



SPECIFICATION OF BULK PRODUCT

DOCUMENT CODE  
QC-BPS-030

PAGE  
1 of 2

VERSION  
01

PRODUCT NAME:	Multivitamin + Lycopene + L-Arginine
DOSAGE FORM:	Softgel Capsule
PRODUCT CODE:	GC61
STORAGE CONDITIONS:	T°: 5-25°C; RH: 45-75%
SHELF LIFE:	2 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	Lycopene from tomato fruit 10% (Lycopersicum esculentum) 30mg	30mg of Lycopene	USP
	Selenium yeast (eq. to 75mcg of Se) 75mg	75mcg of Se	USP
	Vitamin B2	1.70mg	HPLC
	Pyridoxine hydrochloride (eq. to 2.0mg of Vitamin B6) 2.43mg	2mg of Vitamin B6	HPLC
	Vitamin B12	2mcg	HPLC
	Thiamine monohydrate (eq. to 1.5mg of Vitamin B1) 185mg	1.5mg of Vitamin B1	HPLC
	Ethyl DL-alpha tocopherol (eq. to 1.5 I.U of Vitamin E) 100mg	1.5 I.U of Vitamin E	HPLC - INTERNAL
	Nicotinamide	20mg	HPLC
	L-Arginine from Soy protein (Glycine max L.)	100mg	
	Anhydrous magnesium oxide (eq. to 10mg of Mg) 16.59mg	10mg of Mg	Gravimetry <USP36>
	Anhydrous zinc oxide (eq. to 20mg of Zn) 24.89mg	20mg of Zn	Gravimetry <USP36>
PHYSICAL ANALYSIS	Shape	Oblong	INTERNAL
	Length (mm)	23.88 - 25.88	
	Width (mm)	7.35 - 9.35	
	Total weight (mg)	1480mg ± 10%	
	Size	24	
	Color	Dark Opaque Red	
	Disintegration	NMT 30 min	USP <701>



SPECIFICATION OF BULK PRODUCT

DOCUMENT CODE  
QC-BPS-030

PAGE  
2 of 2

VERSION  
01

FEATURES OF SECONDARY PACKAGING MATERIALS

MATERIAL		SPECIFICATIONS
SHIPPING BOX	Quantity of capsules per box	6000
	Measures (bottom x width x long)	29.5*24.0*28.0cm
		11.61*9.45*11.02"
	Gross weight	9.00Kg
		19.87Lb
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: _____