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

CERTIFICATE OF ANALYSIS

Sulfadiazine silver

Batch No.: DR20140310	Quantity:182kg
Manufacture Date: 2014.03.10	Expiry Date: 2017.03.10

TESTS:

Items	Specification	Results
Appearance	White to off-white crystalline powder	Conforms
Identification	A:Infrared absorption	Conforms
	B.The R,value of the principal spot in the	
	thin-layer chromatogram of the test solution as	
	obtained in the test for chromatogram purity	Conforms
	corresponds to that obtained from standard	
	solution A	
	C:Dissolve about 1g in 15ml of ammonium	
	hydroxide and 15ml of water in a 50ml	
	volumetric flask, dilute with water to volume,	Conforms
	and mix: the solution so obtained responds to	
	the tests for silver	
Loss on drying	≤0.5%	0.28%
Limit of nitrate	≤0.1%	0.05%
	No secondary spot in the chromatogram of the	
Chromatogram purity	test solution is greater or more intense than the	Conforms
	principal spot obtained from standard solution	
	B(1.0%)	
	The sum of all secondary spots observed is not	Conforms
	greater than 2.0%	
Silver content	29.3~30.5%	29.51%
Assay	98.0~102.0%	99.70%
Particle size	The average particle size is not greater than	
	10μm and the size of not more than 10% of the	Conforms
	particles is greater than 40µm.	

Conclusion: The results conform with USP34

质检专用章

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