

Certificate of Analysis

Product name: Ketoprofen
Batch number / Weight: 25G07-B18-015634 / 10 g
Producer / Producer Batch Number: BEC Chemicals / KTF-2408189M
Analyzed according to: Ph. Eur. 11.8
Number of Analysis / Certificate no.: 25G07-B18 / QO0022904

	Requirement	Result	Unit	Standard remark
Appearance	White or almost white, crystalline powder	Conform		
Identification	C	Conform		
Appearance of solution	Clear / <= Y6	Conform		
Related substances	Acc. to Ph. Eur.			
Impurity A	<= 0,10	< 0,05	%	
Impurity C	<= 0,10	0,000	%	
Unspecified impurities	<= 0,10	0,052	%	
Total impurities	<= 0,4	0,10	%	
Loss on drying	<= 0,5	0,00	%	
Sulfated ash	<= 0,1	0,00	%	
Assay	99,0 - 100,5	99,88	% m/m	
Metallic residues	CHMP/ICH/353369/2013	Conform		
Residual solvents	CPMP/ICH/82 260/06	Conform		
TSE/BSE-statement:	EMA/410/01 guidance compliant – no contamination	Conform		

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 FSNE lab

Release:

19-10-2025
 Agnieszka Pszczółka
 Qualified Person

Expiration: 31-7-2029

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.