



## TECHNICAL DATA SHEET

6-TDS-ENG-2019

PROCAINAMIDA HCL (PH.EUR. y USP)		
DESCRIPTION DCI: PROCAINAMIDE HYDROCHLORIDE		DESCRIPTION DOE: PROCAINAMIDA HIDROCLORURO
CAS Nº: 614-39-1	EC Nº: 210-381-7	AEMPS CODE: 2207CH
MOL. WEIGHT: 271.79	MOL. FORMULA: C <sub>13</sub> H <sub>22</sub> ClN <sub>3</sub> O	ARTICLE CODE: 6

ATTRIBUTES	SHOULD BE
Appearance	White or very slightly yellow, crystalline powder, hygroscopic
Solubility	Very soluble in water, freely soluble in alcohol, slightly soluble in acetone
Identification C	Complies
Identification D	Complies
Appearance of solution	Clear and not more intensely coloured than reference solution B6
pH	5.6 - 6.3
Related substances	=< 0.5 %
Heavy metals	=< 20 ppm
Loss on drying	=< 0.5 %
Sulfated ash	=< 0.1 %
Assay	98.0 - 101.0 %
Residual solvents	
Ethanol	=< 0.5 %

### COMPLIES WITH

European Pharmacopoeia 9.0

### STORAGE

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

### REMARKS

PROCAINAMIDE HCL is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline.

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

### Properties

PROCAINAMIDE is a medication that acts at the heart level as a class I antiarrhythmic agent, indicated in the treatment of certain heart rhythm disorders. It is administered intravenously or orally and acts by blocking the sodium channels in the heart muscle, thus prolonging the duration of the action potential of the cardiac cell.

### Adverse effects

PROCAINAMIDE has extracardiac effects, producing a reduction in peripheral vascular resistance that can cause arterial hypotension, especially with the accelerated infusion of the drug intravenously.

The most notable adverse reactions include the appearance of a syndrome similar to systemic lupus erythematosus, characterized by rash, fever, muscle aches and arthritis. In some patients, non-infectious pleuritis or pericarditis may appear. All these reactions are more frequent with prolonged use of the medication. Occasionally, diarrhea, hepatitis and agranulocytosis have been reported.