

杭州东瑞医药科技有限公司
HANGZHOU DAWN RAY PHARMACEUTICAL CO.,LTD.

CERTIFICATE OF ANALYSIS

L-Glutathione Reduced

Batch No.: DR20151202	Quantity: 1.0kg
Manufacture Date: 2015.12.02	Expiry Date: 2018.11

TESTS:

Items	Specification	Results
Appearance	White or almost white, crystalline powder or colourless crystals	white, crystalline powder
Solubility	freely soluble in water, very slightly soluble in ethanol and in methylene chloride	Complies
Identification	S.O.R.: $-15.5^{\circ} \sim -17.5^{\circ}$	-15.9°
	Infrared: Conforms to the Reference Spectrum	Conforms to the Reference Spectrum
Appearance of solution	Clear And Colorless	Complies
Specific Optical Rotation	$[\alpha]_{D20}$: $-15.5^{\circ} \sim -17.5^{\circ}$	-15.9°
Related substances:	- Impurity A (L-cysteinylglycine) $\leq 0.5\%$	Complies
	- Impurity B (Cysteine) $\leq 0.5\%$	Complies
	- Impurity C (L-glutathione oxidised) $\leq 1.5\%$	Complies
	- Impurity D(L- γ -glutamyl-L-cysteine) $\leq 1.0\%$	Complies
	- Total Impurities $\leq 2.5\%$	Complies
Chlorides	$\leq 200\text{ppm}$	Complies
Sulphates	$\leq 300\text{ppm}$	Complies
Ammonium	$\leq 200\text{ppm}$	Complies
Iron	$\leq 10\text{ppm}$	Complies

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Heavy Metals	≤10ppm	Complies
Loss on drying	≤0.5%	0.1%
Sulfated ash	≤0.1%	0.03%
Bacterial Endotoxin	<0.1EU/mg	Complies
Assay	98.0~101.0%	98.6%

Conclusion: The results conform with the EP7.0 standard.

Analyst: Joe Yu Checker: Agnes Zhong QA.Manager: Sun Wenhui



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