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METAPHARMACEUTICAL

N DE LOTE: 0161222

20/12/2022

CERTIFICATE OF ANALYSIS

SULFATHIAZOLE

Code: QF 0132

Date	Batch Nr	Weight in kg	Client
16/12/22	QF0132 L07/20	25,00	METAPHARMACEUTICAL, S.L.

N	PARAMETERS	ANALYSIS	SPECIFICATIONS	REFERENCES
1	Appearance:	Conform	A white or slightly yellowish, crystalline powder.	Ph. Eur. monograph
2	Identificación: IR Melting point	 Conform 202ºC	 Conform 200ºC – 203ºC	 Ph. Eur. 2.2.24 Ph. Eur. 2.2.14
3	Appearance of solution:	Conform	Clear and nmt GY4	Ph. Eur. 2.2.1 Ph. Eur. 2.2.2
4	Acidity:	Conform	< 0,1 ml of 0.1 M NaOH	Ph. Eur. monograph
5	Related substances: Sulphanilamide N4-Acetylsulfathiazole 2-aminothiazole (determined in raw material N4-Acetylsulfathiazole)	<0,5 % <0,10% <0,10% <0,10%	≤ 0,5% ≤ 0,10% ≤ 0,10% ≤ 0,10%	Ph. Eur. 2.2.29
6	Sulphated ash:	0,06%	≤ 0,1%	Ph. Eur. 2.4.14
7	Loss on drying	0,2%	≤ 0,5%	Ph. Eur. 2.2.32
8	Assay:	100,8%	99,0-101,0%	Ph. Eur. Monograph
9	Residual solvents: Benzene	 < 2 ppm	 < 2 ppm	 ICH Q3C(R6)

Manufacturing date: 09/03/2020

Date of analysis: 30/04/2020

*** Retest date:** 09/03/2025

Storage: Store protected from light

(*) Retest data to be confirmed by the stability results.

SULFATHIAZOLE is according the requirements of the current edition of European Pharmacopoeia Monograph (0742).

Quality Control,

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