



Australian Government

Department of Health

Therapeutic Goods Administration

Microbiological testing of medicines containing Green-lipped Mussel

TGA Laboratories testing report

Version 1.0, June 2020

TGA Health Safety
Regulation

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Introduction

Complementary medicine oral dosage forms on the ARTG that contain green-lipped mussel (*Perna canaliculus*) as the active ingredient are generally indicated to help reduce joint pain.

Green-lipped mussels are marine shellfish that are efficient filter feeders, concentrating microorganisms, algal biotoxins and chemical pollutants from the waters in which they are farmed and harvested. Consumption of contaminated shellfish can cause serious adverse effects in humans. From 2017 to 2019 the TGA Laboratories undertook testing projects to monitor the microbiological quality of medicines containing green-lipped mussel supplied in Australia.

Complementary medicines containing green-lipped mussel that are supplied in Australia must comply with Therapeutic Goods (*Microbiological Standards for Medicines*) (TGO 100) Order 2018¹, clause 11(2), Schedule 1, in relation to microbial count and absence of specified microorganisms. TGO 100 also requires medicines to be free from contamination with objectionable organisms. *Vibrio parahaemolyticus* and *Listeria monocytogenes* are examples of objectionable organisms that could contaminate medicines derived from shellfish and pose a risk to consumer safety. As such, these medicines are expected to be free from contamination with these objectionable organisms. See Table 1 for the acceptance criteria applied.

Testing

Testing was performed on twenty seven medicines. Twenty five complied with the requirements of clause 11(2), Schedule 1, of TGO 100 and two failed to comply with this clause (see Table 2).

No specified or objectionable organisms were isolated from any of the samples tested. For one product, the average Total Aerobic Microbial Count for one of three replicate containers tested exceeded the maximum permitted level. For a second product, one of the three containers tested exceeded the maximum permitted level for Bile-tolerant Gram negative bacteria.

One medicine was found not to comply with the labelling standard TGO 92 *Standard for labels of non-prescription medicines* (TGO 92).

Table 1: Tests applied to samples

Test name	Standard applied	Acceptance criteria
Microbial Limits Test	TGO 100, Clause 11(2), Schedule 1	TAMC $\leq 10^4$ CFU/g TYMC $\leq 10^2$ CFU/g Bile-tolerant Gram negative bacteria (BTGN) $\leq 10^2$ CFU/g <i>E. coli</i> : Absent in 1g <i>S. aureus</i> : Absent in 1g <i>Salmonellae</i> : Absent in 10g Absence of objectionable organisms
Label check	TGO 92	Meets the criteria

TAMC = Total Aerobic Microbial Count, TYMC = Total Yeast and Mould Count

Table 2: Batches failing to meet the TGO 100 acceptance criteria

ARTG No	Product Name	Sponsor	Batch No	Expiry Date	Average Counts (CFU/g)	Label Result
208674	Healthy Care New Zealand Green Lipped Mussel 500mg Capsules	Nature's Care Manufacture Pty Limited	695829	30/06/2020	*TAMC 1.1×10^4 TYMC <10 (est.) BTGN <100 (est.) No specified or objectionable organisms isolated	Complies
200811	Nutra-Life Green Lipped Mussel 850mg	Vitaco Health Australia Pty Ltd	129437	14/03/2020	TAMC 2.2×10^3 TYMC <10 (est.) BTGN 1.8×10^3 No specified or objectionable organisms isolated	Complies

* To take into consideration the precision of the microbial plate count method, TGO 100 allows a maximum factor of 2 to be applied to the TAMC, TYMC, and Bile-tolerant Gram negative (BTGN) bacteria count criteria (when tested by plate count methods). For example, where the specification is not more than 10^4 CFU per gram, then the maximum permitted count is 2.0×10^4 CFU/g. The TAMC for one of three replicates was 2.7×10^4 CFU/g, which exceeded the maximum level of 2.0×10^4 CFU/g permitted by TGO 100. (est.) = estimate (when there are less than 25 colonies on a count plate the result is reported as an estimate only).

Table 3: Batch failing to meet labelling requirements

ARTG No	Product Name	Sponsor	Batch No	Expiry Date	Label Result
252035	Joint Care 5 in 1	Universal Nutrition & Beauty Care Pty Ltd	1053	31/03/2020	Does not comply

Table 4: Batches that met the TGO 100 acceptance criteria

ARTG No	Product Name	Sponsor	Batch No	Expiry Date	Result - TAMC	Label Result
270395	Greenshell Mussel with Glucosamine	Ageless IP Pty Ltd	2467	31/03/2019	107 CFU/g (est.)	Complies
284349	Oviit Green Lipped Mussel	Apotex Pty Ltd	170575	29/02/2020	37 CFU/g (est.)	Complies
154245	Dr Natural NZ GlycMussel	Astragrace Corp Pty Ltd	16874	30/06/2020	520 CFU/g	Complies
164090	Aussia Green Lipped Mussel Plus	Aussia Pharma	12630	31/01/2019	<10 CFU/g (est.)	Complies

ARTG No	Product Name	Sponsor	Batch No	Expiry Date	Result - TAMC	Label Result
265472	Good Health Mussel 6000	Australia Cobayer Health Food Co Pty Ltd	Y47C	31/03/2020	73 CFU/g (est.)	Complies
224728	Living Pure Four in One Joint Capsules	Ausvigor Global Pty Ltd	27291	30/11/2018	71 CFU/g (est.)	Complies
256772	Blackmores Lyprinol	Blackmores Ltd	281554	23/01/2020	<20 CFU/g (est.)	Complies
198002	Arthritis Fighter	Caruso's Natural Health Pty Ltd	161843	30/11/2019	24 CFU/g (est.)	Complies
273613	Motipid	Eden Natural Health	14419	31/08/2019	120 CFU/g (est.)	Complies
251212	Dr.Nature 4 in ONE JOINT	Health Sharing Group Pty Ltd	30571	30/11/2018	67 CFU/g (est.)	Complies
148896	Spring Leaf NZ Green Lipped Mussel Essence 2000mg	Homart Pharmaceuticals Pty Ltd	10446	23/02/2020	<20 CFU/g (est.)	Complies
289615	Connie Bonnie Greenshell Mussel 7500	J & J Worldwide Pharma Pty Ltd	15728	31/03/2020	85 CFU/g (est.)	Complies
193682	Arthro Support Formula	JNC Co Pty Ltd T/a Panax Pharm T/a Dr. Pro	1302	31/07/2020	44 CFU/g (est.)	Complies
149888	Seatone	MacLab Australia Pty Ltd	A60552	30/11/2018	<40 CFU/g (est.)	Complies
170866	Nature's Family Premium Green Lipped Mussel 750mg	Nature's Family Australia Pty Ltd	17311	31/07/2020	160 CFU/g (est.)	Complies
273247	Nubolic 4 in One Joint	Nature's Kingdom Australia Pty Ltd	1081	31/07/2020	62 CFU/g (est.)	Complies

ARTG No	Product Name	Sponsor	Batch No	Expiry Date	Result - TAMC	Label Result
212323	Nutrivital Green Lipped Mussel 850mg	Nutrivital Pty Ltd	110849	12/02/2019	71 CFU/g (est.)	Complies
172526	Blooms Green Lipped Mussel	Phytologic Holdings Pty Ltd	838044-1	31/01/2020	11 CFU/g (est.)	Complies
282865	Greenshell Mussel 7500	RBK Nutraceuticals Pty Ltd	2970	31/03/2020	29 CFU/g (est.)	Complies
182781	Mega Green Lipped Mussel 7500	Sini Australia Pty Ltd	03462	30/04/2020	580 CFU/g (est.)	Complies
252035	Joint Care 5 in 1	Universal Nutrition & Beauty Care Pty Ltd	1053	31/03/2020	44 CFU/g (est.)	Does not comply
130527	Bio-Green Lipped Mussel Complex 2500	Universal Pharmaceuticals Pty Ltd	170611	30/06/2020	1.4 x 10 ³ CFU/g	Complies
200811	Nutra-Life Green Lipped Mussel 850mg	Vitaco Health Australia Pty Ltd	136044	07/06/2020	3.2 x 10 ³	Complies
267160	Glucosamine 4-in-1	Wellwisse Pharmaceuticals Pty Ltd	30988	30/06/2019	84 CFU/g (est.)	Complies
180947	Osteoflam Plus	Zifam Pinnacle Pty Ltd	6870	29/02/2020	< 40 CFU/g (est.)	Complies

Outcome

Twenty seven medicines, representing approximately one third of those on the ARTG containing green lipped mussel, were tested for microbiological quality during the 2017 – 2019 period. Twenty five complied with the requirements of clause 11(2), Schedule 1, of TGO 100 and two did not comply.

The two compliance failures were not safety-related and were considered to be minor product quality concerns. Product sponsors were informed of the test results and asked to investigate potential root causes for the elevated counts. Both provided evidence to show that other product batches were unlikely to be affected. Their proposed actions to address the minor quality concerns were considered satisfactory.

A separate medicine was found not to comply with the labelling standard TGO 92 *Standard for labels of non-prescription medicines* (TGO 92); this matter was referred to the Complementary & OTC Medicines Branch, who undertook a compliance review, following which the matter was resolved.

Footnotes

1: *Therapeutic Goods Order No. 77 Microbiological Standards for Medicines* (TGO 77) was in force at the time the project commenced in July 2018. It was automatically repealed (sunset) on 1 October 2018 and remade at this time as TGO 98 *Microbiological Standards for Medicines* (2018,) without regulatory change but with minor editorial changes to improve clarity. TGO 98 was subsequently remade as *Therapeutic Goods (Microbiological Standards for Medicines) (TGO 100) Order 2018*, which came into effect on 8 December 2018, repealing TGO 98 on this date. The microbiological quality requirements in TGO 77, TGO 98 and TGO 100 are equivalent.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	TGA Laboratories	June 2020

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