

Certificate of Analysis

PRODUCT NAME: BioMarine®1140—FSMP
(Food for Special Medical Purpose)
PRODUCT: Shark Liver Oil, Minimally Processed – 1140mg (blister cards)--
from Shark Liver Oil derived from Deep Water Sharks harvested
in the Tasman Sea and waters surrounding New Zealand
PRODUCT NO.: MNSG-156
BATCH NO: 1704074
DATE OF MANUFACTURE: April, 2017
BEST BEFORE/RETEST BY: April, 2020

General	Manufacturing Specification	Results	Method
Pharmaceutical Form	Clear, Soft Gelatin Capsule Containing a Light Golden Oil	Conforms	Observation
Size and Shape	20 Oblong	Conforms*	Observation
Average Fill Weight	1140 mg +/- 5%	1151 mg	USP or equivalent
Disintegration/Rupture time	Max. 15 Minutes	<10 min.	USP or equivalent
Acid ¹	Max. 3 mg KOH/kg	<0.2 mg KOH/kg	Ph. Eur. 2.5.1
Peroxide value ¹	Max. 5 meq/kg	1.1 meq/kg	AOAC 965.33
Anisidine ¹	Max. 20	<5	IUPAC.D.26
Lead ¹	Max. 0.1 mg/kg	Pass	APHA 3125B
Cadmium ¹	Max. 0.1 mg/kg	Pass	APHA 3125B
Mercury ¹	Max. 0.1 mg/kg	Pass	APHA 3125B
Arsenic (inorganic) ¹	Max. 0.1 mg/kg	Pass	APHA 3125B
Total Plate Count	Max. 3,000 CFU/g	<10 CFU/g	Ph. Eur/USP/AOAC
Total Yeast & Mold Count	Max. 300 CFU/g	<10 CFU/g	Ph. Eur/USP/AOAC
<i>Staphylococcus aureus</i>	Negative/10g	Negative/g	Ph. Eur/USP/AOAC
<i>E. coli</i>	Negative/10g	Negative/g	Ph. Eur/USP/AOAC
<i>Salmonella</i>	Negative/10g	Negative/g	Ph. Eur/USP/AOAC
<i>Listeria monocytogenes</i>	Negative/25g	Negative/25g	Ph. Eur/USP/AOAC

Ingredients	Manufacturing Specification	Results	Method
Shark Liver Oil providing:	1140 mg	Conforms	Input
-Alkylglycerols	240 mg	268 mg	Input
from DAGE	610 mg	682 mg	Input
-Squalene	240 mg	253 mg	Input

*Based on fill weight and shape.
Shell ingredients: Gelatin, glycerin and purified water.

¹Analysis performed on oil before addition of other ingredients.



Caroline Lease, Quality
June 26, 2017