

## Case Study.

# OMTRYG: Analysis from API to FPP

### About Mylnefield Lipid Analysis

Mylnefield Lipid Analysis is a leading international laboratory for the specialist analysis of oils and fats. It offers a fully accredited service that has gained an outstanding reputation for high quality and reliability. It is one of the few laboratories in the world that is approved by both the UK MHRA and the US FDA for GMP analysis of oils and fats and it has also undergone a successful GCP inspection by the MHRA.

The laboratory is fully accredited to ISO9001:2008 standards and regularly participates in international ring testing.

### About the case.

OMTRYG is a soft gel capsule product containing a combination of highly concentrated ethyl esters of omega-3 fatty acids, principally eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA), indicated as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe ( $\geq 500$  mg/dL) hypertriglyceridemia.

In 2009, Mylnefield Lipid Analysis was approached by Natural Nutrition (subsequently EPAX and then Trygg Pharma), to conduct stability testing throughout shelf life analysis for the newly developed compound, then known as AKR-963.

### The solution.

With a view to marketing the product in the USA, FDA approval was needed and although Mylnefield Lipid Analysis was certified by the UK's MHRA to both GMP and GCP standards, FDA certification was sought, in order to meet the needs of the customer. Following FDA inspection, GMP was attained in 2013. The most recent FDA inspection was June 2016 at which certification was retained.

Mylnefield Lipid Analysis carried out stability testing for the development stages of AKR-963. The testing initially used European Pharmacopoeia. Following a decision to market the product in the US, it was necessary to change to the U.S. Pharmacopoeia methods, which meant method equivalence testing to validate the previous results over the duration of the stability studies.

Stored at another facility, samples were sent to Mylnefield Lipid Analysis at regular intervals for work which included:

- Appearance
- EPA Ethyl Ester Identification
- DHA Ethyl Ester Identification
- EPA+DHA Ethyl Ester Composition
- Total Omega-3 Acid Ethyl Ester Composition
- Peroxide Value
- Anisidine Value
- Acid Value
- Oligomers



### The outcome.

OMTRYG was approved for marketing in June 2014. Mylnefield Lipid Analysis remains engaged in ongoing batch stability testing for OMTRYG.