Nutrinova® Sorbic Acid – Pharma Grade – Chemical and physical properties according to European Pharmacopoeia 11.0* and US Pharmacopoeia*

Definition

Chemical name	(2E,4E)-Hexa-2, 4-dienoic acid; (E, E)-Sorbic Acid
CAS number	110-44-1
Chemical formula	$C_6H_8O_2$
Relative molecular mass	112.13 (USP-NF)

Description

White to yellowish-white crystalline powder
Freely soluble in methanol and ethyl alcohol (approx. 129 g/L at 20 °C); less soluble in water (approx. 1.2 g/L at 20 °C)

Identification

Ultra-violet absorption	UV-Maximum 264 ± 2 nm (solution of 0.002 g/L in water at pH <3)
IR-spectrum	Complies with reference spectrum

Pharma specific tests

Appearance of solution:	Clear and colourless
Aldehydes	Not more than 0.15 % (as acetaldehyde) (C_2H_4O)
Identification (double bonds)	Positive (USP)
Residual solvents:	According to the requirements of the USP

Purity

Assay	99,0 % to 101,0 % of $C_6H_8O_2$, on the anhydrous basis (Ph Eur) 98,0 % to 102,0 % of $C_6H_8O_2$, on the anhydrous basis (USP-NF)
Water content	Not more than 0.5 % (Karl Fischer method)
Heat resistance	No discoloration after 90 minutes at 105 °C
Melting range	132 - 135 °C (USP-NF)
Sulfated ash	Not more than 0.1 %
Heavy metals	Not more than 10 ppm (expressed as lead)
Lead	Not more than 0.1 ppm
Arsenic	Not more than 0.1 ppm
Mercury	Not more than 0.01 ppm
Cadmium	Not more than 0.02 ppm
Zinc	Not more than 0.1 ppm
Chloride	Not more than 100 ppm
Sulphate	Not more than 150 ppm

* amended version PSoAcPh0200 October 2023

Microbiology

Total mesophilic counts	< 10 KBE in 1 g
Yeasts	< 10 KBE in 1 g
Moulds	< 10 KBE in 1 g
Enterobacteriaceae	< 10 KBE in 1 g
Staphylococcus aureus	negative in 1 g
Pseudomonas aeruginosa	negative in 1 g
Escherichia coli	negative in 1 g
Salmonellae	negative in 10 g

Shelf life

3 years from date of manufacture
provided that the product is stored in the originally closed packaging, protected from sunlight and at ambient temperature (max. 30 °C) and under dry conditions (max. 65 % relative humidity)

Nutrinova® Sorbic Acid Pharma Grade meets the requirements of the European Pharmacopoeia, US Pharmacopoeia and other national Pharmacopoeias.

Nutrinova® Sorbic Acid Pharma Grade conforms also to the purity specifications published by FAO/WHO, those of the US Food Chemicals Codex, those of the JSFA, and/or the EC as well as to national specifications published in food regulations for Sorbic acid. Any existing legal restrictions for the use in foods, drugs and cosmetics must be observed by users of Nutrinova® Sorbic Acid.

Technical Note
The product may contain traces of potassium sorbate. The user is responsible for the microbiological stability of its products. The water used in the production of aqueous Sorbic acid solutions should not contain any reactive substances, such as free chlorine. We recommend following the hygienic requirements according to “Good Manufacturing Practice” (GMP).

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