



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 10, 2020

Supersedes: November 20, 2019

Ref #: S10272-A-GA

Page: 1 of 2

DC #: 20-071

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

Test methods

Specifications

<u>Parameters</u>	<u>Test methods</u>	<u>Specifications</u>
Description	Visual inspection	Fine, bulky, white odorless powder.
Identification (acetate, calcium)	USP	To pass test
Assay (anhydrous basis)	USP	99.0 to 100.5%
Water content	USP	7.0% Max.
pH	USP/EP	7.2 to 8.2
Appearance of solution	EP	Clear and colourless
Readily oxidizable substances	EP	To pass test
Aluminum	ICP-OES (QER-10-53)	2 ppm Max.
Chloride	EP	330 ppm Max.
Fluoride	USP	50 ppm Max.
Nitrate	USP	To pass test
Sulfate	USP	600 ppm Max.
Acetic acid	HPLC (QIN-10-42)	75.1 to 76.7%
Propionic acid	HPLC (QIN-10-42)	500 ppm Max.
Arsenic	USP	3 ppm Max.
Barium	USP	To pass test
Barium	ICP-OES (QER-10-26)	50 ppm Max.
Iron	EP	20 ppm Max.
Lead	USP	10 ppm Max.
Magnesium	ICP-OES (QER-10-26)	500 ppm Max.
Potassium	ICP-OES (QER-10-26)	500 ppm Max.
Sodium	ICP-OES (QER-10-26)	500 ppm Max.
Strontium	ICP-OES (QER-10-26)	500 ppm Max.
Bacterial endotoxins	USP <85>	≤ 25 EU/g
Total aerobic microbial count	USP <61>	≤ 100 CFU/g
<i>E. coli, S. aureus, P. aeruginosa</i>	USP <62>	Absent

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.*



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Typical tapped density

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, EP and USP hemodialysis.

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