

LUSOCHIMICA S.p.A.

COPIA CONFORME ALL'ORIGINALE
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X QUALITY CONTROL MANAGER
28/06/2012

Lot: 0280713

CERTIFICATE OF ANALYSIS

Certificate N.: 269/12

Issue N° 7

Product: SILVER SULFADIAZINE MICRONIZED

Batch: AGSM 112

Conforms to: USP 34 - Lusochimica specifications Issue n° 7 of March 26, 2011

Code: 3750

Manufacturing date: June 2012

Retest date: June 2017

DESCRIPTION AND SOLUBILITY

White to creamy white, crystalline powder, odourless to having a slight odour. Is stable in air, but turns yellow on exposure to light.

Practically insoluble in alcohol, in chloroform, and in ether; freely soluble in 30% ammonium solution; decomposes in moderately strong mineral acids.

TESTS	RESULTS	SPECIFICATIONS
Description	corresponds	corresponding
Solubility	corresponds	corresponding
Identification		
- IR	corresponds	corresponding
- TLC	corresponds	corresponding
- Tests for silver	positive	positive
Loss on drying	0.4%	not more than 0.5%
Nitrate	less than 0.1%	not more than 0.1%
Chromatographic purity (TLC)		
- each impurity	less than 1.0%	not more than 1.0%
- total	less than 1.0%	not more than 2.0%
Silver content	30.0%	29.3% to 30.5%
Assay	100.2%	98.0% to 102.0%
Particle size (internal laser method)	90% less than 5 micron	90% less than 10 micron

Residual solvents content complies to current USP <467> and ICH Q3C

MANUFACTURING SITE: Lusochimica S.p.A. - Lomagna (LC) - ITALY

NOTES: store in tight, light-resistant containers

APPROVED BY Q.C. MANAGER

Date: 25/06/2012

RELEASED BY Q.P.

Release date: 26/06/2012

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