Cambrex

Case Study
Analytical Services

Method development: Managing a diverse range of APIs

Tackling multiple challenges to support pre-clinical and GMP production.

Starting from scratch: Designing custom analytical methods

CDMOs take on material at many different stages of development, and the design of analytic methods must account for the starting conditions in each unique case. In this example, Cambrex adopted a drug substance that lacked available data from previous analytical studies or synthesis. Despite these barriers, they set out to develop analytical methods to support pre-clinical and future GMP production under tight timelines.

Because there was little known about the compound, the team designed methods to assess the starting material, intermediate material and API purity. Screening methods included pH, mobile phases, columns, gradients, and column temperature. Mass spectrometry was used to understand impurity formation so that it could be controlled in the API and starting materials.

Cambrex carefully designed methods for this API to be suitable and phase-appropriate for future GMP use. By defining the background for both starting material and process impurities, they were able to set GMP phase-appropriate specifications for starting materials, intermediates, and the API.

Impurities in the starting material and the API shared similar properties, making separation and retention a particular challenge. The custom analytical methods that were developed for this compound gave the client a method to derive PK and distribution data from pre-clinical samples, which was not attainable using their prior methods.

With reliable methods in place to support future GMP efforts, Cambrex secured two additional analytical projects with this client. No matter the state of the starting point, our talented experts are equipped to meet any challenge and deliver timely results.

Overcome obstacles.

Concerned that your methods are not providing you with specific and accurate data?

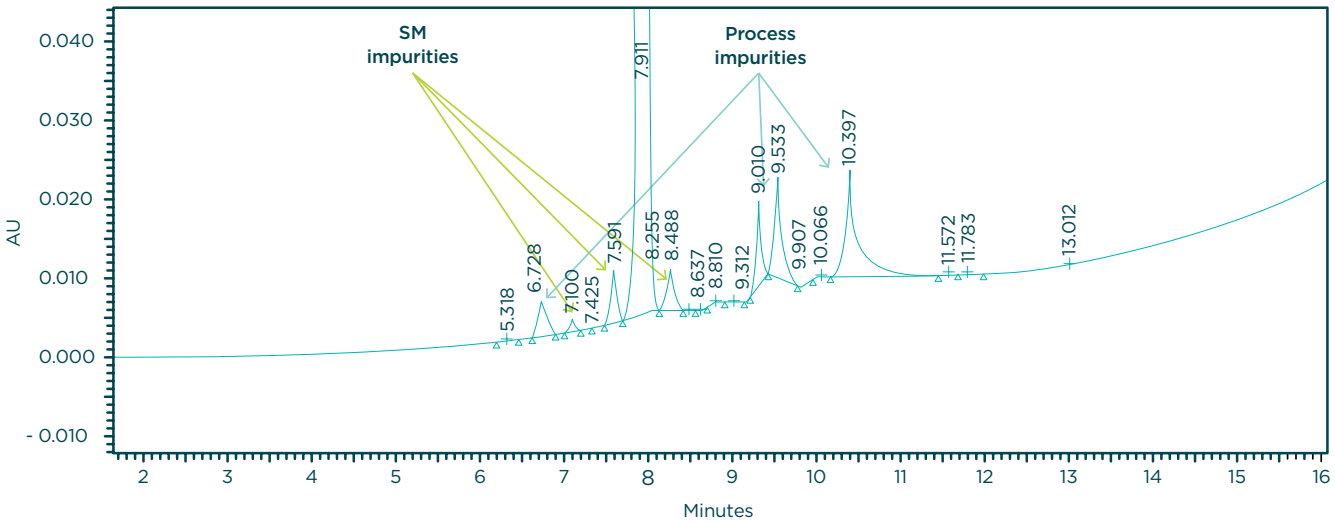
Cambrex provides reliable methods to get you there.

About Cambrex

Cambrex is a leading global contract development and manufacturing organization (CDMO) that provides drug substance, drug product, and analytical services across the entire drug lifecycle.

With over 40 years of experience and a growing team of over 2,200 experts servicing global clients from North America and Europe, Cambrex is a trusted partner in branded and generic markets for API and finished dosage form development and manufacturing.

Separation of impurities



Process impurities were evaluated with starting material to establish GMP phase-appropriate specifications.