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THE MANUFACTURING PROCESS OF THE PRODUCT BELOW IS COVERED BY A REGISTERED FSSC 22000 FOOD SAFETY SYSTEM

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SPECIFICATIONS

SODIUM ACETATE TRIHYDRATE PHARMA

For non-sterile uses only, not intended for injectable use unless further processed for that purpose.

GENERAL

Molecular formula: $C_2H_3NaO_2 \cdot 3H_2O$

CAS #: 6131-90-4

Molecular weight: 136.08 g/mol

Description

White or almost white, crystalline powder or colorless crystals.

Parameters

Methods

Specifications

<u>Parameters</u>	<u>Methods</u>	<u>Specifications</u>
Identification	USP, EP	Passes test
Appearance of solution	EP	Clear and colorless
pH (5%)	EP	7.5 to 9.0
Assay (dry basis)	EP	99.0 to 101.0%
Loss on drying	EP	39.0 to 40.5%
Chloride	EP	200 ppm Max.
Sulfate	USP	50 ppm Max.
Calcium and Magnesium	EP	50 ppm Max. (as Ca)
Potassium	USP	Passes test
Insoluble matter	USP	0.05% Max.
Iron	EP	10 ppm Max.
Reducing substances	EP	Passes test
Aluminum	ICP (QER-10-38)	0.2 ppm Max.
Bacterial endotoxins	USP<85>	2.5 EU/g Max.
Total aerobic microbial count	USP<61>	100 CFU/g Max.
Total combined yeasts and molds count	USP<61>	100 CFU/g Max.
<i>E. coli</i> , <i>S. aureus</i> , <i>P. aeruginosa</i>	USP<62>	Absent

Complies with the USP and EP requirements. Suitable for hemodialysis.

OVI and RS: *This material conforms to the USP/NF limits for organic impurities. Based on our knowledge of the manufacturing process and on controlled handling and storage of the material, we acknowledge that there is no potential for introduction of residual solvents (RS) or organic volatile impurities (OVI) in the material, because, when used, the only solvent in our inorganic synthesis process is water.*

Typical tapped density

56 to 60 lbs/cu.ft.
0.90 to 0.96 g/mL

Typical particle size

On 2000 μ m (US std mesh #10): 1% Max.
Through 45 μ m (US std mesh #325): 2% Max.

Packaging

25 kg multiwall paper bags.

Storage

Store in a dry place, in tight containers, for up to 36 months.

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