

Case Study

Nitrogen analysis of pharmaceutical excipients



Customer: Butterworth Laboratories, United Kingdom

With nearly 40 years' experience, Butterworth Laboratories remains an independent UK contract analytical service providing Method Development, Method Validation, Stability Testing and QC Testing to the pharmaceutical, medical device and chemical industries. They work in partnership with clients who not only recognize expertise in analytical chemistry and standards of service but also value integrity and impartiality.

Application: Nitrogen analysis of pharmaceutical excipients

Butterworth Laboratories monitors the nitrogen content of pharmaceutical excipients such as povidone and crospovidone according to the Kjeldahl method; European Pharmacopoeia 2.5.9 and determination of nitrogen by sulphuric acid digestion and nitrogen determinations to United States Pharmacopoeia <461>. The Nitrogen value relates to the assay and purity of product. Butterworth Laboratories also use the BUCHI instrumentation to look at proteins such as N-Z amine and Bacto yeast extracts.

Equipment: Distillation Unit K-355 and SpeedDigester K-436

Up to 12 prepared samples are placed into the BUCHI K-436, a sealed system with minimal sample loss. Once digested the ammonia is distilled and captured in boric acid using a BUCHI K-355 Kjeldahl unit followed by titration methods that are then used to provide a nitrogen value in %. Butterworth Laboratories previously used a classical glassware method for this application.

Benefit / Conclusion: Unprecedented speed and reliability

The BUCHI K-355 distillation unit in combination with the K-436 SpeedDigester provides an integrated solution that meets Butterworth's customer's requirements. Time is saved as a transfer step of sample to distillation vessel is omitted and chemical handling is safer compared with classical glassware methods. The K-355 in conjunction with the K-436 delivers an efficient process workflow with a series of 6 samples now completed in 45 minutes rather than the 2-3 hours previously.

"Since the system is automated, other jobs in the laboratory can be done while digestion is taking place. The distillation unit has also shown to give good recoveries and precision."

P. Shah, Analytical chemist
