

# TECHNICAL DATA SHEET



**CelluTech**  
Pharma Private Limited

CALCIUM CITRATE MALATE USP-NF

PARAMETERS	SPECIFICATION
<b>Chemical:</b>	
Description	White, odorless, crystalline powder.
Solubility	Freely soluble in diluted 3 N hydrochloric acid and in diluted 2 N nitric acid; slightly soluble in water; insoluble in alcohol.
Identification	
A)	A voluminous white precipitate that is soluble in hydrochloric acid is formed.
B)	The retention times of the citric acid peak and the malic acid peak of the Sample solution correspond to those of the System suitability solution, as obtained in the test for Content of Citrate, Malate, and Fumarate.
Limit of Fluoride	NMT 30 µg/g
Arsenic	NMT 3.0 µg/g
Lead	NMT 1.0 µg/g
Content of Citrate, Malate, and Fumarate	
Sum of Citrate and Malate	NLT 73.0% on the dried basis
Fumarate	NMT 0.1% on the dried basis
pH	4.0 – 8.0
Loss on Drying	8.0% – 11.0%
Assay	NLT 23.0% and NMT 24.2% of calcium, calculated on the dried basis.
<b>Microbial test: (Additional Test)</b>	
a) Total viable aerobic count	Not more than 10 <sup>3</sup> CFU/gm
b) Total yeast & mould count	Not more than 5*10 <sup>2</sup> CFU/gm
b) E.Coli, Salmonella , p.aureuginosa, s.aureus	Shall be absent / gm



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**Note:**

*NMT: Not More Than\*: Customize as per customer requirements.*

*NLT: Not Less Than \*\*: More restrictive than a compendium.*

*The raw materials, manufacturing process, and product shall not contain any of the solvents listed in Organic Volatile Impurities (USP<467>) & residual solvents (Ph – Eur<5.4>).*

**Storage Recommendation :** Preserve in tight Container.

**Re-evaluation Date :** Five (5) years from the date of manufacture.

#### PACKING DETAILS (Available Packaging Type)

Type :	Size :
HDPE Bags/Paper Bags	25 kg / 50 kg
HDPE Drum/ Corrugated Drums	25 kg
Container :	Palletized :
20 ft. (Approx wt.)	10,000 kg
40 ft. (Approx wt.)	20,000 kg

*\* We can customize our packing as per customer requirements.*

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