

## Added functionality Excipients : Jan 11-12, 2010 *An answer to challenging formulations*

### Scope:

A sound scientific understanding of the effect of formulation and manufacturing process is essential to :-

(1) developing a product and process of consistent quality over time and

(2) identifying and controlling critical sources of variation of both, product performance and manufacturing process. The vast majority of drugs marketed today are a combination of one or more active ingredients within a precisely formulated mix of excipients. Excipients are 'unsung heroes' of the drug world-doing all the work & getting none of the glory. "Excipient functionality" is one of the latest buzz phrase, but it is frequently used for understanding the particular nature of excipients. Functionality is linked inextricably to the formulation and process, and all formulations are different, functionality per se is a matter for the excipient user and supplier. With the advent of FDA's process analytical technologies (PAT) initiative, a basic paradigm is proposed that better-controlled products will result from improving control over the process which rely on a better characterization and understanding of excipients and the characteristics that affect their performance in the formulation and the process. However number of factors in the market, including the value of excipients in extending the patent protection of drug systems, is helping to move the contribution of these essential ingredients into the limelight.

### Objectives:

1. To focus on relating fundamental properties of excipients to the underlying scientific principles governing the development and manufacture of various dosage forms.
2. To increase the awareness of the important role materials

play in product and process understanding for developing high quality drug product under the new paradigm of pharmaceutical quality by design.

3. To cover the basic concepts of excipient selection, end-point determination, formulation optimization and prediction & application of statistical concepts.

### Resource Persons

#### Key Note Speaker

- 1) **Dr. Shirish Kulkarni** Vice President, Lupin Research Park, Pune

#### Speakers:

- 1) **Dr. Sanjay Boldhane** Group Leader, R & D, Piramal Life Sciences, Mumbai
- 2) **Dr. Arvindan Vasudevan** Research Scientist, Piramal Life Sciences, Mumbai
- 3) **Dr. S. G. Deshpande** Ex- Principal, C. U. Shah College of Pharmacy, Mumbai
- 4) **Dr. Hema Nair** Professor, Bombay College of Pharmacy, Mumbai
- 5) **Mr. Makarand Avachat** Vice President, Lupin Research Park, Pune
- 6) **Dr. P. R. Vavia** Prof. in Pharmaceutics, UICT, Mumbai
- 7) **Dr. Amruta Bajaj** Prof. in Pharmaceutics, C. U. Shah College of Pharmacy, Mumbai
- 8) **Dr. Abhijit Ghotaskar** Prof. in pharmaceutics, Indra College of Pharmacy, Pune

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Jan 15, 2010

## Chronopharmacology

### Scope:

Chronopharmacology is the science concerned with the variations in the pharmacological actions of various drugs over a period of time of the day. Thus chronotherapeutics is the discipline of therapeutics concerned with delivery of drugs over a certain period of time. The goal of chronotherapeutics is to match the timing of treatment with the intrinsic timing of illness. The mammalian circadian pacemaker resides in the paired suprachiasmatic nuclei (SCN) and influences a multitude of biological processes, including the sleep-wake rhythm. The effectiveness and toxicity of many drugs vary depending on dosing time associated with 24 hr rhythms of biochemical, physiological and behavioural processes under the control of circadian clock. Such chronopharmacological phenomena are influenced by not only the pharmacokinetics but also pharmacodynamics of medications. Identification of a rhythmic marker for selecting dosing time will lead to improved progress and discussion of chronopharmacotherapy. Biological rhythms may influence drug response and some chronopharmacological studies have underlined the influence of time of day on drug pharmacodynamics and pharmacokinetics. The aim of the seminar is to review and underline how biological rhythms may interfere with drug dynamics and kinetics.

### Objectives

1. To discuss basic concepts of circadian rhythm & its role in pharmacology.
2. To review the chronopharmacology in context to chronopharmacodynamics & chronopharmacokinetics.
3. To discuss the role & the importance of chronopharmacology in drug delivery.

### Resource Persons

#### Key note speaker

- 1) **Dr. Kasim Mookhtiar** Chief Scientific Officer, Advinus Therapeutics Pvt. Ltd., Pune

#### Speakers:

- 1) **Dr. S. L. Bodhankar** Prof & Head, Dept. of Pharmacology - Poona College of pharmacy, Pune
- 2) **Dr. S. D. Ambawade** Research Scientist, Agharkar Research Institute, Pune
- 3) **Dr. Radha Yagnanarayan** Prof & Head, Dept of Pharmacology - Smt. Kashibai Navale Medical College & General Hospital, Narhe, Pune
- 4) **Dr. Krishna Iyer** Asst. Prof. of Pharmacology, Bombay College of Pharmacy, Mumbai
- 5) **Dr. N. K. Subhedar** Prof. of Pharmacology, Indian Institute of Science & Education & Research, Pune.

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