

Certificate of Analysis

Product Description

Mesalazine fine

6303

Lot No.:

Quantity:

1962

460 KG

Composon al lot L1357R129
de Faprou Iberia

[Signature]
Belen Reyer

Test Description

Test Results

Specification Limits

Test Method

Appearance

COMPLIES

Almost white or light grey or light pink powder or crystals

Ph. Eur.

Identification

COMPLIES

A: IR spectrum

COMPLIES

complies

Ph. Eur. 2.2.24 / USP <197K>

B: UV spectrum

COMPLIES

complies

USP <197U>

C: Reaction with ferric chloride

COMPLIES

complies

USP

Assay

99,5

98,5 - 101,0 % (on dried basis)

Specific Titration

Loss on drying

0,27

NMT 0,5 %

Ph. Eur. 2.2.32

Appearance of solution

COMPLIES

- Clarity of solution

COMPLIES

clear

Ph. Eur. 2.2.1 / USP

- Absorbance at 440 nm

0,01

NMT 0,15

Ph. Eur. 2.2.25

- Absorbance at 650 nm

<0,01

NMT 0,10

Ph. Eur. 2.2.25

pH

4,1

3,5 - 4,5

USP <791>

Sulphated ash

0,07

NMT 0,2 %

Ph. Eur. 2.4.14

The analytical report quoted above is the result of our quality inspection. It does not release the purchaser from the obligation of carrying incoming inspections and it does not mean to assure characteristics features of the product or a fitness for a specific use. An unobjectionable quality is guaranteed in our product specification.

Geschäftsführer: Dr. Oliver Bolzem, Dr. Wolfgang Burger – Sitz der Gesellschaft Raubling – HRB 16997 – Amtsgericht Traunstein

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Chlorides	0,05	NMT 0,1 %	Ph. Eur. 2.2.20
Sulphates	COMPLIES	NMT 200 ppm	Ph. Eur. 2.4.13
Heavy Metals	COMPLIES	NMT 20 ppm	Specific Method
Hydrog. sulfide/Sulfur dioxide	COMPLIES	complies	USP
Reducing substances	COMPLIES	complies	Ph. Eur.
Related substances	COMPLIES		Specific HPLC
- Sulfanilic acid	0,01	NMT 0,1 %	
- 4-Aminophenol	<10	NMT 200 ppm	
- 3-Aminophenol	<0,01	NMT 0,2 %	
- 2-Aminophenol	<20	NMT 200 ppm	
- 3-Aminobenzoic acid	<0,01	NMT 0,1 %	
- 3-Aminosalicylic acid	0,07	NMT 0,1 %	
- 2,5-Dihydroxybenzoic acid	<0,01	NMT 0,1 %	
- Salicylic acid	0,03	NMT 0,2 %	
- any other impurity	0,04	NMT 0,05 %	
- Total impurities	0,10	NMT 1,0 %	
- Aniline	<1	NMT 5 ppm	Ph. Eur. 2.2.29

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Bulk-Density	141	125 - 250 g/l	USP <618>
Particle size X10	3	2 - 6 µm	Laser
Particle size X50	12	8 - 20 µm	Laser
Particle size X90	43	25 - 50 µm	Laser
Residual solvents	COMPLIES	complies	Ph. Eur. 5.4 / USP <467>

Release Date 04.2010

Retest Date 03.2013

Only Class 3 solvent acetone is likely to be present.

LOD is less than 0,5 %

This lot complies with the requirements of corresponding PharmaZell specification and Ph. Eur. / USP current version

Quality Control Manager
Dr. Hans-Christian Müller

Report date: 26.07.10

Document generated by computer and valid without signature

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