PHARMACEUTICAL DISSOLUTION TESTING

A COMPREHENSIVE, PRACTICAL, 3-DAY CLASSROOM COURSE

24 – 26 SEPTEMBER 2024

DoubleTree by Hilton, Swindon, UK

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Introduction

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, it is important that analysts understand the importance of correctly setting up and sampling from the chosen apparatus.

Provided by Omicron Ltd and presented by Dr Mark Powell of Mark Powell Scientific, this three-day classroom course will cover equipment qualification, development and validation of dissolution procedures, troubleshooting dissolution methods and the use of biorelevant media as a tool to predict in vivo performance.

The course content will be reinforced each day with a live, practical, hands-on session covering correct dissolution apparatus configuration (App 1 and App 2), non-compendial dissolution configuration, verification and calibration of dissolution testers, dissolution best practices and procedures, troubleshooting and more. Please see the 'Course programme' for more information.

Who should attend?

This course is aimed at those new to dissolution testing and analysts with previous experience seeking to improve their skills and knowledge. Upon completion of the course a certificate of attendance will be provided alongside all the presented material.

Fees and Payment

The fees for the course are as follows :

£995 per delegate ex VAT, if booked before 31st July 2024, **£1,195** per delegate ex VAT, if booked thereafter.

Multi-delegate discounts are available, please contact Omicron for more information. See 'Practicalities' for more information on what is included.

Attendance enquiries for the course should be sent to office@omicron-uk.com who will handle all quotations and payments.

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Practicalities

The course will run from Tuesday 24th – Thursday 26th September 2024, and is a classroom-based course being held at the DoubleTree by Hilton, Lydiard Fields, Great Western Way, Swindon, SN5 8UZ.

Each day the course will run to the following schedule, with both the theory and practical sessions will be held in the classroom.

Session 1: 09:00 – 10:30
Morning Break: 10:30 – 11:00
Session 2: 11:00 – 12:30
Lunch: 12:30 – 13:00
Session 3: 13:00 – 14:30
Afternoon Break: 14:30 – 15:00
Session 4: 15:00 – 16:30

Refreshments (a range of tea, coffee and accompaniments) will be provided for the morning and afternoon breaks each day in a breakout area close to the classroom and is included in the course fee.

Lunch will be provided each day in the hotel's 14Twelve restaurant (a two-course hot and cold buffet) and is included in the course fee.

Accommodation is not provided as part of the course fee and must be arranged and paid for privately. Please see 'Travel and Accommodation' for further information.

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Course Programme

Day 1

Why do we perform dissolution testing?

- Overview of dissolution testing in the context of drug development and manufacturing

Dissolution theory, sink conditions and intrinsic dissolution rate

Dissolution and drug release testing apparatus

Examine the various testing apparatus used during dissolution/drug release testing:

- 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)
- Approaches for novel dosage forms

Practical Session:

Correct instrument configuration, setup and checks for Apparatus 1, 2, 5, 6 and non- compendial iterations (small volume, apex, and intrinsic).

Course Programme

Day 2

Requirements for different dosage form types

You will examine the regulatory requirements and data interpretation for the following:

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

Dissolution equipment qualification

- US FDA vs USP approach

Troubleshooting dissolution results

- Gain knowledge to overcome common problems
- Examine a logical stepwise approach for troubleshooting

Practical Session:

Walkthrough of Apparatus 1 and Apparatus 2 ASTM (FDA) and USP qualification procedure. Advisory tests for non-compendial iterations (small volume, apex and intrinsic).

Course Programme

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 gelatine capsules
- Assay requirements

Dissolution method validation

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

Practical Session:

Best practice when performing dissolution testing; media preparation, sample handling, dosage introduction, observations, sampling and filtration. Execution of a dissolution method. Troubleshooting OOS results.

Course Speakers

Classroom and Theory: Dr Mark Powell – Mark Powell Scientific

Mark is a Fellow of the Royal Society of Chemistry with over thirty years' experience as a senior analytical chemist. He has taught pharmaceutical courses and consults for clients all over the world on both early-stage and late-stage drug development projects. He has particular expertise in dissolution method development and chromatography and is in demand as a trainer in topics ranging from pharmaceutical analysis to data integrity and technical report writing.

Practical Sessions: Sam Stringer and Nicola Robinson - Omicron Ltd

Sam Stringer and Nicola Robinson manage the Business Development Unit at Omicron Ltd, the UK distributor for a range of scientific instrumentation specialising in Dissolution and Oral Solid Dose Testing, Chromatography and Spectroscopy. Having spent a number of years in service and technical support roles, both Sam and Nicola have extensive experience supporting clients in the field and remotely to resolve analytical and technical enquiries, as well as having provided on-site dissolution apparatus maintenance and qualification services.

Dr Mark Powell
Mark Powell Scientific

Nicola Robinson
Omicron Ltd

Sam Stringer
Omicron Ltd

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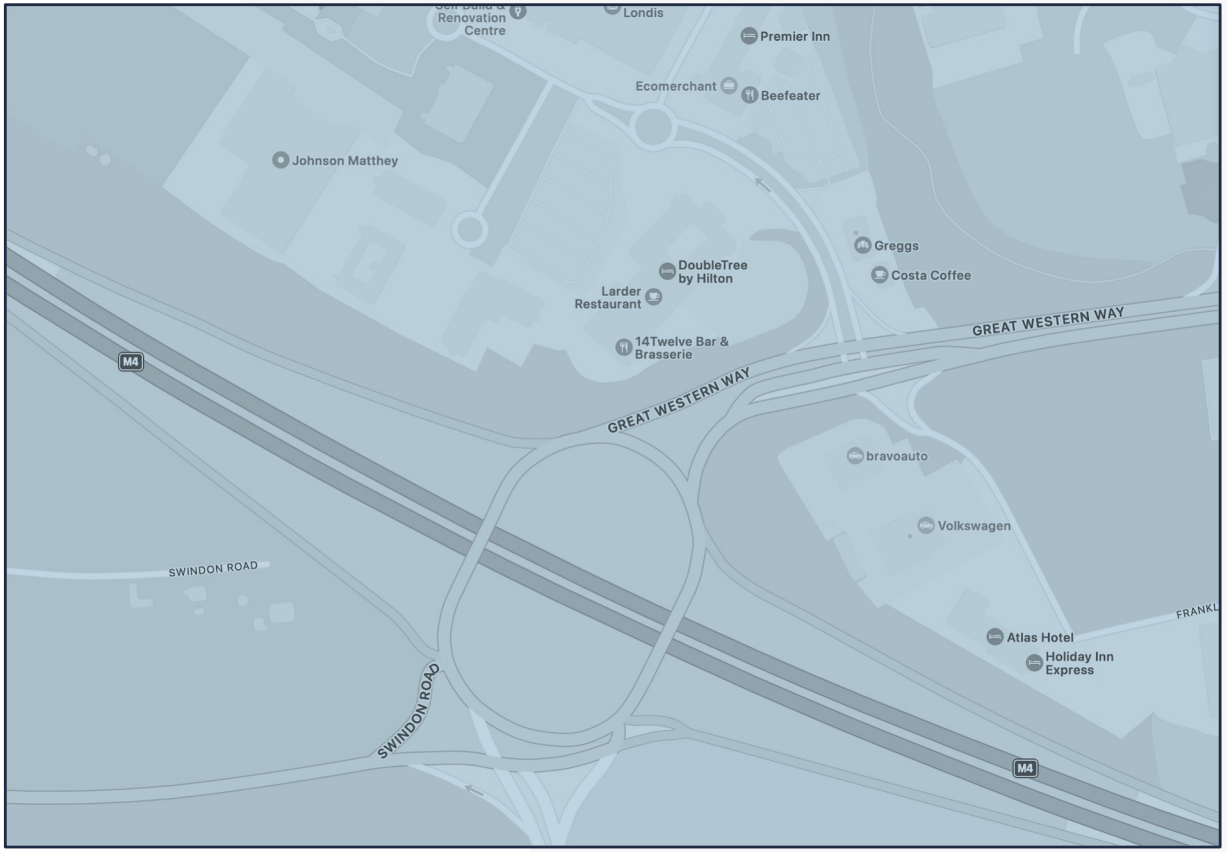
Travel and Accommodation

Getting Here

By Car: The DoubleTree by Hilton is located just off Junction 16 of the M4 motorway, and on-site parking is available. No reservation needed.

By Rail: Swindon has a mainline railway station, with regular services running to London, Bristol, Cheltenham and Reading which all offer connecting services. A private taxi will be required to get to the course venue from the railway station.

By Air: The closest airports are London Heathrow and Bristol. The hotel does not operate an airport shuttle service, so transfers must be arranged privately.



Accommodation

Swindon has a large offering of suitable accommodation to suit all requirements. The most conveniently located accommodation for the course is as follows:

DoubleTree by Hilton, Swindon: https://www.hilton.com/en/hotels/swihndi-doubletree-swindon/
Holiday Inn Express, Swindon West: https://www.ihg.com/holidayinnexpress/hotels/gb/en/swindon/swiwe/hoteldetail
Premier Inn, Swindon West: https://www.premierinn.com/gb/en/hotels/england/wiltshire/swindon/swindon-west-m4-j16.html
Village Hotel, Swindon: https://www.village-hotels.co.uk/swindon

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For all enquiries, please contact Omicron using the following:

+44 1488 682 700

https://www.omicron-uk.com/contact

info@omicron-uk.com