

UTrain

PROSPECTUS

Introduction

UTrain is the pre-prepared training package for in-house use from Mourne Training Services. The aim of this UTrain Prospectus is to provide detailed information on the available modules in UTrain to assist you in selecting the modules which match your training needs. The prospectus will be updated as new modules become available; the date of issue of the prospectus together with a version number is always detailed in the top right hand corner of the first page.

Why UTrain?

The preparation of technical training courses requires expertise in subject matter and training design and is often very time-consuming. UTrain is designed to fulfil your in-house training requirements in pharmaceutical analysis topics, such as HPLC training, in an effective, efficient and economic way. The UTrain e-learning package may be provided in one of three ways:

1. In the virtual environment for learning provided by Mourne Training Services, namely e-MTS.
2. As training materials which can be hosted by the customer on an in-house intranet, Learning Management System (LMS) or similar.
3. On CD-ROM.

The UTrain Package

The UTrain package consists of three key elements:

1. **Training videos** – provides all the necessary subject information. They can be used either by an individual as self-paced learning or in a group training setting. The videos can be viewed as often as required by individual learners.
2. **Exercises** – these are worksheets containing exercises and instructions for practical experiments (where applicable) so that learners can apply their new skills. Detailed

solutions for the exercises are also provided. The exercises and solutions are designed to be printed off as required.

3. **Assessment** – the questions used to measure the learning for the training may be administered in an e-learning module and combined with a review of the learning. A training certificate is awarded on correct completion of all the questions. The certificate contains a space for an in-house signature to certify that all the training was completed satisfactorily.

UTrain Modules

The UTrain package is comprised of a series of modules, each designed to last *approximately* 90 minutes. Individual modules may be selected to suit your training needs.

The first available UTrain modules together make up an introductory HPLC training course entitled *Basic HPLC for Pharmaceutical Analysis*. This e-learning HPLC course is the best possible starting point for any HPLC operator to develop their knowledge and skills. The course is recognised by the **Royal Society of Chemistry** for the purposes of **Continuing Professional Development**.

Further modules on HPLC, including troubleshooting HPLC and HPLC analytical method development, as well as modules on the validation of analytical methods, will be available in the future.

AVAILABLE MODULES:

MODULE 1

What is HPLC?

The learning objective for this module is to understand what is meant by: chromatography, High Performance Liquid Chromatography (HPLC); and the application of HPLC to the chemical analysis of pharmaceuticals.

The theory of chromatography is introduced and the different types are briefly described. The concept of polarity is revised due to its importance in HPLC. High Performance Liquid Chromatography (HPLC) is defined and the different types, namely partition, adsorption, size-exclusion, and ion-exchange, are discussed. The nature and structure of drug molecules are reviewed together with consideration of how their structures make them suitable for analysis by one or more types of HPLC.

MODULE 2

HPLC Stationary Phase

The learning objective for this module is to understand the wide range of available stationary phases and the differences between them, and use this information to identify a particular HPLC column using the relevant descriptive parameters.

The HPLC stationary phase is introduced in terms of the column where each parameter is introduced in turn e.g. packing, bonded phase, particle size, length, etc. The packing is considered in some detail with a discussion of the different materials commonly used, e.g. silica, zirconia, hybrid technologies, etc. This is followed by a discussion of the different types of available bonded phases and the differences between them, including the technologies used for particular problems such as polar analytes and pH stability. The physical parameters of the column such as particle size, pore size, length and internal diameter, and their effects, are then considered.

MODULE 3

HPLC Mobile Phase

The learning objective for this module is to prepare mobile phase for HPLC using different types of solvents, buffers and additives and understand the effect these have on the chromatographic separation.

The most commonly used solvents in HPLC are each introduced and their properties, including polarity and UV cutoff values, discussed. Then the solvents which are commonly used for each of the different types of HPLC, namely partition, adsorption, size-exclusion, and ion-exchange, are considered. The effect of ionisable analytes such as acids and bases in reversed phase partition HPLC is investigated and the use of buffers and other additives explored. Isocratic and gradient elution methods are introduced. Best practice methods for the preparation of mobile phase are described including methods of mixing mobile phases required in gradient analysis. Finally methods for, and the purpose of, mobile phase degassing is considered.

MODULE 4

HPLC Systems & Instrumentation

The learning objective for this module is to identify and understand the purpose of each component of the instrumentation used for HPLC, and how they are connected to each other.

The purpose of each component in a typical HPLC system is explained by introducing each part of a typical instrument in terms of the role that it plays in enabling the interaction of the sample with the stationary phase and mobile phase. The function and key features of each component is discussed in turn, namely mobile phase reservoirs; in-line degassers; pumps and solvent management systems; injection systems; column compartment; column fittings; detectors; waste collection; data processors and chromatography data systems (CDS).

COMING SOON:

MODULE 5

HPLC Analytical Methods

The learning objective for this module is to understand how HPLC is applied to the analysis of pharmaceuticals throughout the drug creation process, and to be able to interpret a HPLC analytical method.

The purpose of HPLC analytical methods throughout the full drug development process, from discovery to manufacturing of commercial products, is explored. The differing requirements at different stages are discussed. The format and contents of HPLC methods and the varying ways in which the method information may be presented is explained. Interpretation of a HPLC method is considered including the decisions which may have to be made by the HPLC operator with respect to method conditions.

IN THE PIPELINE:

Three more modules are planned to complete the Introductory HPLC training course which will comprise of Modules 1 to 8. These will provide guidance on performing HPLC methods, including step by step instructions, and will enable the learner to: use system suitability testing for HPLC analysis and interpret the results using pharmacopoeia criteria; apply calibration and quantification techniques to HPLC analysis and understand the different types of calibration which are commonly used for pharmaceutical analysis.

The other courses currently delivered by Mourné Training Services, namely HPLC troubleshooting, HPLC method development and analytical method validation will be converted to UTrain modules from which you can pick those most suited to your needs.