



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 240330

Product:	PHENYLBUTAZONE
Lot:	240330
Expiry date:	05/01/2026
Reference:	Cumple PhEur11.3
Synonyms:	
Formula:	C ₁₉ H ₂₀ N ₂ O ₂
Molecular weight:	308,38 g/mol

Assay	Result	Specification	
Assay	99,5 %	99,0-101,0%	
Sulphated ashes	0,03 %	<= 0,1 %	
Loss on drying	0,05 %	<= 0,2 %	
Elemental impurities	Conform	Test PhEur	#
Absorbance sol. S (420 nm)	0,01	<= 0,20	
Impurity E	1 ppm	<= 5 ppm	
Related substances (HPLC)	Conform	Test PhEur	
Acidity or alkalinity	Conform	Test PhEur	
Appearance of solution S	Conform		
Residual solvent: Ethanol	<= 5000 ppm	<= 5000 ppm	#
Melting point (Mettler)	107 °C	104 - 107 °C	
Residual solvent: Methanol	<= 3000 ppm	<= 3000 ppm	#
Organoleptic properties	Conform	PhEur	
Total impurities	< 0,025 %	<= 0,5 %	
Identification	Conform (A,C)	Test PhEur (A,C)	
Any other impurity	< 0,025 %	<= 0,1 %	
Impurity C	ND	<= 0,20 %	
Impurity B	< 0,025 %	<= 0,25 %	
Impurity A	< 0,025 %	<= 0,25 %	

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: 23/02/2024

Judgement:
APPROVED

Responsible: B.Chia

Technical director: Montserrat Enrique

Manufacturer: F00037 NANTONG JINGHUA PHARMACEUTICAL, CO. LTD.

Manufacturer batch: BTZ2023015

Product	Name	Capacity	Batch
1144343	FENILBUTAZONA	50 g	240330-I-1
1144343	FENILBUTAZONA	50 g	240330-I-2
1144345	FENILBUTAZONA	250 g	240330-N-1
1144345	FENILBUTAZONA	250 g	240330-N-2
1144345	FENILBUTAZONA	250 g	240330-N-3
1144347	FENILBUTAZONA	1 kg	240330-P-1
1144347	FENILBUTAZONA	1 kg	240330-P-2

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