

GRADUATE PROGRAM IN PHARMACEUTICAL SCIENCES
Dermaceutics 16:720:523 & 16:137:603, 3 Credits, Spring 2015
Thursdays, 6-9 PM, Life Sciences Building Auditorium

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Lecture Schedule: Thursdays 6:00 – 9:00 PM LSB Auditorium 1st Floor

Goals of Course: “Dermaceutics” is an in-depth full semester course designed for graduate level students as well as scientists in the pharmaceutical/personal care and cosmetic industries who need to learn more about the fundamentals of skin, skin absorption, topical/transdermal compound delivery and methodologies for testing the penetration of compounds into skin. We will cover in vivo clinical testing as well as issues with regulatory and intellectual property/patent aspects of formulations and actives applied to the skin.

Learning Objectives:

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

- Explain general in vitro testing procedures for topicals and transdermals
- Discuss regulatory requirements for in vitro absorption testing
- Understand the complexities in setting up in vivo testing panels
- List the different stages of percutaneous absorption
- Be familiar with skin penetration parameters
- Understand the approaches of enhancing and retarding percutaneous absorption of actives
- Discuss the barrier properties of skin, skin biology, skin metabolism of actives

Who Should Attend:

- Skin research and development scientists
- Formulation chemistry experts
- Toxicology and regulatory affairs specialists
- Technical sales and marketing professionals
- New employees needing introductory background
- Legal professionals dealing with I.P., patent litigation in the topical/transdermal areas

Recommended Books for General Reading:

Drugs and the Pharmaceutical Sciences: A series of textbooks and monographs Marcel Dekker Inc. NY and Basel:

- a) Vol. 97 Percutaneous Absorption: Drugs, Cosmetics, Mechanisms, Methodology. 3rd Edition revised and expanded. Edited by Bronaugh, R.L. and Maibach, H.I.
- b) Vol. 91 Dermal Absorption and Toxicity Assessment. Edited by Roberts, M.S. and Walters, K. A.
- c) Vol. 83 Mechanisms of Transdermal Drug Delivery. Edited by Potts, R. O. and Guy, R.H.
- d) Vol. 62 Drug Permeation Enhancement: Theory and Applications. Edited by Hsieh, D.S.
- e) Vol. 53 Prodrugs: Topical and Ocular Drug Delivery. Edited by Sloan, K.B.
- f) Vol. 42 Topical Drug Delivery Formulations. Edited by Osborne, D.W. and Amann, A.H.
- g) Vol. 35 Transdermal Drug Delivery: Developmental Issues and Research Initiatives. Edited by Hadgraft, J. and Guy, R.H.
- h) Vol. 18 Dermatological Formulations. Edited by Barry, B.W.
- i) Vol. 119 Dermatological & Transdermal Formulations. Edited by Walters, K.A.

Delivery System Handbook for Personal Care and Cosmetic Products, edited by Rosen, M. R. William Andrew Publishing, Norwich, NY (2005).

Skin Aging Handbook: An Integrated Approach to Biochemistry and Product Development. Edited by Dayan, N. William Andrew Publishing (2008).

Skin Barrier. Edited by Elias, P.M. and Finegold, K.R. Taylor and Francis (2006).

Lecture Topic	Dates	Lecturer
Objectives, Course Outline		
Introduction, Journal Club, Report Preparation (BMK)	01/22	Drs. Michniak-Kohn/Joseph
<u>Basic Principles</u>		
Skin Structure and Function (LJ)		
<u>Basic Principles</u>		
The stratum corneum and lipids (GM)	01/29	Drs. Michniak-Kohn/Menon
Biochemistry of the skin (GM)		
<u>Skin Aging and Photodamage</u>	02/05	Drs. Rhein/Michniak-Kohn
<u>Principles of Percutaneous Absorption</u>		
Skin penetration pathways	02/12	Dr. Michniak-Kohn
JOURNAL CLUB #1		
Enhancement of drug permeation I	02/19	Dr. Michniak-Kohn
JOURNAL CLUB #2		
Enhancement of drug permeation II	02/26	Dr. Michniak-Kohn
Presentations of Report Plans I		
<u>Formulation Patents, I.P. & Obviousness</u>	03/05	Drs. Davitz/ Michniak-Kohn
Presentations of Report Plans II		
<u>Skin Diffusion & Dissolution</u>	03/12	Dr. Michniak-Kohn

Fick's laws of diffusion
Percutaneous penetration parameters
Drug release studies
JOURNAL CLUB #3 (BMK)

SPRING BREAK

03/19

In vitro and in vivo clinical testing

In vitro cellular skin models (BMK)
In vitro & in vivo animal models (BMK)

03/26

Dr. Michniak-Kohn

Clinical testing in humans (NM)

JOURNAL CLUB #4 (BMK)
CLASS DEBATE (details to be announced)

04/02

Drs. Michniak Kohn/
Muizzuddin

Delivery Systems

Transdermal delivery systems (BMK)

04/09

Dr. Michniak-Kohn

Skin Diseases, Clinical Treatment & Commercialization

Overview & treatment of common skin diseases (OM)
From the Clinic to Commerce (JM)

04/16

Drs. Mills/Mills

Delivery Systems

Topical delivery systems (BM)
JOURNAL CLUB #5 (BM)

04/23

Dr. Michniak-Kohn

Hot Topics:

Vibrational spectroscopy, Microscopy & Imaging (NM)
Beneath The Surface: Compounding's Practical and Unique
Solutions (SR)

04/30

Dr. Mendelsohn / Dr. Rudner

**FINAL EXAM -preparation of Reports that will be due on
Friday MAY 8th, 2015**

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REPORT TOPICS FOR SELECTION-one topic per student and no sharing of topics.

(Topic selected CANNOT BE DIRECTLY RELATED to the current research work of the student):

The Report will be in the format of a NIH Proposal i.e. Title, Abstract, Background, Significance, Preliminary Data, Research Plan, Research Methods, Bibliography. Times New Roman, single-spaced text, 15 pages maximum NOT including the bibliography (minimum 60 references).

Preliminary Outlines –one page abstracts (electronic) will be due FEBRUARY 19th 2015.

1. Painless drug delivery through microneedle-based transdermal patches
2. Investigation of the molecular organization of the lipid matrix in stratum corneum
3. Drug delivery and formulations for the topical treatment of psoriasis
4. Drug delivery and formulations for the topical treatment of atopic dermatitis

5. Nanoemulsions as vehicles in transdermal formulations
6. Design of novel chemical enhancers for transdermal drug delivery
7. Use of iontophoretic approaches to transdermal delivery of anti inflammatory drugs
8. Examination of the role of hair follicles in the percutaneous penetration of drugs
9. Retinoids and other compounds in the treatment of skin aging
10. Transdermal delivery of proteins and peptides
11. Nanocarriers in skin: assessment of toxicity and health safety issues
12. Use of ultrasound in enhancement of transdermal drug delivery
13. Transdermal vaccine delivery: study of novel approaches
14. Wound healing: challenges and successes and proposed new approaches
15. Investigation of new cellular assays for drug toxicity testing and irritation testing
16. Investigation of biochemical metabolic pathways in skin for specific model drug (s)
17. Use of natural ingredients for dermatological formulations
18. Immunology of the skin
19. Transdermal drug delivery, design and limitations of patches
20. Transdermal hormone treatments- challenges and limitations
21. Transdermal drug delivery using hydrogels and creams
22. Novel materials in transdermal patch design
23. Role of Sunscreens in Skin Aging & Protection - Myths and Facts
24. Use of Chinese tea extracts in topically applied formulations-How effective are they?
25. Transdermal drug delivery systems for cancer pain management
26. Approaches to diagnosing and treating skin melanomas
27. Tissue engineered human skin alternatives for treating burn victims and venous ulcers
28. Design and use of medical devices to be used for skin drug delivery
29. The therapeutic potential of Nitric Oxide in dermatology
30. Treatment of skin ulcers in dermatology

PRESENTATION OF REPORT PLANS ON 02/26 and 03/05 IN CLASS:

The abstract of your proposed work will be due **February 19th 2015** and then you will be asked to prepare 4 slides:

- a) **Background & Title** to the subject
- b) **Specific Aims** / Objectives of the proposed research
- c) How these objectives will be achieved i.e. **Materials and Methods** section
- d) What you anticipate will be the **Outcomes** and any **Problems** you may encounter and how will these be solved

Each of you will be asked to present their set of slides during the 02/06 and 03/05 sessions following the Michniak-Kohn lectures.