

## Certificate of Analysis

**Productname:** Dexamethasonum 1:10  
**Number of analysis/Inspection Code:** 1 / KEUR-198229B  
**Batchnumber:** 23E25-F02-385305  
**Reference code / No.:** 3828 / 23E25-F02  
**Analysed according to:** DAC2023/1+

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	9	%	Internal
Assay Dexamethasone	9,50 - 10,50	10,26	%m/m	
Total aerobic microbial count (TAMC)	<10 <sup>3</sup>	Conform	CFU / ml	
Total yeasts and moulds (TYMC)	<10 <sup>2</sup>	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

10/11/23

Expiration: 25-05-25

Conclusion: APPROVED

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