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Characterization of glatiramer acetate C-terminal heterogeneity

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Glatiramer acetate, the active ingredient in the multiple sclerosis drug, CopaxoneTM, developed by Teva is a complex mixture of synthetically produced polypeptides composed of four amino acids, which include glutamic acid, alanine, tyrosine and lysine at a molar ratio of 0.141, 0.427, 0.095, 0.338. Initiation of the synthesis of the polypeptides requires the addition of diethylamine which results in the partial capping of the carboxy-termini. Blue Stream Laboratories has developed a series of analytical and mass spectrometric approaches to analyze the heterogeneity of the carboxy-termini of glatiramer acetate. Such methods and the analysis of several lots of glatiramer acetate to assess comparability between originator and biosimilar lots by these methods will be discussed.

Biography

Mario DiPaola is CSO and Co-Founder of Blue Stream Laboratories, Inc. He holds a PhD in chemistry and also an MBA and has been in the biopharmaceutical industry for 20+ years in various roles from Scientist to Company Executive.

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