



MACCO ORGANIQUES INC.

100 McArthur, suite 112, Salaberry-de-Valleyfield, Quebec, Canada, J6S 4M5

Tel: (450) 371-1066, Fax: (450) 371-5519

Web page address: www.macco.ca, Email: macco@macco.ca



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

Date: March 22, 2018

Supersedes: January 23, 2017

Ref #: S10272-A-G

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DC #: 18-050

SPECIFICATIONS

CALCIUM ACETATE PHARMA AGGLOMERATE

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

GENERAL

Molecular formula: $\text{Ca}(\text{C}_2\text{H}_3\text{O}_2)_2$

CAS #: 62-54-4

Parameters

Description

Identification (acetate, calcium)

Assay (anhydrous basis)

Water content

pH

Appearance of solution

Heavy metals (as Pb)

Readily oxidizable substances

Chloride

Fluoride

Nitrate

Sulfate

Aluminum

Arsenic

Barium

Iron

Lead

Magnesium

Potassium

Sodium

Strontium

Test methods

Visual inspection

USP

USP

USP

USP/EP

EP

USP41<231>, method I

EP

EP

USP

USP

USP

EP

USP

USP, EP

EP

USP

USP

EP

EP

EP

Specifications

Fine, bulky, white odorless powder.

To pass test

99.0 to 100.5%

7.0% Max.

7.2 to 8.2

Clear and colourless

10 ppm Max.

To pass test

330 ppm Max.

50 ppm Max.

To pass test

600 ppm Max.

1 ppm Max.

3 ppm Max.

To pass test, 50 ppm Max.

20 ppm Max.

10 ppm Max.

500 ppm Max.

500 ppm Max.

500 ppm Max.

500 ppm 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)

31 to 35 lbs./cu.ft.

0.50 to 0.56 g/mL

Typical particle size

On 2000 μm (US standard mesh #10): 1% Max.

Through 45 μm (US standard mesh #325): 1% Max.

Packaging

Multiwall (polyethylene and paper) bags and fibre drums.

Storage

Store in a cool and dry place, in tight containers, for up to 2 years.

Bulk pharmaceutical chemical.

Caution: for manufacturing, processing, or repacking

Complies with the USP and EP.

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