

Certificate of Analysis

Productname: Dexamethasonum 1:10
Number of analysis/Inspection Code: 1 / KEUR-196792B
Batchnumber: 22G13-F04-384049
Reference code / No.: 3828 / 22G13-F04
Analysed according to: DAC2022/2+

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white powder	Conform		
Identification A	Conform	Conform		HPLC
Identification C	Conform	Conform		
Particle size	100% < 90 µm	100	%	
Loss on drying	<=15	11	%	Internal
Assay Dexamethasone	9,50 - 10,50	10,05	%m/m	
Total aerobic microbial count (TAMC)	<10 ³	Conform	CFU / g	
Total yeasts and moulds (TYMC)	<10 ²	Conform	CFU / g	
St. aureus	Absent	Conform	/g	
Ps. aeruginosa	Absent	Conform	/g	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
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

01/19/23

Expiration: 13-07-24

Conclusion: APPROVED

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