

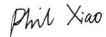
## **CERTIFICATE OF ANALYSIS**

Item Number	CA165D	Lot Number	3GF0024
Item	Tribasic Calcium Phosphate, Directly Compressible Grade, NF		
CAS Number	12167-74-7		
Molecular Formula	Ca <sub>5(</sub> OH)(PO4) <sub>3</sub>	Molecular Weight	502.31

TEST	SPECIFI MIN	CATION MAX	RESULT
GENERAL CHARACTERISTICS			
APPEARANCE	Free Flowing white granules		COMPLIES
ODOR	Ordorless		COMPLIES
Taste	Tasteless		COMPLIES
SOLUBILITY	IN ETHANOL & WATER-INSOLUBLE IN DILUTE HCI-SOLUBLE 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
· ·	Maxi. 25.0% RETAINED ON 40# BSS (390 micron)		10.3%
SIEVE ANALYSIS/ PARTICLE SIZE	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>.



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