



SHENZHOU JIHENG PHARMACEUTICAL CO., LTD.

West of Guoxin Road, Xijingming Village, Donganzhuang Township, Shenzhou County,
Hengshui City, Hebei Province, 053800 CHINA TEL:0086-318-5198558 FAX: 0086-318-5198998

CERTIFICATE OF ANALYSIS

Record code: SZ-REC-ZL028(08)-05

Name of Product	PARACETAMOL		
Lot No.	E32212031	Report No.	2212051
Quantity	9825Kg	Test Date	2022/12/18
Mfg date	2022/12/17	Retest Date	2026/12/16
Quality Standard	EP10.7	Report date	2022/12/25
COS NO.	R1-CEP 2012-148-Rev03		

Tests	Specification	Results
Appearance	White or almost white, crystalline powder .	White, crystalline powder .
Identification	B:IR absorption Complies	Complies
Related substances	Impurity J(chloroacetanilide)not more than10ppm	Not detected
	Impurity K(4-aminophenol)not more than50ppm	Not detected
	Individual unspecified impurity not more than 0.05%	0.02%
	Total impurities not more than 0.2%	0.03%
Sulfated ash	Not more than 0.1%	0.03%
Loss on drying	Not more than 0.5%	0.08%
Residual solvents	Residual content of acetic acid is limited by the test of loss on drying not more than0.5%	<0.08%
Assay	99.0-101.0%(dried substance)	100.0%
Microbial limits	Total aerobic microbial count not more than 10 ³ cfu/g	<10 cfu/g
	Total combined molds and yeasts count not more than 10 ² cfu/g	<10 cfu/g
	Escherichia coli should be absent/g	Not detected
Particle size	d (0.5)	11.152 μm
	d (0.9)	114.180 μm
Conclusion:	Complies with EP10.7	

Reported by: 王明杰

Reviewed by: 张明杰

Approved by: 张明杰