

	SPECIFICATION OF BULK PRODUCT		
	DOCUMENT CODE QC-BPS-007	PAGE 1 of 1	VERSION 01

PRODUCT NAME:	Biotin 900mcg
DOSAGE FORM:	Softgel Capsule
PRODUCT CODE:	GC05
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	Biotin	900mcg	USP
	Arsenic	Máx 1.0 ppm	USP
	Lead	Máx 1.5 ppm	USP
	Cadmium	Máx 1.0 ppm	USP
	Mercury	Máx 0.1 ppm	USP
PHYSICAL ANALYSIS	Shape	Oval	INTERNAL
	Length (mm)	12.38 - 14.38	
	Width (mm)	6.48 - 8.48	
	Total weight (mg)	500mg ± 10%	
	Size	6	
	Color	Opaque Fucsia	
	Disintegration	NMT 30 min	USP <701>

FEATURES OF SECONDARY PACKAGING MATERIALS

	MATERIAL	SPECIFICATIONS
SHIPPING BOX	Quantity of capsules per box	15000
	Measures (bottom x width x long)	24.0*29.0*28.0cm
		9.45*11.42*11.02"
	Gross weight	7.50Kg
		16.56Lb
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: _____