



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 242417

Product:	PHENYLBUTAZONE
Lot:	242417
Expiry date:	25/03/2026
Reference:	Cumple PhEur11.6
Synonyms:	
Formula:	C ₁₉ H ₂₀ N ₂ O ₂
Molecular weight:	308,38 g/mol

Assay	Result	Specification	
Elemental impurities	Conform	Test PhEur	#
Loss on drying	0,05 %	<= 0,2 %	
Sulphated ashes	0,00 %	<= 0,1 %	
Assay	99,2 %	99,0-101,0%	
Acidity or alkalinity	Conform	Test PhEur	
Nitrosamine impurities	Conform		#
Related substances (HPLC)	Conform	Test PhEur	
Impurity E	1 ppm	<= 5 ppm	
Absorbance	0,04	<= 0,20	
Identification	Confome (A,C)	Test PhEur (A,C)	
Any other impurity	0,05 %	<= 0,1 %	
Organoleptic properties	Conform	PhEur	
Total impurities	0,10 %	<= 0,5 %	
Melting point	106 °C	104 - 107 °C	
Residual solvents	Conform		#
Appearance of solution	Conform		
Impurity A	< 0,03 %	<= 0,25 %	
Impurity B	0,05 %	<= 0,25 %	
Impurity C	ND	<= 0,20 %	

Organoleptic characteristics: White or almost white, crystalline powder. Practic. insoluble in water, quite soluble in ethanol 96%. It dissolves in alkaline solutions.

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 17/01/2025

Judgement:
APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

Manufacturer: F00037 NANTONG JINGHUA PHARMACEUTICAL, CO. LTD.

Manufacturer batch: BTZ2023089

Product	Name	Capacity	Batch
1144343	FENILBUTAZONA	50 g	242417-I-1
1144345	FENILBUTAZONA	250 g	242417-N-1
1144347	FENILBUTAZONA	1 kg	242417-P-1

This certificate is not initialled as it is computer processed, it is validated with the originals available at Acofarma.

Original manufacturer's certificate available on request.

(#) Parameter controlled by the manufacturer

(=) UE certificate

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Date of edition: 18/05/2025