The Indian Pharmaceutical Association-Maharashtra State Branch's

Bombay College of Pharmacy

(State Government aided, AICTE & PCI affiliated, Autonomous institute affiliated to University of Mumbai)

Kalina, Santacruz(E), Mumbai-400098

Maharashtra State Branch

Under the aegis of IQAC, Department of Pharmaceutics,

Bombay College of Pharmacy-Autonomous

Organizes a Two-day Comprehensive Training Course

On

Lyophilization Technology

The Theory and Practice of Freeze Drying of Pharmaceuticals

on

February 23rd-24th 2023

Speaker

Dr. Madhav Kamat, Ph.D., R.Ph.

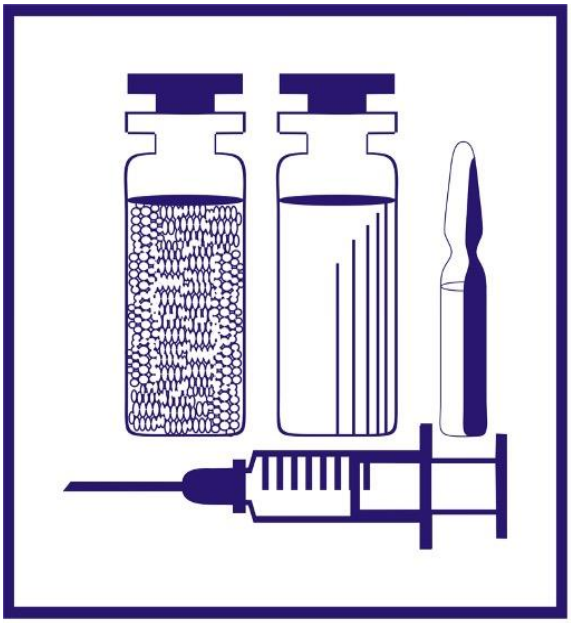
Founder/CEO

Kamat Pharmatech LLC, NJ, USA

www.kamatpharma.com

at

015, Ground Floor, The IPA-MSB's Bombay College of Pharmacy, Kalina, Mumbai - 400098



Course Topics Include

- Small molecules and Biologicals
- Design of Freeze-Drying Cycles
- Cycle Optimization, QbD, and Scale-up/transfer consideration
- Quality Control, Validation, Regulatory aspects
- Equipment, Controls and Qualification
- Container-Closure Selection and Qualification

Course Description

This course presents

- Principles and techniques of lyophilization based on theoretical concepts, engineering elements of heat and mass transfer, and practical industrial applications.
- Scientific aspects of frozen aqueous systems: phase transitions and eutectic/collapse phenomena.
- Pharmaceutical aspects including formulation, manufacturing process, and cycle development, scale-up/transfer, analytical issues, and stability aspects.
- Regulatory requirements including cGMPs, aseptic considerations, validation and qualification and process controls.

Learning Objectives

Upon completion of this course, you will be able to:

- Outline the fundamentals of lyophilized product development and the underlying scientific and engineering principles involved in freezing, primary drying, secondary drying and determination of end of drying.
- Explain the requirements needed to develop efficient freeze-drying cycles.
- List the factors involved in process scale-up, controls, and optimization
- Describe the equipment and instrumentation involved in lyophilization
- Explain the requirements for validation of lyophilization products and processes
- Discuss recent trends in lyophilization of pharmaceuticals

Who Should Attend

The Course is designed for freshers as well as experienced personnel in Pharmaceutical, Diagnostic, Biotechnology and Vaccine industries responsible for the specification, development and production of lyophilized products including

- R&D Personnel
- Production Personnel
- Regulatory Science
- QA/QC
- Pilot Plant Operators
- Chemical Engineers
- Pharmacists

Course Fees & Registration Details

- Registration is open and limited to 25 participants only.
- Course fees per participant: Rs.23,600/- inclusive of GST
- To register for the course, kindly access and submit the filled form provided in the link below
  https://forms.office.com/r/zpLD3Fnntp
- The registration fees can be paid by NEFT to the following bank account or using UPI
  - Name of the Account : The IPAMSB's Bombay College of Pharmacy - Autonomous
  - Bank Name : Canara Bank, Branch : Kalina, Santacruz (East), Mumbai 400029.
  - A/c No: 0116101079370, IFSC Code: CNRB0000116.

Course Director

Dr. Madhav Kamat is the Founder/CEO of Kamat Pharmatech LLC, a pharmaceutical consultancy/development firm, having more than 35 years of sound industrial experience specializing in the area of injectable products and processes. Dr. Kamat has a wide experience in product/process development (small molecule and biologicals) involving formulation development, lyophilization, scale-up/technology transfer, and sterile manufacturing of more than 20 injectable products. He is well recognized for his expertise in lyophilization, nanosuspension technology, aseptic technology, and other sterile manufacturing processes. His recent interests are formulation and process development of biological products and IV injectable products of water insoluble drugs.

Dr. Madhav Kamat is an alumnus of Bombay College of Pharmacy. He received his B. Pharm and M. Pharm from Bombay University and Ph.D. from the College of Pharmacy at University of Kentucky, USA. Dr. Kamat's Ph. D. dissertation was based on lyophilization technology, and he has authored many publications on sterile products and lyophilization.

Dr. Kamat worked at Bristol-Myers Squibb Company for last seventeen (17) years in Technical Operations and finally reached the position of Director, R&D. Prior to BMS, Dr. Kamat worked at Centocor Inc. and Johnson & Johnson for eight (8) years. For the last ten (10) years, Dr. Kamat is the CEO of Kamat Pharmatech LLC – a specialized development laboratory for injectable and tropical products. Dr. Kamat has been a visiting professor at the College of Pharmacy, University of Kentucky and at New Jersey Institute of Technology, NJ. Dr. Kamat is also a Registered Pharmacist in the States of Pennsylvania and New Jersey.

For any queries please contact:

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Course Outline

Day 1
8:00 a.m.: Registration and Breakfast
8:30–9:00 a.m.: Welcome and Review of Learning Objectives
- Course introduction and format

9:00–10:00 a.m.: Introduction to Freeze-Drying
- Basic theory and brief history

10:15–11:00 a.m.: Physical Properties and characterization of Materials
- Crystalline vs. amorphous vs. mixed systems
- Critical temperatures: Eutectic melting, glass transition (Tg and Tg'), and collapse temperatures
- Principles of thermal analysis – theory and equipment
- Freeze-dry microscopy equipment and techniques

11.00 to 11.15 a.m.: Tea Break & Networking
11:15–12:15 noon: Fundamentals of Freeze-Drying – Freezing
- Ice nucleation and growth
- Eutectic and/or glass formation
- Annealing theory and techniques

12.15 to 1.00 p.m.: Lunch Break & Networking
1:00–3:00 p.m.: Fundamentals of Freeze-Drying – Various stages
- Primary drying: Introduction to heat and mass transfer operations
- Influence of pressure and temperature on process Characteristics

Secondary drying: Mechanism for moisture loss and retention
- End of drying: Determination of termination of cycles

3.00 to 3.30 p.m.: Tea break & Networking
3:30–4:00 p.m.: Container Closure Systems
- Influence on heat and mass transfer: Impact of molded vs tubing vials
- Container closure qualifications: Container-closure operational qualification (CCOQ), Container-closure integrity testing (CCIT), Delamination issues, vial breakage etc.

4:00–5:00 p.m.: Formulation Development – Small and Large Molecules
- Pre-formulation assessment
- Selecting acceptable formulation components
- Examples

Day 2
8:30–9:30 a.m.: Lyophilization Process Development and Cycle Design
- Reviewing and utilizing the thermal analysis data
- Designing optimized freezing, primary, and secondary drying regimens

9:30–10:15 a.m.: Quality Control of Lyophilized products
- Finished product testing
- Appearance of cake, moisture content, other inspection issues
- Stability tests

10.15 to 10.30 a.m.: Tea Break & Networking
10:30–12:00 noon: Scale-Up and Cycle Transfer, Maximum Throughput Capability
12.00 to 1.00 p.m.: Lunch Break & Networking
1:00–2:00 p.m.: Understanding Pharmaceutical Freeze Dryers
- Components of a freeze dryer
- Measurement/Control systems
- CIP, SIP; Stoppering; Automated loading
- Computer/PLC control of research and production

freeze drying
2:00–3:00 p.m.: Other considerations
- Non-aqueous lyophilization, controlled nucleation, vacuum in vials, bulk freeze drying, remote sensing of product temperatures
- Syringe Freeze-drying
- Review of some representative freeze-drying cycles
- Some significant publications

3.00 to 3.15 p.m.: Tea break & Networking
3:15–4:00 p.m.: Validation and regulatory aspects
- Regulatory requirements, QbD Principles
- Validation of Freeze-Dryer
- IQ/OQ, FAT/SAT
- Regulatory Compliance: Review of applicable regulatory guidance documents, Inspectional observations, and corrective actions

4:00–5:00 p.m.: Discussion & Feedback session