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**Annasaheb Dange College of B. Pharmacy, Ashta**

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# PHARMACEUTICAL ORGANIC CHEMISTRY - II

As per PCI Syllabus  
for B. Pharm Semester - III



- Mr. Ganesh D. Mote
- Ms. Shubhangi S. Kharat





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For B. Pharm Semester – III



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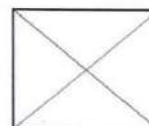


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**As per revised PCI Syllabus**

for D Pharmacy, B Pharmacy and BSc (Chemistry) Students

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## About the Book :

This Practical Manual for Pharmaceutics-I, is an attempt to put forth the theoretical background and specific information and experiments as per revised PCI syllabus (course regulation 2014). This is the first book as per revised syllabus to provide fundamental principles used in formulation preparation and their documentation as adapted by pharmaceutical industry, like batch manufacturing record and raw material weighing record of preparation.

This book contains theoretical background and short introduction and practical procedure of Syrup, Elixir, Linctus, Solutions, Suspensions, Emulsions, Powders, Granules, Semisolids, Suppositories, Gargles and Mouthwashes.

Authors have made special attempt at explaining practical procedure, storage, direction, precaution, labeling, batch manufacturing record and raw material weighing record of preparation to be compiled during practical in laboratory. This book will be useful to degree students of Pharmacy in understanding basic fundamental principles involved during formulation and their documentation as adapted by the pharmaceutical industry.

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# Micro- and Nanotechnologies- Based Product Development

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2.

**Chapter 1**

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**Descriptive Study: *In silico* and Physicochemical Assessment of the Effectiveness of Hydroxy / Amino Acids as Auxiliary Substances to Improve the Complexation Efficiency of  $\beta$ -cyclodextrin towards Bosentan**

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**ABSTRACT**

The effectiveness of certain hydroxy and amino acids as an auxiliary substance to improve the complexation efficiency (CE) of  $\beta$ -cyclodextrin ( $\beta$ CD) towards Bosentan (BOS), a poorly soluble endothelin receptor antagonist, were assessed to enhance its physicochemical performance. The phase solubility studies conducted in distilled water demonstrated a better choice of L-Arginine (ARG) as an auxiliary substance to improve CE and association constant ( $K_a$ ) of  $\beta$ CD. As complementary evidence, *in silico* calculations were performed to foresee the stability, possible interactions and geometry of BOS inside the  $\beta$ CD cavity, optimizing ARG again as an auxiliary substance. Subsequently, the solution state thermodynamic investigations revealed entropy driven complexation process. The lyophilized complexes were characterized by FTIR, DSC, XRPD and SEM. Thermodynamic studies suggested that inclusion phenomenon was entropy driven, and spontaneous. Prepared lyophilized complexes gave clear, transparent water solution indicating the complexes possessing lower sized particles of drug, achieved by inclusion phenomenon. The protein binding study resulted inclusion phenomenon was responsible for maintaining the unbound drug in plasma, which resulted in minimization of dose and dose frequency. The performance of ternary complex was found to be appreciating in overall assessment, indicating better effectiveness of ARG as an auxiliary substance in improving CE of  $\beta$ CD towards BOS.

**Keywords:** Bosentan;  $\beta$ -cyclodextrin; hydroxy acids; amino acids; thermodynamics; lyophilization; *in silico*; physicochemical.

**1. INTRODUCTION**

Bosentan monohydrate (BOS), 4-tert-butyl-N-[6-(2-hydroxyethoxy) -5- (2-methoxyphenoxy) -2-(pyrimidin-2-yl) pyrimidin-4-yl] benzene-1-sulfonamide (Fig. 1) is a white crystalline powder acting as non-peptide antagonist of human endothelial-1 receptor [1]. It is mainly recommended in the treatment of pulmonary arterial hypertension [2]. Basically, it has been classified as a BCS class-II drug, thus, exhibiting poor aqueous solubility, resulting in low bioavailability [3]. Inadequate oral bioavailability often limits desired therapeutic outcome and patient compliance. Therefore, improving both physicochemical and biopharmaceutical characteristics of BCS class II drugs has always attracted the attention of most of the researchers to improve the therapeutic efficacy of such molecules.

Inclusion complexation with  $\beta$ -cyclodextrin ( $\beta$ CD) is an industrially feasible approach to modify the physicochemical properties of poorly water soluble drugs [4].  $\beta$ CD act as a powerful complexing and solubilizing agent resulting in an improvement in dissolution, bioavailability and stability of a drug

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