



## TECHNICAL DATA SHEET

0046-TDS-ENG-2024

<b>ACIDO ACETILSALICILICO (EUR. PH.)</b>		
DESCRIPTION DCI: ACETYLSALICYLIC ACID		DESCRIPTION DOE: ACETILSALICILICO ACIDO
CAS Nº: 50-78-2	EC Nº: 200-064-1	AEMPS CODE: 176A
MOL. WEIGHT: 180,15	MOL. FORMULA: C9H8O4	ARTICLE CODE: 0046

ATTRIBUTES	SHOULD BE
Appearance	White or almost white crystalline powder
Solubility	Slightly soluble in water, freely soluble in ethanol (96 %)
Identification A	Complies
Identification B	Complies
Appearance of solution	Clear and colourless
Related substances	
Impurity A	=< 0.15 %
Impurity B	=< 0.15 %
Impurity C	=< 0.15 %
Impurity D	=< 0.15 %
Impurity E	=< 0.15 %
Impurity F	=< 0.15 %
Unspecified impurities	=< 0.05 %
Total impurities	=< 0.25 %
Sulfated ash	=< 0.1 %
Loss on drying	=< 0.5 %
Assay	99.5 - 101.0 %

### COMPLIES WITH

European Pharmacopeia 11.0

### STORAGE

Store in a cool place. Keep the container tightly closed in a dry and well-ventilated place.

### REMARKS

Acetylsalicylic acid is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.