

	SPECIFICATION OF BULK PRODUCT		
	DOCUMENT CODE QC-BPS-048	PAGE 1 of 1	VERSION 02

PRODUCT NAME:	Silymarin
DOSAGE FORM:	Softgel Capsule
PRODUCT CODE:	GC37
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	Standardized seeds extract of Milk Thistle 80% (eq. to 133.6mg of Silymarin) 167.0mg	133.6mg of Silymarin	HPLC
PHYSICAL ANALYSIS	Shape	Oval	INTERNAL
	Length (mm)	14.75 - 16.75	
	Width (mm)	8.37 - 10.37	
	Total weight (mg)	880mg ± 10%	
	Size	13	
	Color	Opaque Blue	
	Disintegration	NMT 30 min	USP <701>

FEATURES OF SECONDARY PACKAGING MATERIALS

	MATERIAL	SPECIFICATIONS
SHIPPING BOX	Quantity of capsules per box	10000
	Measures (bottom x width x long)	28.5*25.5*21.0cm
		11.22*10.04*8.27"
	Gross weight	9.52Kg
		20.97Lb
	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: _____