Conler

Lianyungang Kangle Pharmaceutical Co., Ltd

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Certificate of Analysis

Product: **Paracetamol Crystal** Quantity: 1000kg
Batch No. CW-2312235C MFG Date: 12/2023
Specification: EP11 Retest Date: 11/2028

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:		
Impurity J	Not-detected	≤10ppm
Impurity K	Not-detected	≤50ppm
Unspecified impurities	0.011%	≤0.05%
Total impurities	0.011%	≤0.2%
Loss on drying	0.07%	≤0.5%
Residual solvent (Acetic acid)	<0.5%	≤0.5%
Sulfated ash	0.02%	≤0.1%
Assay	100.0%	99.0~101.0% (dried substance)
Comments: Comply with the requirements of EP11		

Signature:

Reported by: 2024. 01. 03 Approved by: 2024. 01. 03

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Certificate of Analysis

Product: **Paracetamol Crystal** Quantity: 2000kg
Batch No. CW-2312232C MFG Date: 12/2023
Specification: EP11 Retest Date: 11/2028

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:		
Impurity J	Not-detected	≤10ppm
Impurity K	Not-detected	≤50ppm
Unspecified impurities	0.011%	≤0.05%
Total impurities	0.011%	≤0.2%
Loss on drying	0.08%	≤0.5%
Residual solvent (Acetic acid)	<0.5%	≤0.5%
Sulfated ash	0.02%	≤0.1%
Assay	99.6%	99.0~101.0% (dried substance)
Comments: Comply with the requirements of EP11		

Signature:

Reported by: 2024.01.03 Approved by: 2024.01.03