

Certificate of Analysis

Serial No: 2022061704

Product Name:	Hydrochlorothiazide (CAS No.: 58-93-5)		
Batch No.:	C01-20220604	Quantity:	500kg
Manufacturing Date:	May 25,2022	Retest Date:	May 24,2027

Test Items	Specifications	Result
1.Characteristics	A white or almost white, crystalline powder. Very slightly soluble in water, soluble in acetone, sparingly soluble in alcohol. It dissolves in dilute solutions of alkali hydroxides.	Conforms
2. Identification	First Identification: B Second Identification: A,C,D	Conforms
3. Acidity or alkalinity	$\leq 0.4\text{ml}$	$< 0.4\text{ml}$
4. Related Substances	Any Impurity $\leq 0.5\%$	0.22%
	Total Impurities $\leq 1.0\%$	0.42%
5.Chlorides	$\leq 100\text{ppm}$	Conforms
6. Loss on drying	$\leq 0.5\%$	0.10%
7. Sulphatedash	$\leq 0.1\%$	0.01%
8.Tappeddensity	Notavailable	0.78g/ml
9. Loosedensity	$\geq 0.4\text{g/ml}$	0.46g/ml
10.Microorganism Limit	Bacteria $\leq 1000\text{CFU/g}$ Mould and fungi $\leq 100\text{CFU/g}$ Pathogens absent	Absent
11. Particles size	90% less than 180um	Conforms
12. Residual solvents	Methanol $\leq 0.3\%$	ND
	ethanol $\leq 0.5\%$	ND
13. Assay(on dried substance)	98.0-102.0%	99.8%
Packaging and storage: Keep in tight containers, protected from light.		

Conclusion: All the results conform to the requirement of BP2013

Prepared by:	Reviewed by:	Approved by QA:
Zhai Jiahui 2022.09.22 (Signature/Date)	Tang Yanan 2022.09.22 (Signature/Date)	 (Signature/Date)

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Batch No.:	C01-20220604	Quantity:	500kg
Manufacturing Date:	May 25,2022	Retest Date:	May 24,2027

Test Items	Specifications	Result
1) Characters	White, or practically white, practically odorless, crystalline powder. Very Slightly soluble in water; freely soluble in sodium hydroxide solution, in n-butylamine, and in dimethylformamide; sparingly soluble in methanol; insoluble in ether, in chloroform, and in dilute mineral acids.	Conforms
2) Identification	A. IR Absorption	Conforms
	B. UV Absorption	Conforms
3) Loss on drying	≤0.5 %	0.10%
4) Residue on ignition	≤0.1 %	0.01%
5) Chloride	≤0.035%	Conforms
6) Selenium	≤0.003%	<0.003%
7) Related compounds	Benzothiadiazine related compound A ≤ 1.0 %	0.22%
	Chlorothiazide ≤ 0.5 %	0.05%
	5-Chlorohydrochlorothiazide ≤ 0.5 %	ND
	Hydrochlorothiazide dimer ≤ 0.5 %	ND
	Any other individual impurity ≤ 0.5 %	0.08%
	Total impurities ≤ 0.9 % (Excluding Benzothiadiazine related compound A)	0.20%
8) Assay	98.0~102.0 % on the dried basis	99.8%
Additional items (In-house)		
9) Formaldehyde	≤15ppm	<15ppm
10) Tapped density	Not available	0.78g/ml
11) Loosed density	≥0.4g/ml	0.46g/ml
12) Microorganism Limit	Bacteria ≤1000CFU/g Mould and fungi ≤100 CFU /g Pathogens absent	Absent
13) Particles size	90% less than 180um	Conforms
14) Residual solvents	Methanol ≤ 0.3 %	ND
	ethanol ≤ 0.5%	ND
Packaging and storage: Keep in tight containers, protected from light.		

Conclusion: All the results conform to the requirement of USP2021

Prepared by:	Reviewed by:	Approved by QA:
Zhai Jiahui 2022.09.22 (Signature/Date)	Tang Yanan 2022.09.22 (Signature/Date)	Xu Jiahua 2022.09.22 (Signature/Date)

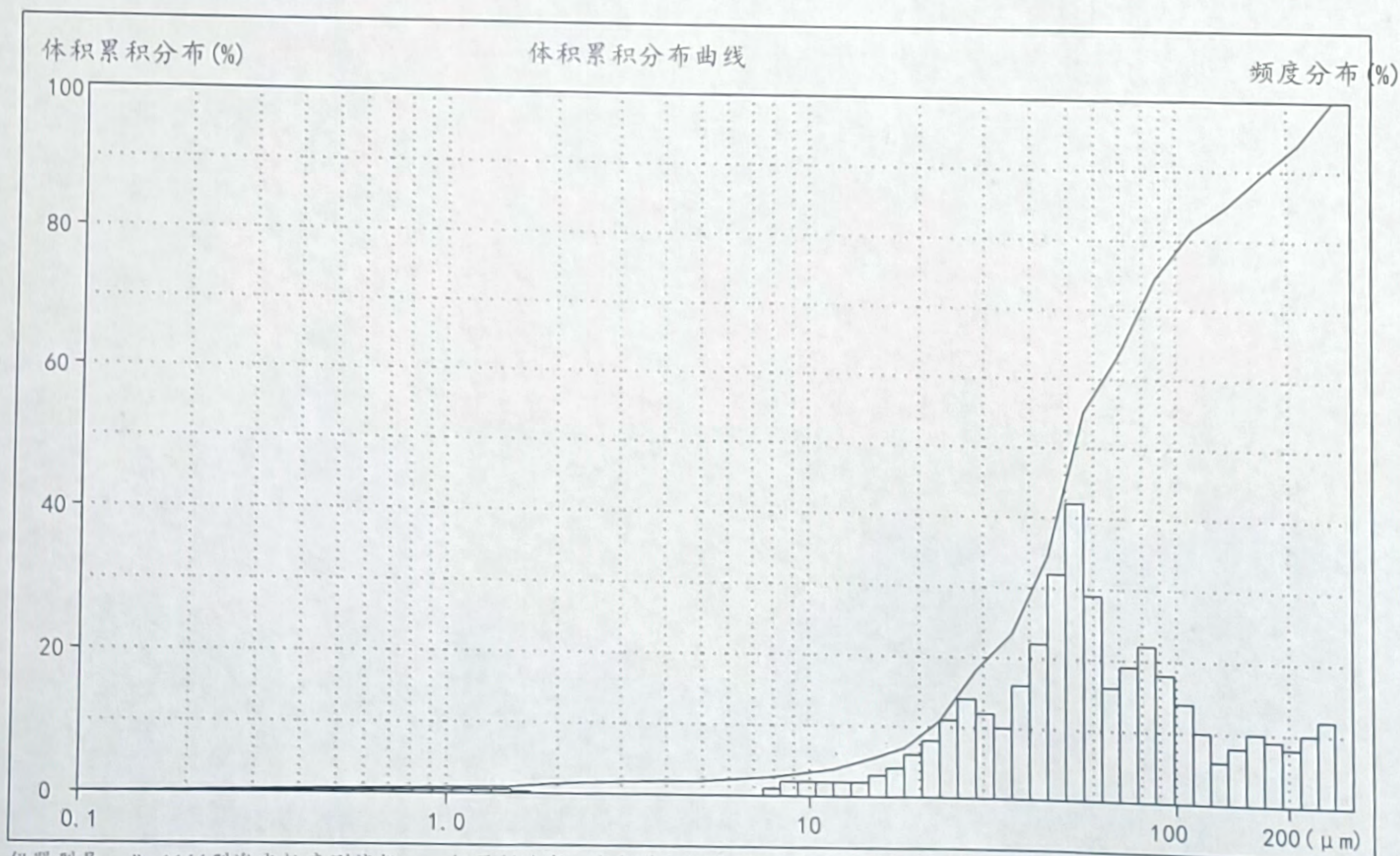


泰兴市国忠超细粉有限公司

试样名称 : 氢氯噻嗪
试样编号 : C01-20220604
试剂名称 : H2O
操作人员 : W
浓 度 : 62
表面积/体积 : 1974 cm²/cm³
测试日期 : 2022-09-23 14:48:02

累积10%粒径: 22.03 μm
累积50%粒径: 53.02 μm
累积90%粒径: 177.38 μm
累积97%粒径: 244.42 μm
平均粒径: 84.07 μm
Mode : Lf

粒径 (μm)	体积累积分布 (%)	频度分布 (%)	粒径 (μm)	体积累积分布 (%)	频度分布 (%)	粒径 (μm)	体积累积分布 (%)	频度分布 (%)
1.0	0.55	0.55	25.0	13.64	1.31	68.0	62.79	0.67
2.0	1.37	0.82	26.0	14.97	1.33	70.0	63.52	0.73
3.0	1.74	0.37	27.0	16.25	1.29	72.0	64.41	0.89
4.0	1.88	0.13	28.0	17.45	1.20	74.0	65.48	1.07
5.0	1.92	0.04	29.0	18.50	1.05	76.0	66.68	1.20
6.0	2.22	0.30	30.0	19.40	0.89	78.0	67.97	1.29
7.0	2.45	0.22	32.0	20.85	1.46	80.0	69.32	1.35
8.0	2.69	0.25	34.0	22.12	1.27	85.0	72.69	3.37
9.0	3.01	0.31	36.0	23.50	1.38	90.0	75.58	2.89
10.0	3.30	0.30	38.0	25.24	1.74	95.0	77.73	2.15
11.0	3.61	0.31	40.0	27.40	2.16	100.0	79.29	1.56
12.0	4.00	0.39	42.0	29.98	2.59	105.0	80.42	1.13
13.0	4.49	0.49	44.0	33.01	3.03	110.0	81.28	0.86
14.0	5.00	0.52	46.0	36.50	3.48	115.0	82.01	0.73
15.0	5.47	0.47	48.0	40.32	3.83	120.0	82.68	0.67
16.0	5.89	0.42	50.0	44.28	3.96	130.0	83.91	1.23
17.0	6.31	0.42	52.0	48.17	3.88	140.0	85.14	1.24
18.0	6.79	0.48	54.0	51.77	3.60	150.0	86.49	1.35
19.0	7.38	0.59	56.0	54.86	3.10	165.0	88.53	2.04
20.0	8.11	0.73	58.0	57.29	2.42	180.0	90.31	1.78
21.0	8.97	0.86	60.0	59.09	1.80	200.0	92.24	1.93
22.0	9.96	0.99	62.0	60.41	1.32	220.0	94.16	1.92
23.0	11.09	1.13	64.0	61.37	0.97	240.0	96.44	2.27
24.0	12.33	1.24	66.0	62.12	0.75	268.0	100.00	3.56



仪器型号: JL-1166型激光粒度测试仪

仪器制造商: 成都精新粉体测试设备有限公司

成都市白马寺街19号 电话: 028-83177668