

BODYBIO

Item # CALM60.8	Finished Product Specifications	Written/Revised by/Date <i>Figuerell</i> 06/11/25
Effective Date: JUN 11 2025	CALM 60 Capsules	Approved By/Date <i>David Summ</i> 06/11/25
Supersedes: 06/14/25		Pg. 1 of 4

Co-Manufacturer

Lot # _____ BB Receiving # _____ MFG Date: _____ Exp Date _____

Test	Specification	Method	Result	Analyst/Date/Ref
Appearance	Clear "0" veggie capsule containing a mottled light brown powder.	Visual		
Content	60 Capsules	Visual		
Packaging	150cc White Round bottle 38 mm White Cap Shrink band Label #: 585	Visual		
Printing	Clear and Correct UPC# 743474789018	Visual		
Average Capsule Weight	646 – 714 mg	Balance		
Weight Variation	% RSD NMT 10%	USP<2091>		
Disintegration	< 30 minutes	USP<2040>		

*Perform yearly and after each 10th lot at approved external laboratory once vendor is qualified.

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Item # CALM60.8	Finished Product Specifications	Written/Revised by/Date <i>F. Small 06/11/25</i>
Effective Date: JUN 11 2025	CALM 60 Capsules	Approved By/Date <i>David Russell 06/11/25</i>
Supersedes: 06/14/25		Pg. 2 of 4

Co-Manufacturer	
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Test	Specification	Method	Result	Analyst/Date/Ref
* Assay Label Claim Manganese (as gluconate and citrate)	Manganese 2.5 mg/capsule (2.5 – 3.6 mg)	ICP-MS		
* Assay Label Claim (Blend totals to 425 mg/capsule)	Taurine- 250 mg/capsule (250 - 375 mg)	HPLC		
	Glycine- 100 mg/capsule (100 - 150 mg)			
	Phosphatidylserine (from sunflower lecithin) 25 mg/capsule (25 – 37.5 mg)			
Total Plate Count	< 10,000 cfu/g	USP<2021>		
Total Yeast and Mold	< 1,000 cfu/g	USP<2021>		
*Specified Micro	<i>E. coli</i> - Absent/10 g	USP<2022>		
	<i>S. aureus</i> - Absent/10 g			
	<i>Salmonella</i> - Absent/10 g			

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Effective Date: JUN 11 2025	CALM 60 Capsules	Approved By/Date <i>J. J. J. 06/11/25</i>
Supersedes: 06/14/25		Pg. 3 of 4

Co-Manufacturer

Test	Specification	Method	Result	Analyst/Date/Ref
*Identification	Rhodiola Rosea Root Extract: Rhodiola Rosea Root Extract is present.	HPTLC		
	The retention time of Taurine matches the retention time of the standard. Difference is not more than 5%.	HPLC		
	The retention time of Glycine matches the retention time of the standard. Difference is not more than 5%.			
	The retention time of Phosphatidylserine matches the retention time of the standard. Difference is not more than 5%.			
*Lead	< 0.5 µg/capsule	USP <2232> ICP-MS		
*Arsenic	< 10 µg/capsule			
*Cadmium	< 4.1 µg/capsule			
*Total Mercury ¹	< 0.3 µg/capsule			

¹ If Total Mercury is greater than 0.3 ug/capsule, perform test for Methylmercury. Methylmercury must be less than 0.3 ug/capsule.

Approved By/Date: _____

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Item # CALM60.8	Finished Product Specifications	Written/Revised by/Date <i>T. Ziemell. 06/11/25</i>
Effective Date: JUN 11 2025	CALM 60 Capsules	Approved By/Date <i>David Ziemell 06/11/25</i>
Supersedes: 06/14/25		Pg. 4 of 4

Co-Manufacturer	
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Revision History

Date of Revision	Change Control #	Revision #	Comments
		0	
		1	
		2	
		3	
		4	
04/29/2024	2479	5	- Added capsule size to appearance - Added NutraStar and Windmill as co-manufacturers - Added average capsule weight spec for Windmill batches - Changed disintegration time to < 30 minutes and removed asterisk for outside testing - Added revision history - Changed spec for phosphatidylserine to NLT 20 mg/capsule to consider for 80% acceptance
05/06/2024	2511	6	Corrected capsule size for appropriate manufacturers.
06/14/24	2556	7	Replaced ID by FT-IR with ID by HPLC retention time. Updated heavy metals specification. Updated Capsule Weight specification. Updated footnote. Updated Rhodiola Rosea Root assay by input to perform Rhodiola Rosea Root assay identification by HPTLC. Added ranges to assay specifications. Removed Listeria. Removed specification for "00" capsule in appearance and capsule weight.
JUN 11 2025	3095	8	Updated limits for active ingredients. Updated heavy metal limits. Updated BodyBio header.

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