

HEBEI JIHENG (GROUP) PHARMACEUTICAL CO., LTD.  
 CERTIFICATE OF ANALYSIS

Product name: Paracetamol tablets	
Specification: 500mg	Batch no.: 190213
Quantity: 5000600 tablets	
Sample source: works shop no.11	Sampling date: Mar.07,2019
According to: BP	Report date: Mar.13,2019
Date of manufacturing:02/2019	Date of expiry:01/2022

Item	Spec.	Result
Description	White, circular, flat beveled Tablets having P/500 Monogram on one Side and plain on the Other side	White, circular, flat beveled Tablets having P/500 Monogram on one Side and plain on the Other side
Identification(1)(2)(3)	Conform	Conform
[Tests]		
Weight Average of Tablet Test	0.576g ±5%	0.5726g
Uniformity of dosage unit	AV≤ 15.0	1.8
Diameter	12.50±1.00mm	12.59 mm
Thickness	4.00±1.00mm	4.68 mm
Hardness	NLT 3 kg/cm <sup>2</sup>	5.6 kg/cm <sup>2</sup>
Dissolution	NLT 75% (Q)	94%
Friability	NMT 1.0%	0.3%
Related substances	Impurity 4-aminophenol not more than 0.1%	0.002%
	Impurity 4'-chloroacetanilide not more than 10ppm	not detected
	Maximum of other Impurity not more than 0.25%	0.14%
Microbial limit		
Aerobe	NMT 10 <sup>3</sup> CFU/G	NMT 10CFU/G
Molds and yeasts	NMT 10 <sup>2</sup> CFU/G	NMT 10CFU/G
Escherichia Coli	NONE	NONE
[Assay]	Content of Paracetamol(C <sub>8</sub> H <sub>9</sub> NO <sub>2</sub> )	99.4%
	Shall be 95.0% to 105.0%	

Conclusion: The product test as per BP2019, comply.

Head of QC: Sun Lihong      Checked by: Ren Xiangxiang      Reporter: Liu Yinping