



## ANALYSIS CERTIFICATE

**Lot/Analysis/Analysis N°: 240432**

Product:	ACETYL SALICYLIC ACID
Lot:	240432
Expiry date:	30/07/2026
Reference:	Cumple PhEur11.3
Synonyms:	
Formula:	C <sub>9</sub> H <sub>8</sub> O <sub>4</sub>
Molecular weight:	180,15 g/mol

Assay	Result	Specification	
Identification	Conform (A,B)	Test PhEur (A,B)	
Organoleptic properties	Conform	PhEur	
Melting point (Mettler)	141 °C		
Appearance of solution	Conform	Complies	
Related substances (HPLC)	Conform		
Loss on drying (vacuum)	0,02%	<= 0,5%	
Sulphated ashes	0,01%	<= 0,1 %	
Assay	100,4 %	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	< 0,03 %	<= 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: 04/03/2024

Judgement:  
APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

Manufacturer: F00052 SHANDONG XINHUA PHARMACEUTICAL, CO. LTD.

Manufacturer batch: 231381

Product	Name	Capacity	Batch
1101064	ACIDO ACETILSALICILICO	100 g	240432-J-2
1101064	ACIDO ACETILSALICILICO	100 g	240432-J-3
1101064	ACIDO ACETILSALICILICO	100 g	240432-J-4
1101065	ACIDO ACETILSALICILICO	250 g	240432-N-2
1101065	ACIDO ACETILSALICILICO	250 g	240432-N-3
1101065	ACIDO ACETILSALICILICO	250 g	240432-N-4
1101067	ACIDO ACETILSALICILICO	1 kg	240432-P-2
1101067	ACIDO ACETILSALICILICO	1 kg	240432-P-3
1101067	ACIDO ACETILSALICILICO	1 kg	240432-P-4
1370004	ACIDO ACETILSALICILICO (FLB) (INACTIVO)	100 g	240432-J-1
1370005	ACIDO ACETILSALICILICO (FLB) (INACTIVO)	250 g	240432-N-1
1370006	ACIDO ACETILSALICILICO (FLB) (INACTIVO)	500 g	240432-O-1
1370007	ACIDO ACETILSALICILICO (FLB) (INACTIVO)	1000 g	240432-P-1
1370091	ACIDO ACETILSALICILICO (FLB)	25 kg	240432-T-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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