

重 庆 康 乐 制 药 有 限 公 司

CHONGQING KANGLE PHARMACEUTICAL CO., LTD

CERTIFICATE OF ANALYSIS

Name of the Product:	Chloroquine Phosphate Working Standard	Batch No.:	LLK-200305-M
Batch size:	562.35kg	Test date:	Mar.08, 2020
Quantity :	25kg	Expiry date:	Feb.24, 2022
Specification:	EP9.0	Manufacturing date:	Mar.05, 2020

Item	Specification	Result
Characters	A white or almost white crystalline powder. Free soluble in water and in methanol, very slightly soluble in ethanol(96%)	Conforms
Melting point	about 195°C	195.5°C
Identification	A. UV	Conforms
	C. The precipitate melts at 206°C-209°C;	208°C
	D. Gives reaction of phosphates.	Conforms
Appearance of solution	≤BY5 or GY5	Conforms
pH: (10%w/v)	3.8-4.3	4.1
Related substance (TLC)	Single impurity≤1.0%	Conforms
	Any other impurity ≤0.5%	Conforms
Heavy metals	≤20ppm	Conforms
Loss on drying	≤2.0%	0.4%
Assay	98.5%-101.0%	99.4%
Residual solvents	Ethanol≤5000ppm	1075ppm
	Toluene≤890ppm	<LOD

Conclusion: Conform to the specification of EP9.0.

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2020.03.09

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2020.03.09

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2020.03.09

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