

沈阳福宁药业有限公司

SHENYANG FUNING PHARMACEUTICAL CO., LTD

CERTIFICATE OF ANALYSIS

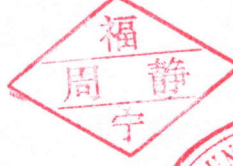
Product name, Spec. & Qty./packing: Sulfadiazine Silver, USP41, 100KG, 25kg/drum		
Batch Number: 20200903		Manufacturing Date: Sep. 16, 2020
Release Date: Sep. 23, 2020		Expiry Date: Sep. 16, 2023
Item	Standard	Results
Appearance	White to creamy-white,crystalline powder, odorless to having a slight odor.Is stable in air,but turns yellow on exposure to light.	Conforms
Solubility	Freely soluble in 30% ammonium solution;slightly soluble in acetone;practically insoluble in alcohol,in chloroform,and in ether.Decomposes in moderately strong mineral acids.	Conforms
Identification	A: Infrared Absorption<197>	Conforms
	B:The retention time of the major peak of the Samplesolution corresponds to that of the Standard solution, as obtained in the Assay.	Conforms
	C: Chemical Identification Tests, Silver:Meets the requirements.	Conforms
Loss on Drying	$\leq 0.5\%$	0.10%
Limit of Nitrate	$\leq 0.1\%$	0.03%
Organic Impurities	Sulfanilic acid $\leq 0.3\%$	< 0.05% (DL)
	Sulfaquanidine $\leq 0.10\%$	< 0.05% (DL)
	Sulfanilamide $\leq 0.10\%$	< 0.05% (DL)
	2-Aminopyrimidine $\leq 0.3\%$	< 0.05% (DL)
	Acetylsulfadiazine $\leq 0.2\%$	< 0.05% (DL)
	Specified unidentified impurity (RRT1.28) $\leq 0.15\%$	0.060%
	Individual unspecified impurity $\leq 0.10\%$	< 0.05% (DL)
	Total impurities $\leq 0.5\%$	< 0.22%
Content of Silver	29.3~30.5%	29.81%
Assay(on the dried basis)	98.0~102.0%	99.47%
Particle Size	The average particle size is not greater than 10 μm and the size of not more than 10% of the particles is greater than 40 μm	Conforms

It is hereby certificated that the quality is in conformity with the requirements of the order.

Supervisor:



Corrector:



Inspector:

