

## Certificate of Analysis

**Product name:** **Phenylbutazonum**

**Batch number / Weight:** **22G22-B03-222237 / 250 G**

**Analysed according to:** **Ph. Eur. 10.8**

**Number of analysis / Inspection Code** **22G22-B03 / INS-22-6963**

**Reference Code / No.:** **V01910 / BTZ2022073**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification A	104 - 107	106,6	°C	
Identification C	Conform	Conform		
Appearance of solution	Clear	Conform		
Acidity or alkalinity	Conform	Conform		
Absorbance	<=0,20	0,059		
Related substances	Conform	Conform		
Impurity A	<=0,25	0,000	%	
Impurity B	<=0,25	0,028	%	
Impurity C	<=0,20	0,000	%	
Any other impurity	<=0,1	0,03	%	
Total impurities	<=0,5	0,05	%	
Impurity E	<=5	0,0	ppm	
Loss on drying	<=0,2	0,01	%	
Sulphated ash	<=0,1	0,00	%	
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	100,32	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Residual solvents				
Methanol		<3000	ppm	
Ethanol		<5000	ppm	

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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

Release:

Ewelina Gadzinowska

Qualified Person

26-10-2022

Expiration: 31-03-2025

Conclusion: APPROVED

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