

**MESALAZINUM 25 g**  
Lot No.: 22C01-APR22109

Authorisation:	1890R06090	Date Of Analysis:	29/12/2021
Analytical Reference:	Ph. Eur. 10.6 [07/2019:1699]	Production Number:	080422-GS21122
CNK:	4509-709	Expiry Date:	10/2026

**ANALYTICAL TESTS**

CHARACTERS	SPECIFICATION	RESULT
Appearance	Almost white or light grey or light pink powder or crystals	Complies
IDENTIFICATION	SPECIFICATION	RESULT
Identification B	The spectrum complies with the spectrum obtained with <i>mesalazine CRS</i>	Complies
TESTS	SPECIFICATION	RESULT
Appearance of solution	The solution is clear, absorbance at 440 nm $\leq$ 0.15 and at 650 nm $\leq$ 0.10	Complies
Reducing substances	Blue or violet-brown	Complies
Impurity A	$\leq$ 200 ppm	141 ppm
Impurity C	$\leq$ 200 ppm	8 ppm
Impurity K	$\leq$ 10 ppm	Not detected
Related substances		
Impurity H	$\leq$ 0.3%	< 0.03%
Impurity F	$\leq$ 0.1%	< 0.03%
Impurity J	$\leq$ 0.1%	0.04%
Impurity O	$\leq$ 0.1%	< 0.03%
Impurity P	$\leq$ 0.1%	Not detected
Impurity E	$\leq$ 0.05%	< 0.03%
Impurity G	$\leq$ 0.05%	< 0.03%
Impurity L	$\leq$ 0.05%	Not detected
Impurity M	$\leq$ 0.05%	Not detected
Impurity R	$\leq$ 0.05%	Not detected
Unspecified impurities	$\leq$ 0.05%	< 0.03%
Total	$\leq$ 0.5%	0.04%
Chlorides	$\leq$ 0.1%	0.002%
Sulfates	$\leq$ 200 ppm	Complies
Loss on drying	$\leq$ 0.5%	0.2%
Sulfated ash	$\leq$ 0.2%	0.1%
ASSAY	SPECIFICATION	RESULT
Potentiometric titration	98.5% to 101.5% (dried substance)	99.5%

CONCLUSION:

COMPLIES

RESPONSIBLE PHARMACIST:

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**FSA Chemicals – part of MAGIS PHARMA**

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