



WEB-BASED TRAINING COURSE:

HPLC ANALYTICAL METHOD DEVELOPMENT FOR PHARMACEUTICAL ANALYSIS

This HPLC training course in analytical method development is aimed at analysts who have been performing HPLC analysis and troubleshooting HPLC for approximately 6 months to 1 year, and who wish to develop HPLC methods for pharmaceuticals. The training is delivered using live web-based training, where the MTS trainer and the learner communicate over the internet. The HPLC training course is split into 8 sessions, each of between 60 to 90 minutes in length. The timing for the delivery of the sessions is arranged to suit the learner. For example, a popular choice is to deliver two sessions in a day over a total period of four days. MTS will make every effort to fit in with the schedule that suits you.

Every attendee on a MTS course is asked to fill in a brief survey on their previous experience and training expectations to ensure that the training is optimised for their learning needs.

The standard cost for this HPLC training course, charged per person, is £600 + VAT.

SYNOPSIS:

HPLC analytical method development is a critical process when using HPLC for pharmaceutical analysis. Methods need to separate the desired components satisfactorily, they need to generate the required results, and they must be reproducible and robust so that they can be used time after time without problems. Often method development training courses contain very interesting material and create a good impression but when the analyst returns to the lab they find they don't know where to start!

The selection of suitable HPLC conditions to achieve a desired separation is often both confusing and time consuming. This HPLC training course provides a 5 step strategy which can be followed to develop HPLC methods. The strategy combines in depth theory on method development together with an efficient and straightforward approach. Analysts will learn how to develop a HPLC method that is suitable for their application. Attendees are encouraged to bring along examples of method development challenges for discussion during the training. The learning objectives and full agenda for this training course are provided below.

LEARNING OBJECTIVES:

After taking this course the learner will be able to:

1. Define the objectives for the development of a HPLC analytical method.
2. Effectively assess all the available relevant information relating to the desired method.
3. Understand the effects of the structure of the analyte, e.g. pKa.
4. Select and prepare a suitable sample or samples to be used for the method development.
5. Select suitable scouting conditions to find a suitable column and mobile phase system.
6. Understand the differences between HPLC columns.
7. Perform measurements which indicate the degree of separation for a method, e.g. resolution.
8. Understand the effects of mobile phase composition and temperature on separation.
9. Optimise the chromatographic conditions to result in the best possible separation.
10. Use computer modelling as an aid to method development.



AGENDA



SESSION 1 – IN WHICH WE COVER:

INTRODUCTION TO TRAINING

STEP 1: WHAT ARE YOUR GOALS?

- i. Defining the requirements for your HPLC analytical method: consideration of the analyte, the sample to be tested, the type of test required and the purpose of the test.
- ii. Setting appropriate criteria for the method: consideration of restrictions and preferences for the method.
- iii. Setting suitable objectives for HPLC method development: how to summarise the aim and objectives for the development of your HPLC analytical method.

SESSION 2 – IN WHICH WE COVER:

STEP 2: WHAT DO YOU ALREADY KNOW?

- i. Identifying potential sources of information.
- ii. Assessing the effects of the structure of the analyte
- iii. Assessing available information relating to impurities.
- iv. Interpretation of available information on interferences likely to be encountered in the method.
- v. How to assess the information obtained from previous work relating to the analytical method.

SESSION 3 – IN WHICH WE COVER:

STEP 3: WHAT SAMPLE(S) WILL YOU USE TO DEVELOP THE METHOD?

- i. Selecting suitable samples for HPLC method development.
- ii. Requirements for stability indicating methods.
- iii. Obtaining a source of the samples selected.
- iv. Preparation of the test sample(s) to be used for method development.

SESSION 4 – IN WHICH WE COVER:

STEP 4: WHAT CONDITIONS WILL YOU USE FOR THE METHOD? – PART I

- i. Selecting initial conditions for HPLC method development: stationary phase and mobile phase.
- ii. Choosing a stationary phase: consideration of HPLC column theory.



SESSION 5 – IN WHICH WE COVER:

STEP 4: WHAT CONDITIONS WILL YOU USE FOR THE METHOD? – PART II

- i. Choosing a mobile phase: consideration of suitable solvents, use of buffers, etc.
- ii. Designing scouting experiments: consideration of the requirements of the method, selection of suitable stationary phase and mobile phase combinations and set-up of the scouting experiments.
- iii. Interpretation of scouting experiments: how to identify promising potential conditions for the method, measurement of resolution, peak shape, etc.

SESSION 6 – IN WHICH WE COVER:

STEP 5: WHAT METHOD PARAMETERS WILL YOU USE? – PART I

- i. The effects of HPLC analytical method chromatographic parameters: e.g. column attributes, mobile phase composition, temperature, flow rate, injection volume, etc.
- ii. Selecting suitable parameters for your method, i.e. optimising the separation: designing optimisation experiments and using computer modelling software.

SESSION 7 – IN WHICH WE COVER:

STEP 5: WHAT METHOD PARAMETERS WILL YOU USE? – PART II

- i. Peak purity evaluation: is there anything under my peak?
- ii. Designing an appropriate system suitability test.
- iii. Optimisation of all remaining method parameters: e.g. concentration of test solutions, method of calibration, calculations, injection sequence, etc.
- iv. Next steps: e.g. testing HPLC column batch-to-batch variability, analytical method validation, monitoring the performance of the method, etc.

SESSION 8 – IN WHICH WE COVER:

WHAT HAVE YOU LEARNED?

- i. Review of learning.
- ii. Assessment.
- iii. Generation of a Training Action Plan for implementation of learning in the workplace.
- iv. Evaluation of training

FOR MORE INFORMATION AND DETAILS OF OTHER COURSES, PLEASE CONTACT US.