

Certificate of Analysis

Productname: Dexamethasoni natrii phosphas
Number of analysis/Inspection Code: 1 / KEUR-180694B
Batchnumber: 19K28-F01-367875
Reference code / No.: 4095 / NZ1885
Analysed according to: PH.EUR10.0

Tests	Requirement	Result	Unit	Standard remark
Appearance	Fine, (almost) white powder; very hygroscopic	Conform		
Identification B	Conform	Conform		IR-spectrum
Identification G	Conform	Conform		HPLC
Appearance of solution	Clear <=B7	Conform		5% <i>m/V</i>
pH	7,5 - 9,5	7,9		1% <i>m/V</i>
Specific optical rotation	+75 - +83	+79		1% <i>m/V</i> ; anhydrous
Related substances	Conform	Conform		HPLC
Impurity A	<=0,5	<0,05	%	
Impurity G	<=0,3	0,1	%	
Impurity B	<=0,2	<0,05	%	
Impurity C	<=0,2	<0,05	%	
Impurity D	<=0,2	<0,05	%	
Impurity E	<=0,2	<0,05	%	
Impurity F	<=0,2	0,0	%	
Unspecified impurities	<=0,10	0,1	%	
Total impurities	<=1,0	0,3	%	
Inorganic phosphates	<=1	<1	%	
Ethanol	<=1,5	0,2	% <i>m/m</i>	GC
Water	<=10,0	4,8	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Dexamethasone disodium phosph	97,0 - 102,0	99,1	% <i>m/m</i>	Anhydrous
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Pharma Cosmetic Polen.

Release:

dr. M.J. Vincenten - van Maanen

Pharmacist - Qualified Person

02/24/20

Expiration: 07-2022

Conclusion: APPROVED

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