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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 ANHYDROUS USP HEMODIALYSIS AGGLOMERATE

For non-sterile uses only; not intended for injectables.

GENERAL

Molecular formula: $C_2H_3NaO_2$

CAS #: 127-09-3

Molecular weight: 82.03

Description

White, odorless, hygroscopic powder that is freely soluble in water.

Parameters

Methods

Specifications

Identification	USP	Passes test
pH (3%)	USP	7.5 to 9.2
Loss on drying	USP	1.0% Max.
Assay (dry basis)	USP	99.0 to 101.0%
Heavy metals (as Pb)	USP41<231>, method I	10 mg/kg Max.
Chloride	USP	350 ppm Max.
Sulfate	USP	50 ppm Max.
Potassium compounds	USP	Passes test
Calcium and Magnesium	USP	Passes test
Insoluble matter	USP	0.05% Max.
Aluminum	USP	0.2 ppm Max.
Bacterial endotoxins	USP<85>	2.5 EU/g Max.
Total aerobic microbial count	USP<61>	100 CFU/g Max.

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 bulk density (tapped)

28 to 32 lbs/cu.ft.
0.45 to 0.51 g/mL

Typical particle size

On 850 μ m (US std mesh #20): 1% Max.
Through 75 μ m (US std mesh #200): 1% Max.

Packaging

20 kg multiwall (polyethylene and paper) bags.

Storage

Store in a cool and dry place, in tight containers, for up to 1 year.

Bulk pharmaceutical chemical.

Caution: for manufacturing, processing, or repacking

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