



Protocols & Products for a Healthy Life

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SACCHAROMYCES BOULARDII

Code: O-B03	Ed. 007	ANALYTICAL METHOD REFERENCE
TESTS	SPECIFICATIONS	Visual
Appearance	Fine to granular, light beige to brown powder or pellets	
Identification:		GB 001-0
- Macroscopic (colony) examination	Round, slightly convex, smooth, off-white to slightly brownish colonies	
- Microscopic examination	Ovoid yeast cells	
- API 20C Aux test	Positive (reference API code: 2000032)	GB 002-0 USP<731>
Assay (viable cells) on d.b.		
Dry substance (LOD at 1 10 °C, 3 h, vacuum)	2 2.0 x /g 2 92.0 0/0	
Bulk density		USP <61 6>, method I USP<786>
Particle size (sieve method)	2 0.6 g/ml 2 90 0/0 < 250 m	Ph. Eur. 2.4.8, method C
Heavy metals	≤10 ppm	Ph. Eur. 2.2.58 or Ph. Eur. 2.2.57
Lead	≤0.5 ppm	Ph. Eur. 2.2.58 or Ph. Eur. 2.2.57
Cadmium	≤0.5 ppm	Ph. Eur. 2.2.58
Mercury	≤0.1 ppm	Ph. Eur. 2.2.58 or Ph. Eur. 2.2.57
Arsenic	≤1.5 ppm	
Microbiological contamination:		Ph. Eur. 2.6.12/ USP <61>
-Total aerobic microbial count	≤10 ³ CFU / g	Ph. Eur. 2.6.12/ USP <61>
-Total combined yeast and mould count	≤10 ² CFU / g	Ph. Eur. 2.6.13/ USP <62>
- Enterobacteriaceae spp.	< 10 ² CFU / g Absent / g	Ph. Eur. 2.6.13/ USP<62>
-E. coli	Absent / g	Ph. Eur. 2.6.13/ USP<62>
-S. aureus	Absent / 10 g	Ph. Eur. 2.6.13/ USP<62>
-Salmonella spp.		

Date: January 24, 2017

Re-testing period: 24 months

Storage conditions: < 25°C

Packaging: LDPE (low-density polyethylene) bag put in aluminium compound foil bag sealed under vacuum and placed in a suitable external container.