

Drug Delivery System Development

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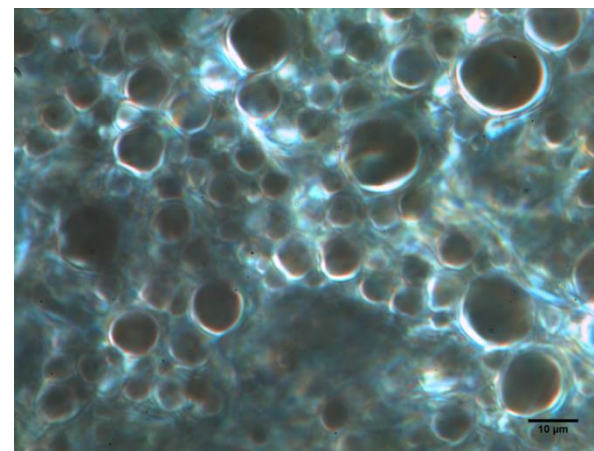
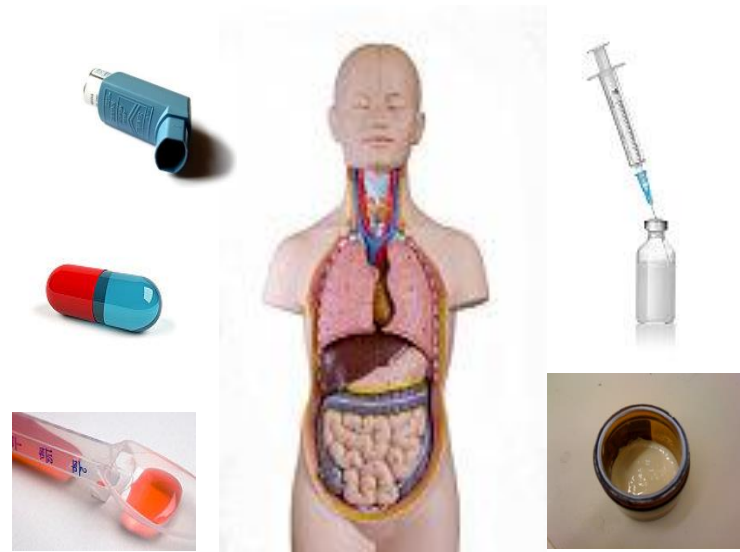
Drug Delivery System (DDS)

- A drug delivery system is defined as a formulation or device that enables the introduction of a therapeutic substance in the body and improves its efficacy and safety by controlling the rate, time, and place of release of drugs in the body
 - Administration
 - Release
 - Transport



Diversity of DDS

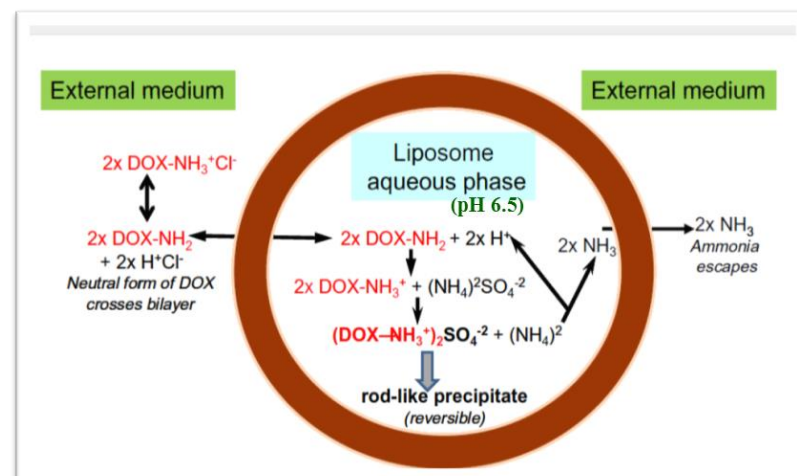
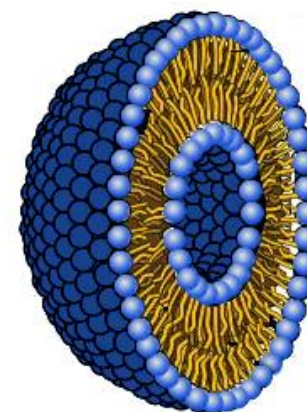
- Route of administration
 - Oral; Nasal; Pulmonary;
 - Topical; Parenteral; etc.
- Design
 - Drug device combination
 - Microemulsions & nanoparticles
- Complexity
 - Simple to multicomponent
 - Down to the molecular level



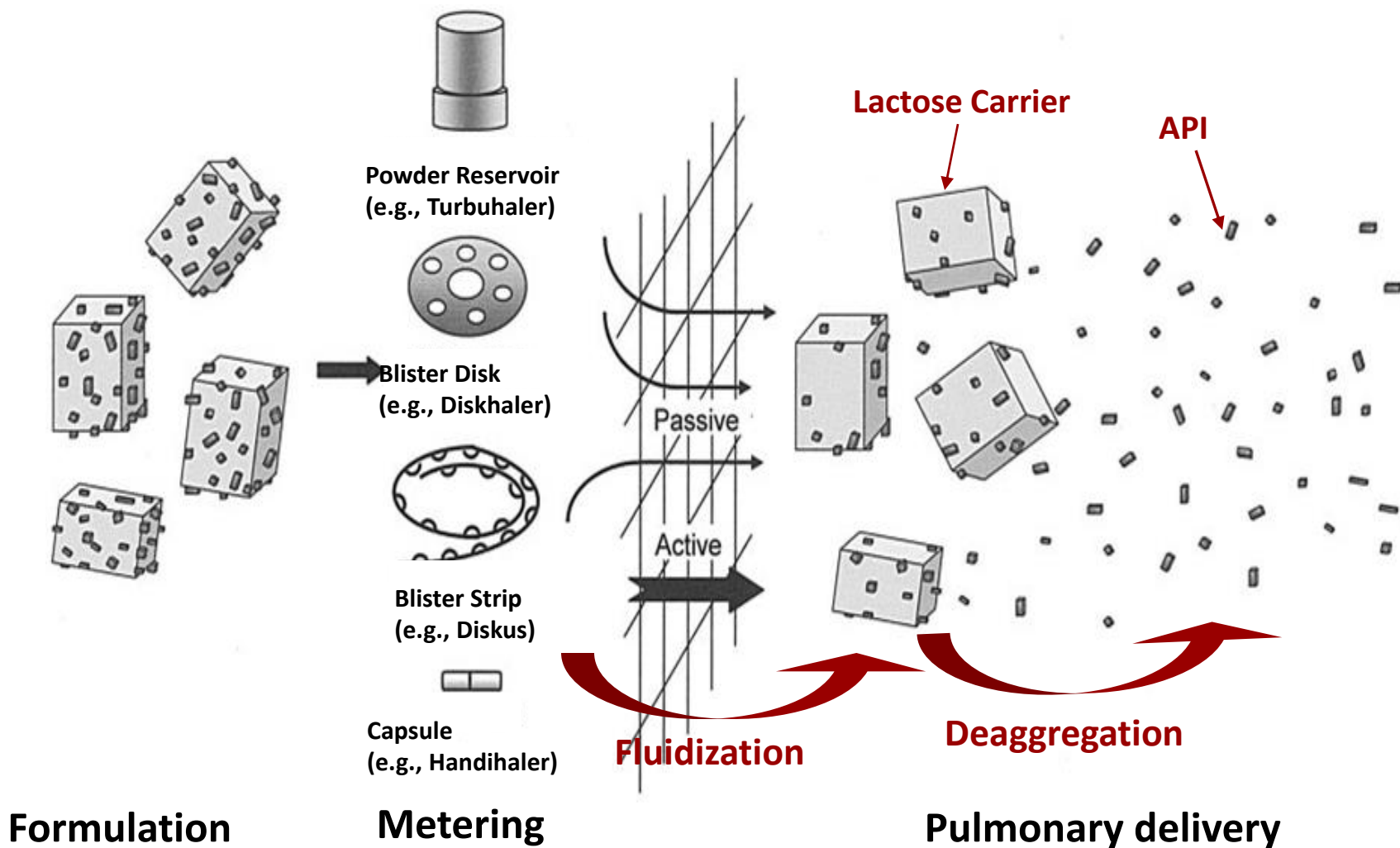
Simple to Complex: DDS of Doxorubicin Hydrochloride



Doxorubicin HCl
Lactose
Methylparaben



Complexity of DDS: Example DPI



Where are we headed?

- Putting patients first
 - Linking process -> product -> patient
- Clinically relevant specifications
 - Clinically relevant specifications are those specifications that help to assure consistent in vivo performance, as proven by their ability to reject batches with inadequate in vivo performance



Clinically Relevant Specifications for DDS

- Consistent safety and efficacy profiles
- Delivery of the intended dose to the patient
- Optimal rate of delivery
- Optimized drug therapy to the patient



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Challenges for DDS

- How to characterize the quality of the drug delivery system?
 - Arrangement of matter (microstructure) may be critical
 - Excipients as critical components (efficacy & safety)
- How to maintain the quality of the DDS?
 - Stability
 - Manufacturing
- Limited availability of in vitro models that can predict in vivo performance
- Generic development and use



Meeting the Challenges Today's Speakers

- **Stephen Hoag, Ph.D.** University of Maryland/Baltimore
 - Methods for the Assessment of Cold Flow in Matrix Transdermal Drug Delivery Systems
- **Maureen Donovan, Ph.D.** University of Iowa
 - In Vitro Assessment of Nasal Deposition Patterns in the Pediatric Population
- **Bodhi Chaudhuri, Ph.D.** University of Connecticut
 - Electrostatic Behavior in Granular Materials

