



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 230146

Product:	PHENYLBUTAZONE
Lot:	230146
Expiry date:	20/10/2025
Reference:	Cumple PhEur11.0
Synonyms:	
Formula:	C ₁₉ H ₂₀ N ₂ O ₂
Molecular weight:	308,38 g/mol

Assay	Result	Specification	
Impurity A	< 0,025%	<= 0,25 %	
Identification	Conform (A,C)	Test PhEur (A,C)	
Any other impurity	< 0,025 %	<= 0,1 %	
Organoleptic properties	Conform	PhEur	
Total impurities	0,03 %	<= 0,5 %	
Impurity B	0,03 %	<= 0,25 %	
Impurity C	< 0,025 %	<= 0,20 %	
Sulphated ashes	0,00 %	<= 0,1 %	
Assay	100,1 %	99,0-101,0%	
Acidity or alkalinity	Conform	Test PhEur	
Related substances (HPLC)	Conform	Test PhEur	
Melting point (Mettler)	107 °C	104 - 107 °C	
Residual solvent: Methanol	< 3000 ppm	<= 3000 ppm	#
Appearance of solution S	Conform		
Residual solvent: Ethanol	< 5000 ppm	<= 5000 ppm	#
Elemental impurities	Conform	Test PhEur	#
Loss on drying	0,09 %	<= 0,2 %	
Impurity E	< 5 ppm	<= 5 ppm	
Absorbance sol. S (420 nm)	0,1	<= 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: 16/02/2023

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00037 NANTONG JINGHUA PHARMACEUTICAL, CO. LTD.

Manufacturer batch: BTZ2022238

Product	Name	Capacity	Batch
1144343	FENILBUTAZONA	50 g	230146-I-1
1144343	FENILBUTAZONA	50 g	230146-I-3
1144345	FENILBUTAZONA	250 g	230146-N-1
1144345	FENILBUTAZONA	250 g	230146-N-2
1144345	FENILBUTAZONA	250 g	230146-N-3
1144347	FENILBUTAZONA	1 kg	230146-P-1
1144347	FENILBUTAZONA	1 kg	230146-P-2
1144347	FENILBUTAZONA	1 kg	230146-P-3
1370189	FENILBUTAZONA (FLB)	50 g	230146-I-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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