

Certificate of Analysis

Product name: Butylhydroxytoluenum
Batch number / Weight: 22K03-B11-219919 / 10 G
Analysed according to: Ph. Eur. 10.8
Number of analysis / Inspection Code 22K03-B11 / INS-22-9307
Reference Code / No.: V01418 / 216029

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Yellow-)white powder or colourless crystals	Conform		
Identification A	69 - 70	Conform		
Identification C	Conform	Conform		
Appearance of solution	Clear <=Y5 or BY5	Conform		
Freezing point	69 - 70	69	°C	
Related substances	<=0,5	Conform	%	
Sulphated ash	<=0,1	0,06	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab Fagron PL, ElSpol

Release:
Ewelina Gadzinowska
Qualified Person

28-11-2022

Expiration: 25-02-2024

Conclusion: APPROVED

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