

Certificate of Analysis

Product name: Phenylbutazonum
Batch number / Weight: 25A31-B16-009256 / 100 g
Analyzed according to: Ph. Eur.11.7
Number of Analysis / Certificate no.: 25A31-B16 / QO0014422
Reference code / No.: V01910 / BTZ2024127

	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification	A, C	Conform		
Appearance of solution	Clear	Conform		
Acidity or alkalinity	Conform	Conform	ml	
Absorbance	<=0,20	0,080		
Related substances	Conform	Conform		
Impurity A	<=0,25	0	%	
Impurity B	<=0,25	0,02	%	
Impurity C	<=0,20	0,02	%	
Any other impurity	<=0,1	0,02	%	
Total impurities	<=0,5	0,07	%	
Impurity E	<=5	<0,5	%	
Loss on drying	<=0,2	0,10	%	
Sulfated ash	<=0,1	0,07	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		DP
Residual solvents	CPMP/ICH/82 260/06	Conform		DP
Assay	99,0 - 101,0	100,20	% m/m	
TSE/BSE-statement:	EMA/410/01 guidance compliant – no contamination	Conform		DP

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

Release:

3-6-2025
 Ewelina Gadzinowska
 Qualified Person

Expiration: 13-9-2027

Conclusion: APPROVED

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