

BODYBIO

Item # 425.5	In Process Specifications	Written/Revised by/Date <i>Daniel ... 05/14/24</i>
Effective Date: MAY 14 2024	Cal-Mag Butyrate Bulk Capsules	Approved By/Date <i>... 05/14/24</i>
Supersedes: 05/02/2024		Pg. 1 of 3

Manufacturer: BodyBio Inc.

Lot# : _____ MFG Date: _____ Exp. Date: _____

Test	Specification	Method	Result	Analyst/Date/Ref
Appearance	Clear "00" capsules containing an off-white powder.	Visual		
Solubility	Soluble in water.	Visual		
Identification	The retention time of Butyric Acid matches the average retention time of the standard. Difference is not more than 5%.	HPLC		
Average Capsule Weight	873.0 mg – 1106.7 mg	USP<41>		
Weight Variation	RSD NMT 10%	USP<2091>		
Total Plate Count	< 1000 CFU/g	USP<2021>		
Total Yeast and Mold	< 100 CFU/g	USP<2021>		
Disintegration	< 30 Minutes	USP<2040>		

* Analysis performed by outside 3rd party laboratories

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Item # 425.5	In Process Specifications	Written/Revised by/Date <i>David Munn 05/14/24</i>
Effective Date: MAY 14 2024	Cal-Mag Butyrate Bulk Capsules	Approved By/Date <i>Allynt 05/14/24</i>
Supercedes: 05/02/2024		Pg. 2 of 3

Test	Specification	Method	Result	Analyst/Date/Ref
*Specified Micro	E. coli- Absent/10g	USP<2022>		
	Salmonella- Absent/10g			
	S. aureus-Absent/10g			
*Assay	Butyric Acid (90-110%) 600 mg/capsule (540-660 mg/capsule)	HPLC		
	Calcium (90-125%) 80 mg/capsule (72-100 mg/capsule)	ICP-MS		
	Magnesium (90-125%) 40 mg/capsule (36-50 mg/capsule)	ICP-MS		
*Lead	NMT 10 µg/day (NMT 5 µg/capsule)	USP<2232> ICP-MS		
*Arsenic	NMT 10 µg/day (NMT 5 µg/capsule)			
*Cadmium	NMT 5 µg/day (NMT 2.5 µg/capsule)			
*Mercury	NMT 2 µg/day (NMT 1 µg/capsule)			

Approved By/Date: _____

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Effective Date: MAY 14 2024	Cal-Mag Butyrate Bulk Capsules	Approved By/Date <i>Allyson ... 05/14/24</i>
Supercedes: 05/02/2024		Pg. 3 of 3

Revision History

Date of Revision	Change Control #	Revision #	Comments
		0	
		1	
01/15/24	2385	2	<ul style="list-style-type: none"> • Changed weight variation spec to RSD NMT 10% • Added ranges for assay testing • Added revision history • Outside testing performed in every bulk lot • Added heavy metals testing
01/25/24	2395	3	<ul style="list-style-type: none"> • Changed weight variation spec to RSM NMT 10% • Added ranges for assay testing • Added revision history • Outside testing performed in every bulk lot • Added heavy metals testing
05/02/24	2504	4	<ul style="list-style-type: none"> • Removed Identification by FT-IR • Added Identification by Retention time by HPLC for Butyric Acid • Updated methods from DSC to USP • Updated footnote
MAY 14 2024	2524	5	<ul style="list-style-type: none"> • Updated specification for heavy metals • Changed bulk lot # to MFG Date • Changed the limit for in-house micro testing

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