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Development of a general gas chromatography method for the quantitation of residual solvents using a QbD approach

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In the pharmaceutical industry, control of solvents during in process control is critical and residual solvents determination is normally included in the specifications of the Drug Product Intermediates (DPI). This control is usually conducted in the Quality Control (QC) laboratories by application of a Gas Chromatography (GC) method. GC methods are normally DPI and solvent specific. As a consequence, a significant number of different GC methods need to be managed on a daily basis in QC laboratories, consuming substantial resources with direct impact on the laboratory efficiency and productivity. The work presented herein intends to describe the development of a general GC method (with headspace), following a Quality by Design (QbD) approach; applicable to the quantitation of solvents that are usually used in DPI manufacturing. The method was proved to be selective, linear, accurate and robust for all solvents under study between 50 ppm and ICH levels. This methodology resulted in a better understanding of the effect of critical method attributes in the responses of the analytical method, allowing the prediction of method behavior to different instrument conditions (increased robustness). Method life cycle management control strategies were also defined, permitting continuous method improvement. This method development included two distinct stages, both using QbD principles. The first stage determined the best GC instrumental conditions, using a Design of Experiments methodology. In the second stage, the matrix effect was tested, leading to the creation of a development flow chart to be used by all users with different DPIs.

Biography

Cátia Sousa has completed her MSc degree in Pharmaceutical Engineering in 2011, from Technical University of Lisbon (Portugal). She has been working in pharmaceutical industry since 2007, in quality control, stability and validation, and now on analytical development at drug product development group in Hovione, Portugal.

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