

## SPECIFICATION

<b>Product</b>	<b>Calcium Carbonate Powder (Ultra Low Lead)</b>
<b>Grade</b>	<b>Powder</b>
<b>Product Code</b>	<b>C/P/07</b>

<b>Document No.</b>	<b>Effective Date</b>	<b>Next review date</b>	<b>Amendment History</b>
<b>SPE/C/P/07</b>	<b>18/02/2010</b>	<b>18/01/2012</b>	<b>NIL</b>

General Characteristics			
<b>Formula</b>	CaCO <sub>3</sub>	<b>Appearance</b>	White powder
<b>Molecular weight</b>	100.09 g/mol	<b>Odor</b>	Odorless
<b>CAS Number</b>	471-34-1	<b>Solubility</b>	In water - Insoluble
<b>EINECS Number</b>	207-139-9		In dilute hydrochloric acid - soluble
<b>HS Code</b>	2836 5000		In dilute nitric acid – soluble

Physical Analysis			
<b>Particle size/Sieve analysis</b>		<b>Method</b>	<b>Powder</b>
Passing through 200# BSS (75micron)		In house	Mini. 98.0%
<b>Bulk Density</b>	Loose Tapped	In house	Mini. 0.70 g/ml Mini. 0.85 g/ml

Chemical Analysis				
Properties	Method	Specification Values		
		Unit	Mini.	Maxi.
Identification	EP	---	Complies	
Substances insoluble in acetic acid	BP	%	---	0.2
Acid insoluble substances in HCl	USP	%	---	0.2
Chloride	BP	ppm	---	330
Fluoride	USP	%	---	0.005
Sulphate	EP	%	---	0.25
Arsenic	USP	ppm	---	3.0
Barium	EP	---	Complies	
Heavy metals (as Pb)	BP	ppm	---	20
Iron	BP	ppm	---	200
<b>Lead*</b>	<b>ICP-MS</b>	<b>ppm</b>	<b>---</b>	<b>0.12</b>
Cadmium*	ICP-MS	ppm	---	1.0
Mercury*	ICP-MS	ppm	---	0.5
Assay as CaCO <sub>3</sub>	BP	%	98.5	100.5
as Ca		%	39.4	40.2
Magnesium and alkali metals	BP	%	---	1.5
Sb + Cu + Cr + Zn + Ba	E170	mg/kg	---	100
Loss on drying	BP	%	---	2.0
Organic volatile impurities	USP	%	Meets the requirement	

\*test done at regular interval.

<b>Microbiological Specification</b>				
<b>Properties</b>	<b>Method</b>	<b>Unit</b>	<b>Mini.</b>	<b>Maxi.</b>
Total aerobic count	In house	cfu/gm	----	1,000
Total yeast and mold count		cfu/gm	----	100
E.coli		Negative/gm	----	Negative/gm
Salmonella		Negative/gm	----	Negative/gm
<b>Nutritional Values</b>				
Calcium (w/w)	Mini. 39.4%			
<b>Shelf Life</b>				
<b>Expiry/Re-test period:</b> 5 years after date of manufacture				
<b>Quality Assurance/ Certificate</b>				
<b>GMP</b>	: Sudeep Pharma Ltd is GMP certified. (Issued by Indian Food & Drug Control Administration. Certificate No.S-GMP/1001064).			
<b>ISO</b>	: Sudeep Pharma Ltd is ISO 9001 : 2000 certified (Issued by M/s Benchmark. Certificate No.3032).			
<b>HACCP</b>	: Sudeep Pharma Ltd is HACCP Certified (Issued by M/s Benchmark. Certificate No.3032H).			
<b>Halal</b>	: Our product is strictly Halal (Registration no. 0550).			
<b>Kosher</b>	: Our product is strictly Kosher.			
<b>Note</b>	: <b>All certificates are available upon request.</b>			
<b>Certificate of Compliance</b>				
<b>GMO:</b> The product does not contain any Genetically Modified Organisms (GMO) or raw materials used in manufacturing of the same are also not genetically modified.				
<b>Non-Irradiation:</b> The product was never subjected to any kind of ionized irradiation and contains no radioactivity not even in minor amounts.				
<b>Allergens:</b> The product does not contain any of the below mentioned allergens: Cereals containing Gluten, Crustaceans, Eggs, Fish, Peanuts, Treenuts, Soybeans, Milk, Sesame seeds, Sulphur Dioxide and sulphites (concentrations >10 mg/kg), Lupin, Molluscs.				
<b>TSE/BSE:</b> The Product is not derived from animal/plant origin & hence this product is free from Transmissible Spongiform Encephalopathy (TSE) and Bovine Spongiform Encephalopathy (BSE). It is synthetically derived.				
<b>Residual Solvent:</b> Class 1, Class 2, Class 3 & Table 4 solvents are not used in the production of our product.				
<b>Vegetarians / Vegans:</b> Our product is suitable for consumption by vegetarians and vegans.				
<b>Storage Recommendations</b>				
Store in a cool, dry place				
<b>Packaging</b>				
25 kg net weight packed in white paper lined HDPE bag with inner liner.				