

NiCHE Case Study



Palmitic Anhydride

Problem:

An EU pharmaceutical customer needed to source a high-purity grade of palmitic anhydride for use in a GMP manufacturing process. The project required the supplier to produce material that was scalable and met the following specification:

- Assay (GC) 99.9%
- Related substances
 - 4 different substances (as methyl derivative) <0.05%
 - Any unspecified impurity <0.05%

NiCHE Solution:

NiCHE Materials identified a GMP-certified partner that could provide a sample within specification, while also having the scalability to meet project demands. The sample was approved by the customer, and documents, including the route of synthesis, were provided as part of the process.

Long-term Outcome:

Project requirements are currently projected to be up to 500kg during 2022-2023. The grade of material is so high, that opportunities have arisen to supply it into another process and open up new geographic territories for sales.

