



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 241892

Product:	ACETYL SALICYLIC ACID
Lot:	241892
Expiry date:	30/06/2027
Reference:	Cumple PhEur11.5
Synonyms:	
Formula:	C ₉ H ₈ O ₄
Molecular weight:	180,15 g/mol

Assay	Result	Specification	
Identification	Conform (A,B)	Test PhEur (A,B)	
Organoleptic properties	Conform	PhEur	
Melting point (Mettler)	140 °C		
Appearance of solution	Conform	Complies	
Related substances (HPLC)	Conform		
Loss on drying (vacuum)	0,00 %	<= 0,5%	
Sulphated ashes	0,00 %	<= 0,1 %	
Assay	100,8 %	99,5 - 101,0 %	
Impurity A	< 0,03 %	<= 0,15 %	
Impurity B	< 0,03 %	<= 0,15 %	
Impurity C	< 0,03 %	<= 0,15 %	
Impurity D	< 0,03 %	<= 0,15 %	
Impurity E	< 0,03 %	<= 0,15 %	
Impurity F	< 0,03 %	<= 0,15 %	
Unspecified Impurities	< 0,03 %	<= 0,05 %	
Total impurities	< 0,25 %	<= 0,25 %	
Residual solvent: Acetic acid	<= 5000 ppm	<= 5000 ppm	#
Elemental impurities	Conform	Test PhEur	#
Nitrosamine impurities	Conform	Test PhEur	#

Organoleptic characteristics: White or almost white, crystalline powder or colourless crystals. Slightly soluble in water, freely soluble in ethanol (96 per cent).

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 22/10/2024

Judgement:
APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

Manufacturer: F00052 SHANDONG XINHUA PHARMACEUTICAL, CO. LTD.

Manufacturer batch: 241186

Product	Name	Capacity	Batch
1101064	ACIDO ACETILSALICILICO	100 g	241892-J-1
1101064	ACIDO ACETILSALICILICO	100 g	241892-J-2
1101065	ACIDO ACETILSALICILICO	250 g	241892-N-1
1101065	ACIDO ACETILSALICILICO	250 g	241892-N-2
1101067	ACIDO ACETILSALICILICO	1 kg	241892-P-1
1101067	ACIDO ACETILSALICILICO	1 kg	241892-P-2
1101067	ACIDO ACETILSALICILICO	1 kg	241892-P-3
1370091	ACIDO ACETILSALICILICO (FLB)	25 kg	241892-T-1
1370091	ACIDO ACETILSALICILICO (FLB)	25 kg	241892-T-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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