



Certificate of Analysis

Productname: Natrii dihydrogenophosp.dihydr
Number of analysis/Inspection Code: 1 / KEUR-100540B
Batchnumber: 13H12-B01-285920 ✓
Reference code / No.: 2036 / B64250A
Analysed according to: PH.EUR 7.8



Tests	Requirement	Result	Unit	Standard remark
Appearance	White, crystalline powder or colourless crystals	Conform		
Identification A	Conform	Conform		Slightly acid
Identification B	Yellow	Conform		Phosphate
Identification C	Conform	Conform		Sodium
Appearance of solution	Clear and colourless	Conform		10% <i>m/V</i>
pH	4,2 - 4,5	4,3		5% <i>m/V</i>
Reducing substances	Conform	Conform		
Chlorides	<= 200	Conform	ppm	
Sulphates	<= 300	Conform	ppm	
Arsenic	<= 2	Conform	ppm	
Iron	<= 10	Conform	ppm	
Heavy metals	<= 10	Conform	ppm	
Loss on drying	21,5 - 24,0	22,6	%	130 °C
Residual solvents	CPMP/ICH/283/95	Conform		Data producer
Assay Sodium dihydrogen phosphate	98,0 - 100,5	99,5	% <i>m/m</i>	
Endotoxins	<= 0,20	Conform	IU / mg	LAL-test
Total aerobic microbial count (TAMC)	<=100	Conform	CFU / g	
Total yeasts and moulds (TYMC)	<=10	Conform	CFU / g	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analyse performed by the authorized lab Proxylabs+Microb..

Release:
Drs. M.V. Garcia Alia
Pharmacist - QA Manager / QP

18-10-13

Expiration: 04-2015 ✓

Conclusion: APPROVED

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