

NiChe Materials Ltd NiChe Market Study



Palmitoleic Acid

Problem:

A customer was looking to source 50–100kg of palmitoleic acid with a specification of >98.5% (by GC assay) for a GMP manufacturing project. At this scale and tight purity standards, the customer had been unable to find any commercial suppliers.

Palmitoleic acid is obtained from sea buckthorn oil, which, although is a seasonal product, has a shelf life of 18 months and is not subject to seasonal availability or pricing fluctuations.

The extraction of sea buckthorn oil to produce palmitoleic acid is a 6-stage process:

1. pH reduction
2. Chemical conversion
3. Chemical conversion – key intermediate present at ~ 55-57%
4. Vacuum distillation – key intermediate present at ~ 70%
5. Chromatography stage – key intermediate present at ~ 98%
6. Chemical conversion – production of palmitoleic acid

NiChe Solution:

NiChe Materials was able to assist in the identification of a suitable low-cost GMP partner located in both the EU and Asia and arranged an audit of the Asian facility by the customer. The supplier has a history of working with natural products, and has developed the extraction, purification and successful scale-up of two other compounds, one of which used patented separation and purification technology. It has cGMP accreditation (SFDA) for another material produced at its Chinese site, and offers cleanrooms and clean packaging areas.

Long-term Outcome:

The scale-up of production to supply 50kg of palmitoleic acid (non GMP) could be achieved in approximately 4 months, with intermediate scale-up quantities of 500g, 1kg and 5kg as required. The manufacturer is already working with patented separation technology and purification technology, scaled up to 50kg/month, for another sea buckthorn extract, so the chemical processes are well-established, and the process lends itself perfectly to stop at the penultimate synthesis stage and transfer production to a GMP facility to meet regulatory requirements.

