

Certificate of Analysis

Product Description

Mesalazine

6160

Lot No.: 2214

Quantity: 242,5 KG

Test Description	Test Results	Specification Limits	Test Method
Appearance	COMPLIES	Almost white or light grey or light pink powder or crystals	Visual test
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
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
pH	4,1	3.5 - 4.5	USP <791>
Sulphated ash	0,08	NMT 0,2 %	Ph. Eur. 2.4.14
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	Inhouse method
Hydrog. sulfide/Sulfur dioxide	COMPLIES	complies	USP

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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.O.Bolzern, Dr.W.Burger – Sitz der Gesellschaft Raubling – HRB 16997 – Amtsgericht Traunstein

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Reducing substances	COMPLIES	complies	Ph. Eur.
Assay	99,7	98.5 - 101.0 % (on dried basis)	Inhouse method
Related substances			Inhouse method
- Sulfanilic acid	0,02	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	0,05	NMT 0.1 %	
- 2,5-Dihydroxybenzoic acid	<0,01	NMT 0.1 %	
- Salicylic acid	<0,02	NMT 0.2 %	
- any other impurity	0,04	NMT 0.05 %	
- Total impurities	0,09	NMT 1.0 %	
- Aniline	<1	NMT 5 ppm	Ph. Eur. 2.2.29
Loss on drying	0,19	NMT 0.5 %	Ph. Eur. 2.2.32
Residual solvents	COMPLIES	complies	Ph. Eur. 5.4 / USP <467>
Bulk-Density	182	g/l	USP <616>
Particle size X10	4	µm	Laser

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Quantity: 242,5 KG

Particle size X50

14 µm

Laser

Particle size X90

53 µm

Laser

Release Date 03.2011

Retest Date 10.2013

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 Assurance Manager

Dr. Stefan Tyroller

Report date: 21.07.11

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