

Therapeutic Goods Administration Draft compositional guideline Calcium Lactate Gluconate

Definition

Production of calcium lactate gluconate involves a combination of two molecules of calcium gluconate and three molecules of calcium lactate. The molecular formula of this product is $\text{Ca}_5(\text{C}_3\text{H}_5\text{O}_3)_6 \cdot (\text{C}_6\text{H}_{11}\text{O}_7)_4 \cdot 2\text{H}_2\text{O}$ and has a molecular weight of 1551.4 (*Martindale: The Extra Pharmacopoeia 31st edition*). Approximately 7.74 gram of calcium lactate gluconate (dihydrate) yields the equivalent of one gram of calcium.

Test	Limits	Method
Appearance:	A white or yellow-tinged white crystalline or granular powder.	
Assay (equivalent to elemental calcium content of 12.92 %)	96.0 – 102.0 % (anhydrous basis)	Complexometric titration
Identification: A. Identification test for calcium B. Identification of lactate C. Identification of gluconate		USP Method <191> USP Identification test B under calcium lactate USP Method <621> (Identification test B under calcium gluconate)
Loss on drying	6 % maximum	USP Method <731>
PH	6.0 – 8.0	10 % solution prepared with water at 25°C
Organic volatile impurities Benzene Chloroform 1,4-Dioxane Methylene chloride Trichloroethylene	< 2.0 µg/g < 60 µg/g < 380 µg/g < 600 µg/g < 80 µg/g	USP Method I <467>
Reducing substances	< 1 %	USP method for reducing substances (see calcium gluconate)
Chlorides	700 ppm	USP Method <221>
Sulphates	500 ppm	USP Method <221>
Heavy metals Arsenic (inorganic)	<20 ppm 3.0 ppm	USP Method II <231> USP Method I <211>