

Capsugel

Certificate of Analysis

Licaps Encapsulation

Customer Name	Essential Source Inc.
Filling Product	Pre Pro
Product Lot Number	6101332

Capsugel General Information			
Capsule Size: 00	Body Color: Natural	Print Logo (B/C):	NA
Capsule Type: L-Vcaps Plus	Cap Color: Natural	Print Ink (B/C):	NA
Product Formula Number	G0041431	Country of Manufacture	USA
Lot Quantity (capsules)	972,437	Manufacturing Date	2/1/2017
Average Capsule Wt, mg	840.98	Conforms to USP <2091> Weight Variation of Dietary Supplements	

Composition	
Raw Material	mg/capsule
FructoOligoSacharides 95% FOS	53.000
Raw Material Inner Capsule	mg/capsule
Size 3 Dark Green Tr (Color V14.700) HPMC Capsule	223.000
Lactobacillus Acidophilus Powder 200B	Lactobacillus Paracasei 400B
Bifidobacterium Longum Powder 100B	Lactobacillus Sporenges Lactospore® 6B
Lactobacillus Plantarum 400B	Lactobacillus Reuteri 100B
Lactobacillus Bulgaricus 50B	Lactobacillus Acidophilus (DDS-1) 200B
Bifidobacterium Infantis (BI-26) 50B	Streptococcus Thermophilus 400B
Lactobacillus Casei 300B	Microcrystalline Cellulose
Lactobacillus Salivarius 300B	Calcium Laurate
Lactobacillus Rhamnosus 200B	Silicon Dioxide
Bifidobacterium Bifidum 100B	

Other Ingredients: Glycerin, Sodium Copper Chlorophyllin, Hypromellose, Water

Testing Requirements			
Microbiological	Specifications	Results	Reference
Yeast and Mold	≤ 300 cfu/g	< 20	CMMEF, 21.51 5th Ed
Salmonella	Absent /10g	Absent	AOAC 2013.09
E. coli	Absent /10g	Absent	AOAC 991.14
S. aureus	Absent /10g	Absent	AOAC 2003.07
Analytical	Specifications	Results	Reference
Total Viable Count (At time of Manufacturing)	≥ 6 Billion cfu/capsule	1.1 x 10 ¹⁰ cfu/capsule	WI-MIC-073
Disintegration	< 30 minutes	6 minutes	WI-CHEM-218

Allergen Statement: Of the 8 major allergens (milk or dairy, egg, fish, shellfish, treenuts, peanuts, soy, wheat or gluten) this product contains: None

This product is manufactured exclusively as a dietary supplement in accordance with 21 CFR 111 - Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements.

Other Quality Requirements	
All Deviations / OOS Investigations / Validations are complete	(Y) / N / NA
List any deviation numbers:	DEV-16-096
Master Batch Record Version Number / effective date	7.6.1.1000.DEV 1/30/17
QA Approval Signature / Date:	<i>Ciara White</i> 02/16/17
Printed Name / Title	Ciara White Quality Assurance Coordinator
2nd Check / Date:	<i>Regina Ballentine</i> 2/16/17
Printed Name / Title	Regina Ballentine Regulatory and Compliance Specialist

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