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## The importance of pump accuracy in sensitive chromatographic separation

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The analytical testing of non-biological complex drugs (NBCD) is an ongoing challenge in the pharmaceutical world. Currently there are no clear guidelines that describe what is considered as a suitable set of tests for the release and monitoring of such complex drugs. As a result, pharmaceutical companies are in pursuit of finding new characteristic analytical methods. Copaxone,<sup>®</sup> a synthetic polypeptide mixture, used for the treatment of Relapsing Remitting Multiple Sclerosis, is one such NBCD. For the past 9 years Teva has invested considerable efforts in developing new characterization analytical methods to further characterize the unique features of Copaxone.<sup>®</sup> Characterization of Copaxone by Cation exchange chromatography (CEX) technique is based on evaluation of ionic (cationic) strength of the sub-populations in polypeptides mixture. The typical chromatogram for Copaxone<sup>®</sup> shows separation of the mixture to 3 main sub-populations. Copaxone<sup>®</sup> is characterized by specific relative area of the three peaks. However, since separation based on cationic strength depends on the charge of the polypeptides, small changes in pH due to inaccuracy of gradient composition may lead to loss of separation. In this study we have shown that pump accuracy is a key element of the method. Major differences in method robustness were found using low and high pressure gradient pump system. The high accuracy binary pump used in UHPLC system was demonstrated to be superior to common HPLC pump system and was critical to obtain high resolution and robust results. This unique and sensitive method provides a powerful tool to characterize the complex mixture of Copaxone<sup>®</sup> and discriminate it from purported generic glatiramoids.

### Biography

Revital Krispin has a practical engineer degree in engineering chemistry and a Bsc degree in life science from open university. she is a senior researcher with 22 years of experience in the discovery & product development analytical laboratory.

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