

	SPECIFICATION OF BULK PRODUCT		
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PRODUCT NAME:	Vitamin D3 2000 I.U + Mg 40mg
DOSAGE FORM:	Softgel Capsule
PRODUCT CODE:	GC53
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	Cholecalciferol (eq. to 2000 I.U of Vitamin D3) 50mcg	2000 I.U of Vitamin D3	HPLC
	Magnesium chloride hexahydrate (eq. to 40.0mg of Mg) 334.50mg	40.0mg of Mg	Gravimetry <USP36>
PHYSICAL ANALYSIS	Shape	Oval	INTERNAL
	Length (mm)	9.90 - 11.90	
	Width (mm)	5.16 - 7.16	
	Total weight (mg)	320mg ± 10%	
	Size	4	
	Color	Milk White	
	Disintegration	NMT 30 min	USP <701>

#### FEATURES OF SECONDARY PACKAGING MATERIALS

	MATERIAL	SPECIFICATIONS
SHIPPING BOX	Quantity of capsules per box	30000
	Measures (bottom x width x long)	30.0*24.0*24.0cm
		11.81*9.45*9.45"
	Gross weight	11.18Kg
		24.84Lb
	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: _____