

Certificate of Analysis

Product: BioMarine®570 – FSMP
 (Food for Special Medical Purpose)

Product Description: Shark Liver Oil, Minimally Processed – 570mg
 from Shark Liver Oil derived from Deep Water Sharks harvested in
 the Tasman Sea and waters surrounding New Zealand

Product No.: MNSG-151 (blister cards)

Batch No.: 1709081

Date of Manufacture: Oct., 2017

Best Before/Retest By: Oct., 2020

| General | Manufacturing Specification | Results | Method |
|-------------------------------|---|--------------|-------------------------------------|
| Description | Clear soft gelatin capsules containing a light golden oil | Conforms | Observation |
| Softgel Size and Shape | 11 Oval | Conforms | Observation |
| Average Fill Weight | 570 mg +/- 5% | 555 mg | USP <2091> or equivalent |
| Rupture Time (on delivery) | Max. 15 minutes | <10 min. | USP <2040> or equivalent |
| Acid Value ¹ | Max. 3 mg KOH/g | 0.4 mg KOH/g | Ph.Eur. or Equivalent |
| Peroxide Value ¹ | Max. 5 meq/kg | 1.6 meq/kg | Ph.Eur./AOAC |
| Anisidine Value ¹ | Max. 20 | <5 | Ph.Eur./IUPAC.D.26 |
| Lead ¹ | Less than 0.1 mg/kg | Passed | AAS/ICP-OES/MS |
| Cadmium ¹ | Less than 0.1 mg/kg | Passed | AAS/ICP-OES/MS |
| Mercury ¹ | Less than 0.1 mg/kg | Passed | AAS/ICP-OES/MS |
| Arsenic ¹ | Less than 2 mg/kg | Passed | AAS/ICP-OES/MS |
| Microbiological Standard | Manufacturing Specification | Results | Method |
| Total Plate Count | Max. 3,000 CFU/g | <10 CFU/g | Ph. Eur/USP/AOAC |
| Total Mold & Yeast Count | Max. 300 CFU/g | <10 CFU/g | Ph. Eur/USP/AOAC |
| <i>Escherichia coli</i> | Negative/10g | Negative/10g | Ph. Eur/USP/AOAC |
| <i>Salmonella</i> | Negative/10g | Negative/10g | Ph. Eur/USP/AOAC |
| <i>Staphylococcus aureus</i> | Negative/10g | Negative/10g | Ph. Eur/USP/AOAC |
| <i>Listeria monocytogenes</i> | Negative/25g | Negative/25g | Ph. Eur/USP/AOAC |
| Ingredients | Specification (per 1 softgel) | Results | Method |
| Shark Liver Oil | 570 mg +/- 5% | Conforms | Formulation and In-process Controls |
| Alkylglycerols ¹ | Min. 120 mg | 129 mg | TLC-FID/Batista & Nunes |
| from DAGE ¹ | Min. 305 mg | 329 mg | TLC-FID/Batista & Nunes |
| Squalene ¹ | Min. 120 mg | 122 mg | TLC-FID/Batista & Nunes |

¹Result based on testing of shark liver oil prior to encapsulation.

Fill ingredients: Shark liver oil. Shell ingredients: Gelatin, glycerin, purified water.



Caroline Lease, Quality
 Dec. 13, 2017