Cátia Sousa et al., Pharm Anal Acta 2016, 7:2(Suppl)
http://dx.doi.org/10.4172/2153-2435.C1.031

OMICS International
conferenceseries.com

International Conference and Exhibition on

Advances in HPLC & Chromatography Techniques

March 14-15, 2016 London, UK

UPLC method implementation: Saving time and costs

Cátia Sousa and **Constança Cacela**
Hovione FarmaCiencia, Portugal

The Pharmaceutical Industry is constantly looking for new strategies to reduce costs and shorten the time for drug development, while assuring product's high quality. For pharma Quality Control (QC) laboratories, one of the goals is to continuously reduce the time of analysis and thereby increase throughput. High Performance Liquid Chromatography (HPLC) is a key analytical technology used routinely in QC laboratories. There is an increasing need for high resolved fast and ultra-fast methods with sufficient resolution to allow peak separation in a few minutes or even seconds. Ultra Performance Liquid Chromatography (UPLC) is the key to achieve this goal. In this presentation, the work conducted during the development of an UPLC method for assay and degradation products assessment in a Drug Product Intermediate (DPI) will be given. Moreover, the advantages of applying this type of method when compared to the traditional HPLC will be shown. During development, the following analytical method parameters were evaluated: accuracy, repeatability, selectivity, precision and LOD of impurities. The DPI UPLC method achieved has a run time of 12 minutes against 70 minutes for the HPLC compendial method of the corresponding API (Active Product Ingredient). It should be mentioned that the API has two different compendial methods, a HPLC one for degradation products evaluation and a volumetric titration method for assay determination. The DPI UPLC method herein presented has the advantage of being suitable for both purposes.

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 is now in analytical development at Drug Product Development group at Hovione, Portugal.

cmsousa@hovione.com

Notes: