

Certificate of Analysis

Product name: **Phenylbutazonum**

Batch number / Weight: **21K10-B03-217156 / 250 G**

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

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification A	104 - 107	105	°C	
Identification C	Conform	Conform		
Appearance of solution	Clear	Conform		
Acidity or alkalinity	Conform	Conform		
Absorbance	<=0,20	0,19		
Related substances	Conform	Conform		
Impurity A	<=0,25	<0,025	%	
Impurity B	<=0,25	<0,025	%	
Impurity C	<=0,20	<0,025	%	
Any other impurity	<=0,1	<0,025	%	
Total impurities	<=0,5	<0,025	%	
Impurity E	<=5	<0,5	ppm	
Loss on drying	<=0,2	0,05	%	
Sulphated ash	<=0,1	0,04	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Phenylbutazone	99,0 - 101,0	100,3	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:
Ewelina Gadzinowska
Qualified Person

18-03-2022

Expiration: 05-03-2024

Conclusion: APPROVED

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