



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 242054

Product:	PHENYLBUTAZONE
Lot:	242054
Expiry date:	25/03/2026
Reference:	Cumple PhEur11.5
Synonyms:	
Formula:	C ₁₉ H ₂₀ N ₂ O ₂
Molecular weight:	308,38 g/mol

Assay	Result	Specification	
Absorbance	0,04	<= 0,20	
Elemental impurities	Conform	Test PhEur	#
Related substances (HPLC)	Conform	Test PhEur	
Impurity E	ND	<= 5 ppm	
Assay	99,8 %	99,0-101,0%	
Loss on drying	0,08 %	<= 0,2 %	
Sulphated ashes	0,00 %	<= 0,1 %	
Impurity C	< 0,03 %	<= 0,20 %	
Identification	Conform (A,C)	Test PhEur (A,C)	
Any other impurity	0,03 %	<= 0,1 %	
Impurity A	< 0,03 %	<= 0,25 %	
Impurity B	0,04 %	<= 0,25 %	
Appearance of solution	Conform		
Acidity or alkalinity	Conform	Test PhEur	
Nitrosamine impurities	Conform		#
Organoleptic properties	Conform	PhEur	
Total impurities	0,07 %	<= 0,5 %	
Melting point	107 ° C	104 - 107 °C	
Residual solvents	Conform		#

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: 07/11/2024

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	242054-I-1
1144345	FENILBUTAZONA	250 g	242054-N-1
1144347	FENILBUTAZONA	1 kg	242054-P-1
1144349	FENILBUTAZONA	10 kg	242054-R-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

ACOFARMA DISTRIBUCIÓN, S.A.

C/ Llobregat, 20 - 08223 Terrassa (Barcelona)

Tel./ 93-736.00.88

www.acofarma.com

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