



# SUDEEP PHARMA LTD

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

## TRI CALCIUM PHOSPHATE BP/EP/USP

### SPECIFICATIONS

MOLECULAR FORMULA :  $\text{Ca}_5(\text{OH})(\text{PO}_4)_3$

MOLECULAR WEIGHT :502.31

| <u>TESTS</u>                           | <u>STANDARDS</u>   |
|--|--|
| 1. DESCRIPTION                         | : WHITE CRYSTALLINE POWDER, ODOURLESS, TASTELESS & STABLE IN AIR.                                  |
| 2. SOLUBILITY                          | : PRACTICALLY INSOLUBLE IN ALCOHOL AND SOLUBLE IN DILUTE HYDROCHLORIC ACID AND DILUTE NITRIC ACID. |
| 3. IDENTIFICATION                      | : TO CONFIRM TEST A :<br>TEST B :  |
| 4. LOSS ON IGNITION                    | : MAXIMUM 8.0 %  |
| 5. ACID-INSOLUBLE SUBSTANCES           | : MAXIMUM 0.2 %  |
| 6. CARBONATE                           | : TO CONFIRM TEST  |
| 7. CHLORIDE                            | : MAXIMUM 0.14 %   |
| 8. FLUORIDE                            | : MAXIMUM 75 PPM   |
| 9. SULPHATE                            | : MAXIMUM 0.5 %  |
| 10. ARSENIC                            | : MAXIMUM 3 PPM  |
| 11. BARIUM                             | : TO CONFIRM TEST  |
| 12. HEAVY METALS                       | : MAXIMUM 15 PPM   |
| 13. NITRATE                            | : TO CONFIRM TEST  |
| 14. pH (20%)                           | : BETWEEN 7.0 TO 8.0   |
| 15. ASSAY                              | : MINIMUM 90% MAXIMUM 100.5%   |
| 16. ASSAY AS CALCIUM                   | : MINIMUM 34.0 % & MAXIMUM 40.0 %  |
| 17. LEAD                               | : MAXIMUM 0.3 PPM  |
| 18. WATER SOLU: SUBSTANCE              | : MAXIMUM 0.5 %  |
| 19. LOSS ON DRYING                     | : MAXIMUM 2.0 % (at 150°C)   |
| 20. 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  |                        | GRANULAR  | MILLED                       |
|----------------|------------------------|-----------|------------------------------|
| SIEVE ANALYSIS | 20 # BSS (800 MICRON)  | Nil       | 95% passing through 200 Mesh |
| (Retained on)  | 40 # BSS (390 MICRON)  | 15 % Max. |                              |
|                | 100 # BSS (150 MICRON) | 70 % Min. |                              |
|                | 300 # BSS ( 53 MICRON) | 95 % Min. |                              |

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