

Lianyungang Kangle Pharmaceutical Co., Ltd

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Certificate of Analysis

Product: Paracetamol Fine Powder

Batch No. CW- 2212112F

Specification: EP10.8

Quantity:150kg

MFG Date: 12/2022

Retest Date:11/2027

Test	Result	Specification
Characters	Conforms	White or almost white crystalline powder, sparingly soluble in water, freely soluble in ethanol(96 percent), very slightly soluble in methylene chloride.
Identification		
B: IR	Conforms	B: Comparison: Paracetamol CRS
Related substances:		
lmpurity J	Not-detected	≤10ppm
Impurity K	<50ppm	≤50ppm
Unspecified impurities	0.011%	≤0.05%
Total impurities	0.011%	≤0.2%
Loss on drying	<0.1%	≤0.5%
Residual Solvent (Acetic acid)	<0.1%	≤0.5%
Sulfated ash	<0.1%	≤0.1%
Assay	100.0%	99.0~101.0% (on the dried sub.)

Comments: Comply with the requirements of EP10.8

Signature:

Reported by:

204. 12, 12

Approved by:

ilan

2022.12.12