

## SPECIFICATION

<b>Product</b>	<b>Calcium Carbonate (HC) 98% Granular</b>
<b>Grade</b>	<b>Granular</b>
<b>Product Code</b>	<b>C/HC/06</b>

<b>Document No</b>	<b>Effective Date</b>	<b>Next review date</b>	<b>Amendment History</b>
<b>SPE/HC/06</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 crystalline 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

**Binder : HPMC**

The raw material used i.e. Calcium Carbonate and HPMC is of Pharmaceutical grades.

**Physical Analysis**

Particle size/Sieve analysis	Method	Granular	
Retained on 16# BSS ( 1.0 mm)	In house	Maxi. 2.0%	
Retained on 60# BSS (250 micron)		Maxi. 75.0%	
Retained on 200# BSS ( 75 micron)		Mini. 80.0%	
<b>Bulk Density</b>	Tapped	In house	Mini. 0.95 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
Lead*	ICP-MS	ppm	---	0.3
Cadmium*	ICP-MS	ppm	---	1.0
Mercury*	ICP-MS	ppm	---	0.5
Assay as CaCO <sub>3</sub>	BP	%	98.0	---
as Ca		%	39.2	---
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.



# SUDEEP PHARMA LTD

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Microbiological Specification				
Properties	Method	Unit	Mini.	Maxi.
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
Nutritional Values				
Calcium (w/w)	Mini. 39.2%			
Shelf Life				
Expiry/Re-test period: 2 years after date of manufacture				
Quality Assurance/ Certificate				
<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>	: All certificates are available upon request.			
Certificate of Compliance				
<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.				
Storage Recommendations				
Store in a cool, dry place				
Packaging				
25kg net weight packed in white paper lined HDPE bag with inner liner.				