PharmaTraining

Pharmaceutical Dissolution Testing - a Hands-on Course

12, 13, 14 & 15 May 2020
13, 14 15 & 16 October 2020

DoubleTree Hilton Hotel, Angel Kings Cross, London UK

Dissolution and drug release tests are directly relevant to the safety and efficacy of many common pharmaceutical dosage forms. To achieve reliable and reproducible results, analysts must understand the importance of correct equipment set-up, sample introduction and sampling. In addition to use of dissolution testers, this three-day course will also cover equipment qualification, data evaluation and development and validation of dissolution procedures.

An optional half day will deal with use of dissolution testing in the assessment of bioavailability and bioequivalence.
Delegates will have the opportunity to set up and run dissolution tests using a USP I/II dissolution tester during the course and the course will include case studies and individual/group exercises.

Course Speaker: Mark Powell

Mark is a Fellow of the Royal Society of Chemistry with over twenty years' experience as an analytical chemist. His PhD project involved the characterisation of bitumen by chromatographic, spectroscopic and thermal methods, providing a good grounding in a wide range of analytical techniques.

He then worked for five years in the environmental industry, with responsibility for the development of analytical methods capable of quantifying very low levels of pollutants in drinking water and a variety of other sample types.

Having joined Liverpool John Moores University's School of Pharmacy and Chemistry in 1997 as a Senior Lecturer, Mark was responsible for the University's MSc programme in analytical chemistry, and was also active in research and consultancy.

In 2003, he joined the newly-formed Quay Pharmaceuticals, a contract research and manufacturing organisation specialising in early-stage drug development, where he was responsible for analytical development. Since 2010, as Scientific Manager, Mark was involved more generally with drug development programmes and also established collaborations with a number of UK universities and instrument manufacturers. His work at Quay has resulted in a number of published papers and presentations at scientific conferences.

ROYAL SOCIETY OF CHEMISTRY Approved training

This courses has approved by the Royal Society of Chemistry for Continuing Professional Development (CPD)

PharmaCourses Ltd
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Programme

Day 1

Why do we perform dissolution testing?

Dissolution theory, sink conditions and intrinsic dissolution rate

Dissolution and drug release testing apparatus

- Rotating basket (USP Apparatus 1)
- Rotating paddle (USP Apparatus 2)
- Reciprocating cylinder (USP Apparatus 3)
- Flow-through cell (USP Apparatus 4)
- Paddle over disc (USP Apparatus 5)
- Rotating cylinder (USP Apparatus 6)
- Reciprocating holder (USP Apparatus 7)
- Franz cell
- Non-compendial approaches (including small-volume apparatus and peak vessels)

Practical session: setting up a dissolution tester with basket and paddle apparatus

Day 2

Requirements for different dosage form types (including data interpretation)

- Immediate release
- Extended release
- Delayed release
- Transdermal delivery systems

Dissolution equipment qualification

Practical session: delegates will perform a dissolution test on an immediate release drug product

Day 3

Dissolution method development

- General requirements
- Selection of dissolution medium (including uses of biorelevant media)
- Apparatus and agitation rate
- Sampling (time points & filtration)
- Special requirements for gelatin capsules
- Assay requirements

Dissolution method validation

- Setting acceptance criteria with reference to drug product specifications
- Specificity
- Linearity/range
- Accuracy/recovery
- Precision
- Robustness
- Solution stability

Day 4 (half day—optional) ***advise when booking***

Dissolution and the assessment of bioavailability/bioequivalence

- Bioavailability and bioequivalence—definitions and *in vivo* evaluation
- *In vitro* biowaivers
- *In vitro-in vivo* correlation

Who should attend?

This 3.5 day hands-on course will benefit anyone requiring an intensive introduction to dissolution testing and the associated procedures working in the following areas:

- Regulatory Affairs
- Pharmaceutical Development
- Analytical Development
- Project Management
- Quality Control

This course supported by

Omicron UK

www.omicron-uk.com

DISTEK CREATING A STIR

Venue:

DoubleTree Hilton Hotel Angel Kings Cross, 60 Pentonville Road, London, N1 9LA
Website: www.http://doubletree3.hilton.com/ Close to Angel underground and Kings Cross/St Pancras Stations

Please note accommodation is not included in course fee.

Course Programme 2020

Hands-on Tablet Development including the principles of pre-formulation, formulation and process development
1, 2 & 3 April *and* 2, 3 & 4 December 2020, **Croydon Greater London**
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QbD and Lifecycle Management of Analytical Methods
21 & 22 May 2020, **London**
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Stability Testing in Pharmaceutical Development and Manufacture
8 & 9 June 2020 **London**
***

HPLC Analytical Method Development and Validation
22 & 23 June 2020 **London**
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HPLC Troubleshooting 24 June 2020 **London**
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Pharmaceutical Packaging – an introductory course
25 & 26 June *and* 30 November & 1 December 2020 **London**
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Introduction to the Formulation and Stabilisation of Protein and Peptide Drugs 14 & 15 September 2020 **London**
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Latest Advances in the Formulation & Stabilisation of Protein and Peptide Drugs 16 & 17 September 2020 **London**
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Powder Technology for Pharmaceutical Development and Manufacturing
23, 24 & 25 September 2020 **London**
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Parenteral Products
tba 2020 **London**
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Pharmaceutical Granulation and Compression
tba 2020 **London**
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GMP Auditor Training for Quality Systems
tbc November 2020 **London**
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Development of Stability-Indicating HPLC Methods
tbc November 2020 **London**
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HPLC Analytical Method Development and Validation
tbc November 2020 **London**
***

Pharmaceutical Aerosols, Dry Powder Inhalation Systems and Nasal Delivery Devices
tbc 2020 **London**
***

Pharmacokinetics in Drug Development - an integrated approach
23 & 24 November 2020 **London**

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REGISTRATION DETAILS:

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12, 13, 14 & 15 May 2020

Early-bird Fee: 3.5 day course £1665.00 (+VAT if applicable, see VAT notes)

Discounted rate for registering and paying before **1 April 2020**

Full Fee: 3.5 day course £1850.00 (+ VAT if applicable, see VAT notes)

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VAT NOTES:

UK: Under UK law all UK-based applications are subject to VAT at the prevailing rate however most UK VAT registered companies/organisations can reclaim this tax.

EU: With effect from 1 January 2011 applications from delegates whose companies are based in EU countries will not be subject to VAT **PROVIDED THAT** valid VAT ID details are provided at the time of booking, otherwise VAT will be charged.

OTHER: With effect from 1 January 2011 applications from delegates whose companies are based outside of the UK/EU will be outside the scope of VAT, ie no VAT is charged or payable.

Methods of Payment available:

o Cheque (**Please make payable to "PharmaCourses Ltd")**

o Bank transfer o Credit/Debit Card

Data Protection

PharmaCourses Ltd gathers personal data in accordance with the UK Data Protection Act 1998 and we may use this to contact you by telephone, fax, post or email to tell you about other products and services. If you have any queries or want to update any of the data that we hold then please contact us.

Online Registration is available on our website:

www.pharma-training-courses.com

PharmaCourses Ltd is a company registered in England and Wales No. 08509096

Terms and Conditions:

Delegate fees: Delegate fees are inclusive of course documentation, refreshments and lunch. Payment of the registration fee must be paid within 14 days of commencement of the course. Upon receipt of payment, a proof of payment will be sent to you.

Cancellation Policy: Full refunds less a handling fee of £100 will be made for cancellations received in writing within 28 days of the commencement of the course. Refunds of 50% will be made for cancellations received in writing between 28 and 7 days prior to the commencement of the course. Regrettably no refunds will be made after 7 days prior to commencement of the course. Substitutions can be made at any time.

Liability: PharmaCourses Ltd reserves the right to change the programme, speakers, date or venue without notice or cancel the event. If cancellation occurs delegates will be notified as soon as possible and will receive full refund of fees paid.