

Certificate of Analysis

Product Description

Mesalazine Fine Extra

9155

Lot No.:

6109

Quantity:

431,8 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. / USP
- Absorbance at 440 nm	0,02	NMT 0,15	Ph. Eur.
- Absorbance at 650 nm	<0,01	NMT 0,10	
Identification	COMPLIES		
A. IR spectrum	COMPLIES	complies	Ph. Eur. / USP
B. Retention time	COMPLIES	complies	In-house method (HPLC)
Assay	100,2	98,5 to 101,5 % (on dried basis)	Ph. Eur.
Related substances	COMPLIES		In-house method (HPLC)
- Sulfanilic acid(O)	<0,03	NMT 0,1 %	
- 4-Aminophenol(A)	<30	NMT 200 ppm	
- 2-Aminophenol(C)	<60	NMT 200 ppm	
- 3-Aminosalicylic acid(F)	<0,03	NMT 0,1 %	
2,5 dihydroxy-benzoic acid (G)	<0,03	NMT 0,05 %	

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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.

PharmaZell (Vizag) Pvt. Ltd.

Plot No. 115,

Ramky Pharma City (I) Ltd. SEZ

Visakhapatnam - 531 021, AP, INDIA

Tel: +91-6024 236019

Fax: +91-6024-236016

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- Salicylic acid(H)	<0,03	NMT 0,2 %	
- 4-Aminosalicylic acid(E)	<0,03	NMT 0,05 %	
-3,5-Diaminosalicylic acid (J)	<0,03	NMT 0,1 %	
-5-Amino-2-hydroxy-3-(4-sulphophenyl)-benzoic acid (P)	0,04	NMT 0,1 %	
- any other impurity	<0,03	NMT 0,05 %	
- Total impurities	0,04	NMT 0,5 %	
- Aniline(K)	<1	NMT 5 ppm	Ph. Eur.
Heavy Metals	COMPLIES	NMT 10 ppm	Ph. Eur.
Chlorides	0,02	NMT 0,1 %	Ph. Eur.
Sulphates	COMPLIES	NMT 200 ppm	Ph. Eur.
Sulphated ash	0,05	NMT 0,2 %	Ph. Eur./ USP
Hydrogen sulfide/Sulfur dioxide	COMPLIES	complies	USP
Reducing substances	COMPLIES	complies	Ph. Eur.
Loss on drying	0,11	NMT 0,5 %	USP
pH	4,1	3,5 to 4,5	USP
**Residual solvents	COMPLIES	complies	Ph. Eur. 5.4 / USP <467>
Particle size distribution	COMPLIES		Ph. Eur. 2.9.31
- X(50)	7	<10 µm	

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- X(90)	21	<30 µm
- X(95)	26	NMT 50 µm

Release Date 03.09.2019 16:17:51

Relest Date 08.2022

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

This batch/lot is manufactured in full compliance with cGMP
and corresponding registration files.

*** Only Class 3 solvent Acetone is likely to be present, it shall be controlled by
LOD is less than 0,5 %

Manager, Quality Assurance
CH.S Srinivasa Raju

Report date: 06.09.19

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