SUDEEP PHARMA LTD

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

DI BASIC CALCIUM PHOSPHATE DIHYDRATE BP/EP/USP

SPECIFICATIONS

MOLECULAR FORMULA : $CaHPO_4 2H_2O$ **MOLECULAR WEIGHT :172.1**

TESTS		STANDARDS
1. DESCRIPTION	:	WHITE CRYSTALLINE POWDER, ODOURLESS, TASTELESS.
2. SOLUBILITY	:	PRACTICALLY INSOLUBLE IN ALCOHOL AND SOLUBLE IN DILUTE HYDROCHLORIC ACID AND DILUTE NITRIC ACID.
3. IDENTIFICATION	:	TO CONFIRM TEST A : TEST B :
4. LOSS ON IGNITION	:	MINIMUM 24.5 % & MAXIMUM 26.5 %
5. ACID-INSOLUBLE SUBSTANCES	:	MAXIMUM 0.1 %
6. CARBONATE	:	TO CONFIRM TEST
7. CHLORIDE	:	MAXIMUM 330 PPM
8. FLUORIDE	:	MAXIMUM 50 PPM
9. SULPHATE	:	MAXIMUM 0.5 %
10. ARSENIC	:	MAXIMUM 3 PPM
11. BARIUM	:	TO CONFIRM TEST
12. HEAVY METALS	:	MAXIMUM 30 PPM
13. MONO & TRI CAL. PHOSPHATE REQUIRED.	:	MIN. 11.5 ML & MAX.12.5 ML 1M HCl
14. ORG. VOLATILE IMPURITIES	:	MEETS REQUIREMENTS
15. IRON	:	MAXIMUM 400 PPM
16. ASSAY	:	MINIMUM 98 % & MAXIMUM 105 %
17. LEAD	:	MAXIMUM 0.3 PPM
18. LOSS ON DRYING	:	MAXIMUM 1.0 %
19. MICROBIAL PURITY		
a) TOTAL COMBINED YEAST & MOLD COUNTS.	:	MAXIMUM 100 CFU/GM
b) E.COLI	:	SHOULD BE NEGATIVE
c) SALMONELLA	:	SHOULD BE NEGATIVE

PARTICLE SIZE		UNMILLED	D.C. GRADE	MILLED/POWDER
SIEVE ANALYSIS (Retained on)	30 # BSS (500 MICRON)	0.5 % Max.	0.5 % Max.	95% passing through 200 Mesh
	100 # BSS (150 MICRON)	55 % Min.	60 % Min.	
	200 # BSS (75 MICRON)	---	90 % Min.	
	300 # BSS (53 MICRON)	95 % Min.	98 % Min.	