

Certificate of Analysis

Product name: **Benzoylis perox. cum aqua**

Batch number / Weight: **22K19-B01-213245 / 100 G**

Analysed according to: **Ph.Eur.11.0**

Number of analysis / Inspection Code **22K19-B01 / INS-22-10243**

Reference Code / No.: **V01790 / 7612212651**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, amorphous or granular powder	Conform		
Identification B	Conform	Conform		
Acidity	Conform	Conform		
Related substances	Conform	Conform		
Impurity A	$\leq 0,25$	0,00	%	
Impurity B	$\leq 1,5$	0,14	%	
Impurity C	$\leq 0,25$	0,00	%	
Unspecified impurities	$\leq 0,10$	$< 0,02$	%	
Chlorides	$\leq 0,4$	$< 0,4$	%	
Water (Karl Fischer)	$\geq 20,0$	27,76	%m/m	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Dibenzoyl peroxide	70,0 - 77,0	74,43	%m/m	
Total aerobic microbial count (TA)	≤ 100	< 10	CFU / g	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

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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 lab,CBMiA

Release:
Dominika Soltysik
Qualified Person

16-01-2023

Expiration: 06-11-2023

Conclusion: APPROVED

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