重庆康乐制药有限公司
CHONGQING KANGLE PHARMACEUTICAL CO., LTD
CERTIFICATE OF ANALYSIS

Name :	Sulfadiazine	Batch No.:	HMD-180401
Batch size:	509.57kg	Test Date:	Dec.31,2018
Quantity:	——	Retest Date:	Apr.28,2020
Specification:	EP9.0 & COS	Manufacturing Date:	Apr.29,2018

Items	Specification	Result
Appearance	White, yellowish-white or pinkish-white, crystalline powder or crystals.	yellowish-white crystalline powder
Solubility	Practically insoluble in water, slightly soluble in acetone, very slightly soluble in ethanol (96%). It dissolves in solutions of alkali hydroxides and in dilute mineral acids.	Conforms
Identification	A: The infrared absorption spectrum of sample corresponds to that of Sulfadiazine CRS.	Conforms
Appearance of solution	≤Y_5, BY_5 or GY_5	<GY_5
Acidity	≤0.2ml	0.07ml
Related substances	Impurity A≤0.3%	Not detected
	Impurity B≤0.3%	Not detected
	Impurity E≤0.2%	<0.03%（DL）
	Impurity F≤0.15%	0.08%
	Max single unspecified impurity≤0.05%	0.04%
	Total impurities≤0.5%	0.16%
Hydrazine hydrate	≤7ppm	0.3ppm
Loss on drying	≤0.5%	0.1%
Sulfated ash	≤0.1%	0.04%
Calcium acetate	≤10ppm	<10ppm
Assay	99.0%～101.0%(on the dried basis)	99.5%

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Conclusion: Conform to EP9.0 &COS specification.

QA MANAGER: 吴涛 2019.12.05 **CHECKER:** 2019.12.05 **ANALYST:** 王秋秋 2019.12.05

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