METAPHARMACEUTICAL IND SL
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TECHNICAL DATA SHEET

891-TDS-ENG-2023

ACIDO SORBICO (PH.EUR)		
DESCRIPTION DCI: HEXA-2,4-DIENOIC ACID	DESCRIPTION DOE: ÁCIO HEXA-2,4-DIENOICO	
CAS Nº: 110-44-1	EC Nº: 203-768-7	AEMPS CODE: ---
MOL. WEIGHT: 112.1	MOL. FORMULA: C6H8O2	ARTICLE CODE: 891

ATTRIBUTES	SHOULD BE
Appearance	White or almost white, crystalline powder
Solubility	Slightly soluble in water, freely soluble in ethanol (96 %)
Identification A	Complies
Identification C	Complies
Melting point	132 - 136 ºC
Appearance of solution	Clear and colourless
Aldehydes	=< 0.15 %
Water	=< 1.0 %
Sulfated ash	=< 0.2 %
Assay	99.0 - 101.0 %

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

Keep the product in a tightly closed container, protected from sunlight and heat.

REMARKS

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

The product is not of animal origin and no animal product is used in its production, so it is risk-free BSE/TSE.

The product is not derived from GMO. No genetically modified organism is used in its production and no GMO product comes in contact with the product during any stage of production.

Properties and uses
SORBIC ACID has antibacterial and antifungal properties, particularly against molds and yeasts. Its activity decreases to pH> 6.0 - 6.5, with an optimum of 4.5. They are used as a preservative in pharmaceutical and cosmetic preparations. It has the advantage over SORBIC ACID of having a greater solubility in water. Efficacy increases when combined with other antimicrobials or with glycols such as propylene glycol. In emulsions it is better to use equal parts of the acid and the potassium salt because of the partition coefficient. Potassium sorbate has also been used to increase the ocular bioavailability of timolol. The aqueous solutions of Potassium sorbate can be sterilized by autoclaving.

Dosage
Usually at 0.1 - 0.2%, sometimes up to 0.6% SORBIC ACID.

Side effects
They are not toxic products, but topically they can cause irritation and hypersensitivity reactions. Also irritation of eyes and mucous membranes. Incompatibilities: Non-ionic surfactants, some plastics, oxidizing and reducing agents, and heavy metal salts. Alkalis in the case of SORBIC ACID.

Other observations
SORBIC ACID is easily oxidizable, especially in the presence of light, sometimes adding an antioxidant such as propyl gallate 0.02%