

SPECIFICATION

Product	Calcium Carbonate (MD+AC) 92.5% Granular (Ultra Low Lead)
Grade	Granular
Product Code	C/MA/10

Document No	Effective Date	Next review date	Amendment History
SPE/MA/10	18/02/2010	18/01/2012	NIL

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

Binder : Maltodextrin & Gum Acacia

The raw material used i.e. Calcium Carbonate, Maltodextrin and Gum Acacia 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%	
Bulk Density	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	---	0.12
Cadmium*	ICP-MS	ppm	---	1.0
Mercury*	ICP-MS	ppm	---	0.5
Assay as CaCO ₃	BP	%	92.5	---
as Ca		%	37.0	---
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. 37%			
Shelf Life				
Expiry/Re-test period: 2 years after date of manufacture				
Quality Assurance/ Certificate				
GMP : Sudeep Pharma Ltd is GMP certified. (Issued by Indian Food & Drug Control Administration. Certificate No.S-GMP/1001064).				
ISO : Sudeep Pharma Ltd is ISO 9001 : 2000 certified (Issued by M/s Benchmark. Certificate No.3032).				
HACCP : Sudeep Pharma Ltd is HACCP Certified (Issued by M/s Benchmark. Certificate No.3032H).				
Halal : Our product is strictly Halal (Registration no. 0550).				
Kosher : Our product is strictly Kosher.				
Note : All certificates are available upon request.				
Certificate of Compliance				
GMO: The product does not contain any Genetically Modified Organisms (GMO) or raw materials used in manufacturing of the same are also not genetically modified.				
Non-Irradiation: The product was never subjected to any kind of ionized irradiation and contains no radioactivity not even in minor amounts.				
Allergens: 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.				
TSE/BSE: 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.				
Residual Solvent: Class 1, Class 2, Class 3 & Table 4 solvents are not used in the production of our product.				
Vegetarians / Vegans: Our product is suitable for consumption by vegetarians and vegans.				
Storage Recommendations				
Store in a cool, dry place				
Packaging				
25 kg net weight packed in white paper lined HDPE bag with inner liner.				