

BUSINESS CASE STUDY

PDR-Separations  **LLC**

DALP, AutoMDS, AutoPREP
Real-Time Spectral Deconvolution

All Liquid Modes
and Scales

A large pharmaceutical company manufacturing active pharmaceutical ingredients (API)

PROBLEM

The company was having difficulty with isolating and purifying trace impurities in APIs for the identification and characterization required by regulatory agencies.

GOALS/SOLUTIONS

PDR-Separations was contracted to install a spectral deconvolution system on a pilot-scale SMB system.

The customer wanted to isolate trace impurities in APIs for proper analysis and characterization along with making short runs using very little time to develop methods.

PDR-Separations installed a flow cell before the recycling pump and connected the flow cell to a spectrometer and light source via fiber optic cables.

PDR-Separations' software was installed and deconvolves the UV spectra and plots concentration of each component in real-time.

BENEFITS/ACHIEVEMENTS

With concentration of each component plotted in real-time it is easy to see the desired minor peak and adjust SMB parameters to move that peak towards raffinate or extract ports.

This technique, as opposed to extracting and analyzing multiple samples via HPLC which delayed purity results for an hour or more, resulted in much shorter run times.

Method optimization is much faster and more deterministic. Results of each adjustment is clear within a few SMB cycles.

The new system and procedures have increased throughput by at least 10 times and made many purifications possible that were unrealistic before due to the previous extended method optimization time.

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