

European Continuing Education College

Pharmaceutical Granulation and Compression

Three Day Intensive Course with an Emphasis on High Speed and Fluid Bed Granulation, Layering, Pellet Manufacture, Roller Compaction, Oral Dispersion Technology, Scale-Up, Transfer Technology, Melt Extrusion, Spray Drying and Compression Machinery

**Holiday Inn Hotel, Oxford Circus, London, UK
6th, 7th and 8th February 2012**

Course Background

Granulation and compression are two very important processes that are carried out extensively by most pharmaceutical companies. However, the theory of granulation is little understood and the selection of a particular machine and granulation method, is often done on the basis of tradition, rather than by using strict scientific or cost-benefit criteria. The basic techniques have changed dramatically in recent years and granulation for controlled release, extrusion, spheronisation, fluidisation techniques, spray drying, melt extrusion, oral dispersion technology and roller compaction are new technologies that are increasingly being used in modern pharmaceutical production, which exhibit many advantages over previously available techniques. As with granulation, compression is also little understood and why some materials/formulations will compress well whilst others compact with difficulty, is slowly being elucidated. The Course will examine current granulation and compression theory and practice. Emphasis will be made as to how this theory and practice relates to current pharmaceutical development and production, with special reference to the machinery used. Scale-Up, Transfer Technology and SUPAC will also be addressed. A particular feature of the Course will be the workshop on new melt extrusion technology.

Course Objectives

The aims of the Course are to provide a comprehensive and sound understanding of the theory and practice of tablet granulation and compression and to appreciate the various processes batch or continuous, that are available. The importance of the granulation process in producing good quality tablets will be emphasised. The modern techniques of extrusion, spheronisation, powder layering, roller compaction, fluid-bed processing, spray drying, melt extrusion, oral dispersion technology and tablet compression will be covered. The Course will be taught primarily by industrial scientists who have been closely involved with investigating these granulation and compression processes and thus a pragmatic approach will be adopted throughout.

Summary of Key Benefits of Attending

At the end of the Course participants will have:

- An understanding of the fundamental principles of granulation and the advantages, disadvantages and potential of the various granulation, layering, spray drying, oral dispersion, extrusion and spheronisation methods
- An understanding of the techniques and processes available for granulation in relation to controlled release products
- Detailed knowledge on current ideas and thoughts on Scale-Up, Transfer Technology and SUPAC
- An appreciation of some of the compression problems that can arise and how they can be overcome
- A knowledge of the factors that should be taken into consideration when selecting granulation and compression equipment

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Summary of Key Benefits of Attending

At the end of the Course participants will have:

- Specialist knowledge on fluid-bed granulation, roller compaction, layering, spray drying, oral dispersion technology and melt extrusion
- Detailed knowledge on compression machinery
- An appreciation of the techniques available and their limitations for end-point granulation control
- A knowledge of the reasons why problems arise in the granulation and compression processes and how these problems can be avoided

Who Should Attend

All who are working in pharmaceutical research, formulation, development, production, QA/QC and registration who require a sound understanding of the various granulation and compression methods and who wish to appreciate some of the advantages of the newer methods of granulation, spheronisation, roller compaction, layering, melt extrusion and compression that are now available.

Course Outline

Methods and Reasons for Granulating

Overview of granulation and compression. Techniques available. Theory of granulation.

Excipients

Review of available excipients; advantages and disadvantages. Rationale for selection

Properties of Granules

Measurement of granule properties. Ideal granule characteristics.

Granulation for Controlled Release

Review of current methods.

High Speed Granulation and End-Point Control

Introduction and history. Machine design. Fixed bowl vertical; fixed bowl horizontal. Removable bowl. Operation. Practical experiences. Review of suppliers. Granulation end-point. Diosna probe. Review of techniques of monitoring impellor torque. Slip meter control. Automated control of whole process.

Integrated Mixer-Granulator Dryers

Review. Advantages and disadvantages. Equipment available.

Fluid Bed Granulation

Operation. Equipment selection. Fully automated systems. Rotary granulators. Comparison of methods.

Layering

Solution, suspension and dry powder layering.

Spray Drying

F.S.D. Spray Drying

Pellet Manufacture

Techniques available. Spray drying. Drum granulation. Comparison of methods.

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Course Outline

Extrusion and Spheronisation

Extrusion theory. Basic rheological modelling/formulation indicators. Types of extruders. Commercial extruders. Development extruders. Melt Extrusion: Carriers for Melt Extrusion, Solid Dispersions, Examples of Extruders/Other Equipment, Parameters Affecting Melt Extrusion, Formulation and Process Design Problems. Laboratory modelling. Properties of extrudates. Moisture movement across extrudates. The role of microcrystalline cellulose. Spheronisation: spheronisation theory. Commercial equipment. Problems of spheronisation. Evaluation of pellets.

Hot Melt Extrusion

Review of process. Why hot melt extrusion. Types of solid dispersions. Types of carrier. Equipment. Case study

Roller Compaction

Review of the current state of roller compaction. Equipment available. Advantages and disadvantages.

Compression Theory

Review. Why some materials compress satisfactorily whilst others compact poorly. Theory related to practice.

Compression Machinery

Review of the current state of press design. Removable turrets and cleaning of presses

Compaction Simulators

Review and uses

Tabletting and Tooling Problems

A review of problems that arise in production and how to avoid producing poor quality tablets.

Oral Dispersion Tableting Technology

Review of methods. Advantages and disadvantages of the technology. Equipment required.

Scale-Up, Transfer Technology and Supac

Workshop

A workshop will be arranged on hot melt extrusion processes.

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Lecturers

Michael H. Rubinstein B.Pharm., Ph.D., M.R.Pharm.S., M.I.Chem.E., C.Eng., Q.P. (Course Director)

Professor Rubinstein is C.E.O of Quay Pharmaceuticals Ltd., a contract pharmaceutical R & D and Clinical Trials Manufacturing company on the Wirral. Previously he was Professor of Pharmaceutical Technology and Director of the School of Pharmacy and Chemistry at Liverpool John Moores University. His research interests include the examination of the granulation process and he has published and lectured widely in the field of tableting technology and the formulation of solid dosage forms. Professor Rubinstein has worked for AstraZeneca and GlaxoSmithKline in production technical support, pharmaceutical development and research. He has published over 200 research papers and articles in the area of solid dosage form technology and in particular in tablet compression. He lead one of the only academic research teams using a high speed Compaction Simulator to fundamentally characterise powder compression. Professor Rubinstein is both a Chemical Engineer and a Pharmacist with Q.P. Status, is the author of 5 books in pharmaceutical technology and two patents and is the series editor of the book series in Pharmaceutical Technology now published by Taylor & Francis Ltd. Professor Rubinstein is a consultant to a number of pharmaceutical companies and governments and is the Conference Co-Ordinator for the annual Pharmaceutical Technology Conferences.

Geert Verreck M.Eng., Ph.D.

Dr Verreck is a Scientist in the Pharmaceutical Sciences Department of Johnson and Johnson in Belgium. He is responsible for the evaluation of the solid dispersion approach for new active compounds, including hot melt extrusion and solubility techniques. He has published 37 papers and is the author of 6 patents in this area.

Ian Smales B.Sc.

Mr Smales is an Associate Scientist at Pfizer Central Research and has responsibilities for optimization, scale-up and technology transfer of pharmaceutical products. He has specialist expertise in wet and dry granulation and in particular roller compaction.

Paul Burton C.Chem, M.R.S.C.

Mr Burton has had extensive experience as a Formulation and Process Development Scientist with Beecham Products, Cyanamid UK and SmithKline Beecham Pharmaceuticals. He has been involved in new product introduction, scale-up of solid dosage forms and process validation. Currently he is Process Technology Manager for Glatt Protech where he has responsibility for applications of fluidised bed technology, high shear granulation and tablet coating technologies.

Terry Lewis

Mr Lewis is Operations Manager at I.Holland Ltd., U.K. His is accountable for all technical activities of the company and has 28 years expertise in compression and tooling problems.

Harald Stahl Ph.D.

Dr Stahl is Senior Pharmaceutical Technologist with Niro Pharma Systems with world-wide process responsibility for the technologies supplied by Niro Pharma Systems. Previously he worked in the Pharmaceutical Development Division of Schering AG in Germany.

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Lecturers

Jan Vogeeler B.Sc.

Mr Vogeeler is Managing Director of Courtoy N.V., manufacturers of tablet presses in Belgium. He has pioneered the design of new tablet machinery to enable tablets to be produced at faster speeds with minimal clean and down time and has a huge wealth of experience in novel design of compression machinery.

Ian Muir BSc., Ph.D.

Dr Muir is Vice-President of Zydis at Cardinal Health in the U.K. He is responsible for product development for the fast dissolve Zydis technology. He has had previous experience in various aspects of product development from early compound selection to scale-up and commercialization.

Gordon Prudhoe BSc

Mr Prudhoe is Quality Assurance Technical Group Manager for Sanofi-Sythelabo. His responsibilities include technical support for production and co-ordination, planning and execution of all transfer activities both in and out of Sanofi-Sythelabo plants worldwide. Mr Prudhoe was previously Manager in charge of the formulation and analytical groups and has developed over 50 generic products. Mr Prudhoe has worked in the industry for over 20 years in a development/production support role.

Marina Levina MSc., Ph.D.

Dr Levina is Global Technical Manager, Excipients at Colorcon Ltd. and is responsible for all technical aspects of the range of Colorcon excipients. She has experience in the production of tablets by conventional and by ultrasound assisted compaction and with the development of solid oral dose formulations for both immediate release and sustained release applications

Fees and Registration

The participation fee is £1495.00 (exclusive of VAT). Places are strictly limited and therefore applications will be accepted on a first come basis. Under UK law all applications are subject to Value Added Tax (VAT) irrespective of the country of origin of participants. Most VAT registered companies/organisations can reclaim this tax. The fee includes full personal participation, extensive bound course notes, luncheons and light refreshments, on all days of the Course. Dinner at night is not included. Cancellations cannot be accepted less than 14 days prior to the start of the Course, but substitutions may be made at any time. The Course language will be English. An approved Certificate of Attendance will be given to each participant at the end of the Course.

Timing of the Course

Registration will be at 8.45am on Monday 6th February and the Course will commence promptly at 9.00am. The Course will finish at about 17.00 on Wednesday 8th February. The Course will end at about 18.00 on each of the first two days.

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ECEC - Registration Form

Course - Pharmaceutical Granulation and Compression

Please fill in the following details to apply for a place. No payment is necessary now. When filling in the form, fields marked with an asterisk (*) are compulsory. Your form will not be submitted if they are left blank.

Personal Details

First name: *	<input type="text"/>
Surname: *	<input type="text"/>
Organisation:	<input type="text"/>
Job title:	<input type="text"/>
Address: *	<input type="text"/>
Post/zip code: *	<input type="text"/>
Telephone no:	<input type="text"/>
Extension:	<input type="text"/>
Fax no:	<input type="text"/>
Email address: *	<input type="text"/>

I wish/do not wish to receive future mailings from ECEC about forthcoming courses. (Please note, we do not disclose your email address to any third party)

Accommodation

Accommodation will be at the: Holiday Inn Hotel, Oxford Circus, London, UK
Room Rates: Single Room - Bed & Breakfast per person, per night £159.00
Twin Room - Bed & Breakfast per person, per night £189.00
Double Room - Bed & Breakfast per person, per night £189.00

Choose accommodation Type:

- I don't want accommodation
- I would like a Single Room - Bed & Breakfast
- I would like a Twin Room - Bed & Breakfast
- I would like a Double Room - Bed & Breakfast

Choose which days:

- Sunday 5th February 2012
- Monday 6th February 2012
- Tuesday 7th February 2012
- Wednesday 8th February 2012

Other nights (please specify): _____

* Please note: Under UK law all applications are subject to Value Added Tax (VAT), irrespective of the country of origin of the Participant

PLEASE FAX THIS COMPLETED FORM TO +44 (0)151 724 6343