

NiCHe Case Study



Dimethyl (methyl)phosphonate

Problem:

A global pharmaceutical company was using dimethyl(methyl)phosphonate (DMMP) as a key raw material in a manufacturing process, and was seeking a reliable, second supplier. As this is a process-critical material, review and approval of any potential supplier's route of synthesis (RoS) would need to form part of the approval process.

NiCHe Solution:

NiCHe Materials identified a CGMP-compliant supplier that had been producing DMMP for many years for its own in-house requirements. The customer's target specification for the product was:

- Assay $\geq 95\%$
- Unknown Impurity $\leq 0.2\%$

The RoS was reviewed, with samples then supplied and tested by the customer. A subsequent request was made to quantify, and reduce one critical impurity, which was proprietary to this customer, down to $\leq 0.1\%$.

Long-term Outcome:

The supplier reviewed its in-house production process, made the necessary changes and now offers customised material with the following specification:

- Assay $\geq 99.0\%$ (GC)
- Critical impurity $\leq 0.1\%$ (non-detected)

Furthermore, the supplier has adopted the new process/material specification for its own in-house quality specifications.

