



SUDEEP PHARMA LTD

129/1/A, GIDC, NANDESARI, DIST. BARODA (INDIA)

CALCIUM CARBONATE (HC) 98.0 % (GRANULAR)

Molecular Formula : CaCO₃

Molecular Wt : 100.09

SPECIFICATIONS

<u>TESTS</u>	<u>STANDARDS</u>
1. COLOUR	: WHITE CRYSTALS
2. IDENTIFICATION	: TO CONFIRM TEST AS PER EP/USP.
3. ACID INSOLUBLE SUBSTANCE	: MAXIMUM 0.2%
4. LOSS ON DRYING	: MAXIMUM 2.0 % (AT 200°C 2 HOURS)
5. HEAVY METALS	: MAXIMUM 20 PPM
6. BARIUM	: TO CONFIRM TEST AS PER BP/EP/USP
7. IRON	: MAXIMUM 200 PPM
8. MAGNESIUM & ALKALI METALS	: MAXIMUM 1%
9. CHLORIDE	: MAXIMUM 250 PPM
10. SULPHATE	: MAXIMUM 0.25%
11. LEAD	: MAXIMUM 0.5 PPM
12. FLUORIDE	: MAXIMUM 50 PPM
13. MERCURY	: MAXIMUM 0.5 PPM
14. ORGANIC VOLATILE IMPURITY	: MEETS THE REQUIREMENT AS PER USP.
15. ARSENIC	: MAXIMUM 2 PPM
16. CADMIUM	: LESS THAN 1 MG/KG
17. Sb + Cu + Cr + Zn + Ba	: LESS THAN 100 MG/KG
18. BULK DENSITY (50 TAPPED)	: NOT LESS THAN 0.9 Gm/ML
19. ASSAY (As CaCO ₃)	: MINIMUM 98.0%
(As Ca)	: MINIMUM 39.2%
20. PARTICLE SIZE (SIEVE ANALYSIS)	
PASSING THOROUGH 16 MESH	: MINIMUM 98 %
RETAINED ON 60 MESH	: MAXIMUM 75%
PASSING THROUGH 200 MESH	: MAXIMUM 20%
21. MICROBIAL PURITY	
a) Total Aerobic Microbial count	: MAXIMUM 1000 CFU/GM
b) Total Yeast & Mold count	: MAXIMUM 100 CFU/GM
c) Escherichia Coli	: SHOULD BE NEGATIVE
d) Salmonella Species	: SHOULD BE NEGATIVE

BINDER: H P M C.

We certify that our product is non-GMO material with identity preserved. The raw materials used i.e. Calcium Carbonate and H.P.M.C. are of Pharmaceutical (BP/EP/USP) grades.
