



HEBEI JIHENG (GROUP) PHARMACEUTICAL CO., LTD.

368 Jianshe Street Hengshui City Hebei, P.R.China 053000

Tel: +86 318-2133598 fax: +86 318-2182958 web: www.jihengpharmaceutical.com

4. Certificate of analysis of API

HEBEI JIHENG (GROUP) PHARMACEUTICAL CO., LTD.



No. 368 Jianshe Street, Hengshui City, Hebei Province, 053000 P.R. China

Tel: +86 318 2165838 Fax: +86 318 2165838

CERTIFICATE OF ANALYSIS

Name of Product	PARACETAMOL		
Lot No.	51701080	Report No.	01080
Quantity	2075 Kg	Report Date	2017/01/12
Mfg. date	2017/01/09	Exp. date	2021/01/08
Quality Standard	BP2016		

Tests	Standards	Results
Appearance	White or almost white, crystalline powder .	White, crystalline powder .
Solubility	Sparingly soluble in water, freely soluble in alcohol, very slightly soluble in methylene chloride.	Sparingly soluble in water, freely soluble in alcohol, very slightly soluble in methylene chloride.
Identification	A: Melting point 168~172℃	169.3~170.3℃
	C: IR absorption Complies	Complies
Related substances	Impurity J(chloroacetanilide) not more than 10ppm	Not Detected
	Impurity K(4-aminophenol) not more than 50ppm	2ppm
	Impurity F(4-nitrophenol) not more than 0.05%	Not Detected
	any other impurity not more than 0.05%	0.028%
	Total of other impurities not more than 0.1%	0.028%
Sulfated ash	Not more than 0.1%	0.07%
Heavy metals	Not more than 20ppm	Less than 20ppm
Loss on drying	Not more than 0.5%	0.14%
Residual solvents	Residual content of acetic acid is limited by the test of loss on drying not more than 0.5%	0.14%
Assay	99.0-101.0%(dried substance)	99.3%
Conclusion :	Complies with BP2016	
Reported by: 刘峰 李峰	Reviewed by: 李峰	Approved by: 孙丽红