spectrum™
chemicals & laboratory products

CERTIFICATE OF ANALYSIS

Item Number	CA165A	**Lot Number**	3GH0006
Item	Tribasic Calcium Phosphate, 200 Mesh, 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 powder		COMPLIES
ODOR	Ordorless		COMPLIES
Taste	Tasteless		COMPLIES
SOLUBILITY	IN ETHANOL & WATER-INSOLUBLE IN DILUTE HCl-SOLUBLE IN DILUTE NITRIC ACID-SOLUBLE		COMPLIES
CHEMICAL ANALYSIS			
IDENTIFICATION A&B (USP)	COMPLIES		COMPLIES
ACID INSOLUBLE SUBSTANCES (USP)		0.2%	0.074%
CARBONATES (USP)	COMPLIES		COMPLIES
CHLORIDE (USP)		0.14%	<0.14%
SULPHATE (USP)		0.8%	< 0.8%
FLUORIDE (USP)		75PPM	24PPM
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%	35.20%
WATER SOLUBLE SUBSTANCES (USP)		0.5%	0.40%
DIBASIC SALT AND CALCIUM OXIDE (USP)	13.0ml	14.3 ml	13.5 ml
LOSS ON DRYING(800℃) (USP)		8.0%	3.10%
RESIDUAL SOLVENTS	COMPLIES		NO RESIDUAL SOLVENTS USED
ADDITIONAL TESTS			
LEAD (ICP-MS)		1.0PPM	COMPLIES
CADMIUM (ICP-MS)		1.0PPM	COMPLIES
MERCURY (ICP-MS)		0.5PPM	COMPLIES
PH(10%) (IH)	5.1-5.7		5.48
PHYSICAL ANALYSIS			
BULK DENSITY (TAPPED)	0.55 g/ml		0.80g/ml
PARTICLE SIZE / SIEVE ANALYSIS	Mini. 95% PASSING THROUGH 200# BSS (75 micron)		98.4%
MICROBIOLOGICAL TEST			
TOTAL AEROBIC MICROBIAL COUNT		1000CFU/G	COMPLIES
TOTAL YEAST AND MOULD COUNT		100 CFU/G	COMPLIES
ESCHERICHIA COLI		ABSENT/10G	ABSENT/10G
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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