spectrum™
chemicals & laboratory products

# CERTIFICATE OF ANALYSIS

| | | | |
|---|---|---|---|
| **Item Number** | CA165D | **Lot Number** | 3GF0024 |
| **Item** | Tribasic Calcium Phosphate, Directly Compressible Grade, NF | | |
| **CAS Number** | 12167-74-7 | | |
| **Molecular Formula** | $Ca_{5(}OH)(PO4)_3$ | **Molecular Weight** | 502.31 |

| TEST | SPECIFICATION MIN | MAX | RESULT |
|---|---|---|---|
| **GENERAL CHARACTERISTICS** | | | |
| APPEARANCE | Free Flowing white granules | | COMPLIES |
| ODOR | Ordorless | | COMPLIES |
| Taste | Tasteless | | COMPLIES |
| SOLUBILITY | IN ETHANOL & WATER-INSOLUBLE<br>IN DILUTE HCl-SOLUBLE<br>IN DILUTE NITRIC ACID-SOLUBLE | | COMPLIES |
| **CHEMICAL ANALYSIS** | | | |
| IDENTIFICATION A&B (USP) | COMPLIES | | COMPLIES |
| ACID INSOLUBLE SUBSTANCES (USP) | | 0.2% | 0.075% |
| CARBONATES (USP) | COMPLIES | | COMPLIES |
| CHLORIDE (USP) | | 0.14% | <0.14% |
| SULPHATE (USP) | | 0.8% | < 0.8% |
| FLUORIDE (USP) | | 75PPM | 25PPM |
| ARSENIC (USP) | | 3.0 PPM | <3.0 PPM |
| BARIUM (USP) | COMPLIES | | COMPLIES |
| NITRATE (USP) | COMPLIES | | COMPLIES |
| HEAVY METALS(as Pb) (USP) | | 30PPM | <30PPM |
| ASSAY as Ca (USP) | 34.0% | 40.0% | 36.70% |
| WATER SOLUBLE SUBSTANCES (USP) | | 0.5% | 0.40% |
| DIBASIC SALT AND CALCIUM OXIDE (USP) | 13.0ml | 14.3 ml | 13.1 ml |
| LOSS ON DRYING(800℃) (USP) | | 8.0% | 4.44% |
| LEAD (ICP-MS) | | 3.0PPM | COMPLIES |
| CADMIUM (ICP-MS) | | 1.0PPM | COMPLIES |
| MERCURY (ICP-MS) | | 0.1PPM | COMPLIES |
| RESIDUAL SOLVENTS | COMPLIES | | NO RESIDUAL SOLVENTS USED |
| **PHYSICAL ANALYSIS** | | | |
| BULK DENSITY (TAPPED) | 0.80 g/ml | | 0.85 g/ml |
| SIEVE ANALYSIS/ PARTICLE SIZE | Maxi. 25.0% RETAINED ON 40# BSS (390 micron) | | 10.3% |
| | Mini. 80.0% RETAINED ON 100# BSS (150 micron) | | 80.4% |
| | Mini. 95.0% RETAINED ON 300# BSS (53 micron) | | 96.8% |
| **MICROBIOLOGICAL TEST** | | | |
| TOTAL AEROBIC MICROBIAL COUNT | | 1000CFU/G | COMPLIES |
| TOTAL YEAST AND MOULD COUNT | | 100 CFU/G | COMPLIES |
| ESCHERICHIA COLI | | ABSENT/G | ABSENT/G |
| SALMONELLA | | ABSENT/10G | ABSENT/10G |

| | | | |
|---|---|---|---|
| EXPIRATION DATE | | | 30-APR-2022 |
| MANUFACTURE DATE | | | 01-MAY-2017 |

RESIDUAL SOLVENTS: USP, Chapter <467> limits the residual solvent content of a drug product to the permitted daily exposure (PDE) level given in that chapter. This Spectrum Certificate of Analysis reports any residual solvents that are likely to be present in the material as a result of manufacturing and/or processing. Residual solvents of Class 1 are identified and quantified when present in the material. Residual solvents of Class 2 or Class 3 are identified and the maximum limit is reported unless Class 2 solvents are present at levels greater than Option 1 limits or Class 3 solvents are present at levels greater than 0.5%. It is the responsibility of the producer of a finished dosage form to ensure that the aggregate residual solvent content meets applicable requirements set forth in USP, Chapter <467>.

Phil Xiao

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