

Lot. 0320320



安丘市鲁安药业有限责任公司
ANQIU LU'AN PHARMACEUTICAL CO., LTD.

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Certificate of Analysis

Date of Certificate:	2019.07.23		
Product:	Paracetamol(Acetaminophen)		
Batch No.:	1951458		
Quantity:	5000kg		
Packing:	25kg/fibre drum		
Manufacturing Date:	2019.07.18		
Relest Date:	2023.07.18		
Release Date:	2019.07.23		
COS No.:	R1-CEP2000-124-Rev 08		
Standard:	Current EP		
Tests	Specification	Analysis Results	Test Reference
Characteristics:	Appearance: A white, or almost white, crystalline or crystalline powder. Solubility**: Sparingly soluble in water, freely soluble in ethanol, very slightly soluble in methylene chloride.	Conforms	EP monograph for Paracetamol
Identification:	IR spectrum conforms to that of the reference standard.	Conforms	EP 2.2.24
Loss on Drying:	≤0.5%	0.12%	EP 2.2.32
Sulfated ash:	≤0.1%	0.02%	EP 2.4.14
Related Substances:	Impurity K: 4-Aminophenol: ≤50ppm	2.2ppm	USP monograph for Acetaminophen, HPLC method
	Impurity J: Chloroacetanilide: ≤10ppm	ND*	
	Unspecified impurities***: ≤0.05%	0.009%	
	Total impurities: ≤0.2%	0.023%	
Assay (dried substance):	99.0-101.0%	99.7%	EP monograph for Paracetamol, Titration method)
Particle size:	Min.80% pass 100 mesh	Conforms	Air Jet Sieve Method
Residual Solvents	Glacial acetic acid is used in Acetaminophen production, and it can be determined by Loss on Drying not more than 0.5%.		
Storage and Transportation Conditions:	Preserve in tight and light-resistant containers.		
Conclusion:	It conforms to Current EP.		
The name and address of the original manufacturer: Anqiu Lu'an Pharmaceutical Co., Ltd. No.35 Weixu North Road, Anqiu, Shandong, China.			
We, Anqiu Lu'an Pharmaceutical Co., Ltd. as a manufacturer of Paracetamol hereby certify that this batch has been manufactured by us in full compliance with GMP requirements of the local Regulatory Authority. GMP No.SD20170560 valid till 2022-05-01 issued by China State Drug Administration as per which GMP rules were inspected by Chinese and ICH guidelines.			
QA Manager:		Analyst:	

*: ND means not detected.

**: Skip test. It will be tested once a month.

***: Reporting threshold: 0.03% (except for impurity J and

Manufacturer: Anqiu Lu'an Pharmaceutical Co., Ltd.

