chapter0713		2023-06-06
		21	Determination of Saponification Value	ChP2020 Vol IV General chapter0713		2023-06-06
		22	Determination of Hydroxyl Value	ChP2020 Vol IV General chapter0713		2023-06-06
		23	Peroxide Value	ChP2020 Vol IV General chapter0713		2023-06-06
		24	Determination of Iodine Value	ChP2020 Vol IV General chapter0713		2023-06-06
		25	Limit Test for Chlorides	ChP2020 Vol IV General chapter0801		2023-06-06
		26	Limit Test for Sulfates	ChP2020 Vol IV General chapter0802		2023-06-06
		27	Limit Test for Iron	ChP2020 Vol IV General chapter0807		2023-06-06
		28	Limit Test for	ChP2020 Vol IV General chapter0821		2023-06-06

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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		2023-06-06
		30	Limit Test for Ammonium	ChP2020 Vol IV General chapter0808		2023-06-06
		31	Determination of Loss on Drying	ChP2015 Vol IV General chapter0831		2023-06-06
		32	Determination of Water	ChP2020 Vol IV General chapter0832		2023-06-06
		33	Determination of Residue on Ignition	ChP2020 Vol IV General chapter0841		2023-06-06
		34	Determination of Organic Solvent Residue	ChP2020 Vol IV General chapter0861		2023-06-06
				USP-NF General Chapters 467(Official as of 1-Dec-2020)		2023-06-06
		35	Colour of Solution	ChP2020 Vol IV General chapter0901		2023-06-06
				EP11th edition 2.2.2		2023-06-06
				BP2023 Appendix IV B		2023-06-06
		36	Clarity of Solution	ChP2020 Vol IV General chapter0902		2023-06-06
				EP11th edition 2.2.1		2023-06-06
		37	Test for Particulate Matter in Injection	ChP2020 Vol IV General chapter0903		2023-06-06
		38	Crystallinity	ChP2020 Vol IV General chapter0981	Accredited only for method I	2023-06-06



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		№	Item/ Parameter			
		39	Determination of Particle Size and Distribution of Particle Size	ChP2020 Vol IV General chapter0982		2023-06-06
		40	Determination of Particle Size	ChP2020 Vol IV General chapter0105		2023-06-06
				ChP2020 Vol IV General chapter0109		2023-06-06
				ChP2020 Vol IV General chapter0113		2023-06-06
				ChP2020 Vol IV General chapter0115		2023-06-06
		41	Determination of Osmolality	ChP2020 Vol IV General chapter0632		2023-06-06
		42	Determination of Disintegration	ChP2020 Vol IV General chapter0921		2023-06-06
		43	Disintegration Test for Suppositories and Vaginal Tablets	ChP2020 Vol IV General chapter0922		2023-06-06
		44	Dissolution Test, Drug Release Test	ChP2020 Vol IV General chapter0931	Except for method VI and methodVII	2023-06-06
				USP-NF General Chapters 711(Official as of 1-May-2022)		2023-06-06
				EP11th edition 2.9.3		2023-06-06
		45	Test for Content Uniformity	ChP2020 Vol IV General chapter0941		2023-06-06



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		№	Item/ Parameter			
				JP XVIII General Tests 6.02		2023-06-06
				EP11th edition 2.9.6、2.9.40		2023-06-06
				USP-NF General Chapters 905(Official Prior to 2013)		2023-06-06
		46	Minimum Fill	ChP2020 Vol IV General chapter0942		2023-06-06
		47	Test for Tablet Friability	ChP2020 Vol IV General chapter0923		2023-06-06
		48	Description	ChP2020 Vol I 、 II 、 IV General chapter monographs		2023-06-06
		49	Volumetric Analysis	ChP2020 vol I 、 II 、 IV(Volumetric Analysis)		2023-06-06
		50	Gravimetric Analysis	ChP2020 vol I 、 II 、 IV(Gravimetric Analysis)		2023-06-06
		51	Testing for inorganic ion	ChP2020 Vol I 、 II		2023-06-06
		52	Delivery amount in a dose	ChP2020 Vol IV General chapter0112		2023-06-06
		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		2023-06-06
				ChP2020 Vol IV General chapter0112		2023-06-06
				ChP2020 Vol IV General chapter0113		2023-06-06
		54	Adhesion test	ChP2020 Vol IV General chapter 0122	Accredited only for method I and	2023-06-06

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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
					method II	
				ChP2020 Vol IV General chapter 0952	Accredited only for method I and method II	2023-06-06
		55	Adhesion test	SoID JX20170061		2023-06-06
		56	Adhesion test	SoID JX20160171		2023-06-06
		57	Test for excipient property	ChP2020 Vol IV General chapter 0122		2023-06-06
		58	Weight of cataplasm	ChP2020 Vol IV General chapter 0122		2023-06-06
		59	Test for Sterility	ChP2020 Vol IV General chapter 1101		2023-06-06
				EP11th edition 2.6.1		2023-06-06
				USP-NF General Chapters 71(Official Prior to 2013)		2023-06-06
		60	Microbial Limit tests	ChP2020 Vol IV General chapter 1105		2023-06-06
				ChP2020 Vol IV General chapter 1106		2023-06-06
				ChP2020 Vol IV General chapter 1107		2023-06-06
				EP11th edition 2.6.12		2023-06-06
				EP11th edition 2.6.13		2023-06-06



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		№	Item/ Parameter			
				EP11th edition 5.1.4		2023-06-06
				USP-NF General Chapters <61>(Official Prior to 2013)		2023-06-06
				USP-NF General Chapters <62> (Official Prior to 2013)		2023-06-06
				USP-NF General Chapters <1111> (Official Prior to 2013)		2023-06-06
		61	Test for Bacterial Endotoxin	ChP2020 Vol IV General chapter 1143		2023-06-06
		62	identification	ChP2020 Vol IV General chapter 0301 (General identification)		2023-06-06
				ChP2020 Vol IV General chapter 0401 (Ultraviolet-Visible Spectrophotometry)		2023-06-06
				ChP2020 Vol IV General chapter 0402 (Infrared Spectrophotometry)		2023-06-06
				ChP2020 Vol IV General chapter 0502 (Thin-layer Chromatography)		2023-06-06
				ChP2020 Vol IV General chapter 0512 (High Performance Liquid Chromatography)	Except for CAD detector and multidimensional HPLC	2023-06-06
				ChP2020 Vol IV General chapter 0521 (Gas Chromatography)		2023-06-06
				ChP2020 Vol IV General chapter 0703 (Oxygen Flask Combustion)		2023-06-06



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		№	Item/ Parameter					
		63	related substances	ChP2020 Vol IV General chapter0514 (Size-Exclusion Chromatography)		2023-06-06		
				ChP2020 Vol IV General chapter0406 (Atomic Absorption Spectrophotometry)		2023-06-06		
				ChP2020 Vol IV General chapter0401 (Ultraviolet-Visible Spectrophotometry)		2023-06-06		
				ChP2020 Vol IV General chapter0502 (Thin-layer Chromatography)		2023-06-06		
				ChP2020 Vol IV General chapter0512 (High Performance Liquid Chromatography)	Except for CAD detector and multidimensional HPLC	2023-06-06		
				ChP2020 Vol IV General chapter0521 (Gas Chromatography)		2023-06-06		
		64	assay			ChP2020 Vol IV General chapter0401 (Ultraviolet-Visible Spectrophotometry)		2023-06-06
						ChP2020 Vol IV General chapter0406 (Atomic Absorption Spectrophotometry)		2023-06-06
						ChP2020 Vol IV General chapter0512 (High Performance Liquid Chromatography)	Except for CAD detector and multidimensional HPLC	2023-06-06



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				ChP2020 Vol IV General chapter0521 (Gas Chromatography)		2023-06-06
				ChP2020 Vol IV General chapter0513 (Ion Chromatography)		2023-06-06
				ChP2020 Vol IV General chapter0621 (Determination of Optical Rotation)		2023-06-06
				ChP2020 Vol IV General chapter0701 (Potentiometric Titration and Dead-stop Titration)		2023-06-06
				ChP2020 Vol IV General chapter0702 (Non-aqueous Titration)		2023-06-06
				ChP2020 Vol IV General chapter0704 (Determination of Nitrogen)		2023-06-06
				ChP2020 vol I、II、IV(Volumetric Analysis)		2023-06-06
				ChP2020 vol I、II、IV(Gravimetric Analysis)		2023-06-06
				ChP2020 Vol IV General chapter0514 (Size-Exclusion Chromatography)		2023-06-06
				ChP2020 Vol IV General chapter0402 (Infrared Spectrophotometry)		2023-06-06
		65	Resistance to crushing of tablets	EP11th edition 2.9.8		2023-06-06
		66	Determination of Conductivity	ChP2020 Vol IV General chapter0681		2023-06-06
		67	Inductively coupled plasma-atomic emission spectroscopy(ICP-AES) determination	ChP2020 Vol IV General chapter0406		2023-06-06
				ChP2020 Vol IV General chapter0411		2023-06-06



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		68	Total number of discharges per container	ChP2020 Vol IV General chapter0111		2023-06-06
				ChP2020 Vol IV General chapter0112		2023-06-06
		69	Uniformity of delivered dose	ChP2020 Vol IV General chapter0106		2023-06-06
				ChP2020 Vol IV General chapter0112		2023-06-06
		70	Absorptivity	ChP2020 Vol IV General chapter0401 (Ultraviolet-Visible Spectrophotometry)		2023-06-06
		71	Transmittance of solution	ChP2020 Vol IV General chapter0401 (Ultraviolet-Visible Spectrophotometry)		2023-06-06
		72	Determination of Water	USP-NF General Chapters 921(Official as of 01-May-2022)		2023-06-06
		73	Turbidity	USP-NF General Chapters 855(Official as of 01-May-2019)		2023-06-06
		74	Measurement ment of consistency by penetrometry	ChP2020 Vol IV General chapter0983		2023-06-06
		75	Potassium(Kalium)	ChP2020 Vol IV General chapter0406		2023-06-06
				ChP2020 Vol IV General chapter0411		2023-06-06
		76	Calcium	ChP2020 Vol IV General chapter0406		2023-06-06
				ChP2020 Vol IV General chapter0411		2023-06-06
		77	Sodium(Natrium)	ChP2020 Vol IV General chapter0406		2023-06-06
				ChP2020 Vol IV General chapter0411		2023-06-06



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		78	Magnesium	ChP2020 Vol IV General chapter0406		2023-06-06
				ChP2020 Vol IV General chapter0411		2023-06-06
		79	Phosphorus	ChP2020 Vol IV General chapter0406		2023-06-06
				ChP2020 Vol IV General chapter0411		2023-06-06
		80	Zinc	ChP2020 Vol IV General chapter0406		2023-06-06
				ChP2020 Vol IV General chapter0411		2023-06-06
		81	Lead(Plumbum)	ChP2020 Vol IV General chapter0406		2023-06-06
				ChP2020 Vol IV General chapter0411		2023-06-06
		82	Arsenic	ChP2020 Vol IV General chapter0406		2023-06-06
				ChP2020 Vol IV General chapter0411		2023-06-06
		83	Mercury(Hydrargyrum)	ChP2020 Vol IV General chapter0406		2023-06-06
				ChP2020 Vol IV General chapter0411		2023-06-06
		84	Cadmium	ChP2020 Vol IV General chapter0406		2023-06-06
				ChP2020 Vol IV General chapter0411		2023-06-06
		85	Aluminium	ChP2020 Vol IV General chapter0406		2023-06-06
				ChP2020 Vol IV General chapter0411		2023-06-06



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		86	Nickel	ChP2020 Vol IV General chapter0406		2023-06-06
				ChP2020 Vol IV General chapter0411		2023-06-06
		87	Chromium	ChP2020 Vol IV General chapter0406		2023-06-06
				ChP2020 Vol IV General chapter0411		2023-06-06
		88	Antimony (Stibium)	ChP2020 Vol IV General chapter0406		2023-06-06
				ChP2020 Vol IV General chapter0411		2023-06-06
		89	Palladium	ChP2020 Vol IV General chapter0406		2023-06-06
				ChP2020 Vol IV General chapter0411		2023-06-06



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