

	SPECIFICATION OF BULK PRODUCT		
	DOCUMENT CODE QC-BPS-046	PAGE 1 of 1	VERSION 01

PRODUCT NAME:	Calcium + Vitamin D2
DOSAGE FORM:	Softgel Capsule
PRODUCT CODE:	GC07
STORAGE CONDITIONS:	T°: 5-25°C; RH: 45-75%
SHELF LIFE:	3 years

PRODUCT QUALITY INFORMATION

	TEST	SPECIFICATIONS	METHOD
MICROBIOLOGICAL ANALYSIS	Total Plate Count	NMT 1000 cfu/g	USP <2021>
	Yeast and Mold	NMT 100 cfu/g	USP <2021>
	E Coli	Negative	USP <2021>
CHEMICAL ANALYSIS	Ergocalciferol (eq. to 250 I.U of Vitamin D2) 6.25mcg	250 I.U of Vitamin D2	HPLC
	Calcium carbonate (eq. to 200.2mg of Ca) 500mg	200.2mg of Ca	Gravimetry <USP36>
PHYSICAL ANALYSIS	Shape	Oval	INTERNAL
	Length (mm)	15.25 - 17.25	
	Width (mm)	9.06 - 11.06	
	Total weight (mg)	1400mg ± 10%	
	Size	13	
	Color	White	
	Disintegration	NMT 30 min	USP <701>

FEATURES OF SECONDARY PACKAGING MATERIALS

	MATERIAL	SPECIFICATIONS
SHIPPING BOX	Quantity of capsules per box	5000
	Measures (bottom x width x long)	24.0*29.0*27.5cm
		9.45*11.42*10.83"
	Gross weight	9.05Kg
		19.98Lb
Thickness	Double Canal (6mm)	

ING QUALITY POLICIES IN FORCED FOR THIS PRODUCT

POLICY NUMBER	POLICY DESCRIPTION
QP 001	RADIATION MUST NOT BE PERFORMED IN ANY STEP OF THE MANUFACTURING PROCESS

Elaborated by: _____	Elaborated by: _____	Elaborated by: _____
Position: _____	Position: _____	Position: _____
Signature: _____	Signature: _____	Signature: _____
Date: _____	Date: _____	Date: _____