

Certificate of Analysis

Productname: Betamethasoni-17-valeras 1:10
Number of analysis/Inspection Code: 1 / KEUR-196933B
Batchnumber: 22G13-F03-383587
Reference code / No.: 3828 / 22G13-F03
Analysed according to: DAC 2022/1

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white powder	Conform		
Particle size	100% < 90 µm	100	%	
Identification A	Conform	Conform		HPLC
Identification C	Conform	Conform		
Loss on drying	<=15,0	10,9	%	Internal
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Betamethasone valerate	9,50 - 10,50	9,87	%m/m	
Total aerobic microbial count (TAMC)	<10 ³	Conform	CFU / g	
Total yeasts and moulds (TYMC)	<10 ²	Conform	CFU / g	
Ps. aeruginosa	Absent / g	Conform	/ g	
St. aureus	Absent	Conform	/ g	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Eurofins.

Manufacturer / Country : Fagron Services BV / NL
CEP :

Release:
Anthony Amoureux
Qualified Person

02/13/23

Expiration: 04-08-25

Conclusion: APPROVED

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