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Reconsideration of Pharmaceutical Chemistry Syllabus in South Indian Pharmacy Curriculum

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Research Article

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Abstract

The objective of this research is to highlight the need for considerable attention in the development and designing of the pharmacy curriculum. This paper is focusing on knowledge of some topics like green chemistry, computational chemistry, impurity study, cleaning validation and their importance in graduate level pharmaceutical chemistry course.The knowledge of above mentioned topics will help to enhance technical and practical background of the students for different careers in pharmaceutical industry and chemical education.

Keywords: Pharmaceutical Chemistry, Green Chemistry, Computational Chemistry, Impurity, Cleaning Validation

Introduction

Chemistry has showed an enormous change in the last fifty years. In all these aspects such as wet chemical procedures to highly skilled instrumental methodologies qualified pharmacists are required nowadays. Although the professional needs have increased the demand on the practical knowledge, the fundamental concept applied in pharmaceutical chemistry syllabus is to be revised.

In the new millennium the drug design is based on combinatorial chemistry coupled to high-throughput screening. Medicinal chemistry plays a key role as a central interpreter of the underlying structure–activity relationships such as the overall process of drug discovery and development. Pharmacy professionals should have an excellent knowledge about the bulk drug manufacturing, combinatorial chemistry, chemoinformatics, ligand-based drug design, molecular mechanics, prodrug and quality control for career opportunity in pharma industry.

By the time pharmacy students encounter the application of pharmaceutical chemistry in the isolation, purification, and characterization, synthesis of pharmacologically active agents from natural sources, or from synthetic agents, drug design and development, drug action, drug transport, drug delivery, and targeting, some of the basic important concepts may have been forgotten. It is therefore essential that pharmacy educators should identify teaching and learning strategies that foster a true and lasting comprehension of the main theoretical physico-chemical and technical skills in pharmaceutical chemistry. Moreover, the students should be able to connect these concepts to their professional daily role in the industry, in bio analytical determinations and in the research and development of new drugs and formulations. One of the teaching techniques applied nowadays is the introduction of the important topics which are useful in the daily routine of the students.
In the Graduate syllabus of pharmacy we have a specified branch of pharmaceutical chemistry which depends on the chemical disciplines such as organic, inorganic, analytical, medicinal, physical chemistry and also on medico-biological discipline such as applied biochemistry with deficiency of current practical understanding. This paper discusses the lack of recent practical knowledge in pharmaceutical chemistry syllabus which is nowadays applied in pharmaceutical industries.

GREEN CHEMISTRY

Green Chemistry or environmentally benign chemistry is the design of chemical products and processes that reduce or eliminate the use and generation of hazardous substances [1]. Green chemistry can be applied to organic chemistry, inorganic chemistry, biochemistry, analytical chemistry, and even physical chemistry. It aims to minimize the hazard and maximize the efficiency of any chemical. In green chemistry the synthetic methodologies should be designed to use and generate substances that possess little or no toxicity to human health and the environment. Synthetic methods should be conducted at ambient temperature and pressure. Unnecessary derivatisations like blocking group, protection/deprotection, and temporary modification of physical/chemical processes should be avoided whenever possible.Catalytic reagents should be as selective as possible.Chemical products should be designed so that at the end of their function they do not persist in the environment and break down into innocuous degradation products. Analytical methodologies are to be further developed to allow for real-time in-process monitoring and control prior to the formation of hazardous substances. Substances and the form of a substance used

in a chemical process should be chosen so as to minimize the potential for chemical accidents, including poisonous gas releases, explosions, and fires. It is clear that many research academics recognize the significance of green chemistry. However, the discussion of green chemistry has not found its way into the chemistry curriculum.

COMPUTATIONAL CHEMISTRY

Computational chemistry uses the principles of computer science to assist in solving chemical problems. It uses the results of theoretical chemistry, incorporated into efficient computer programmes, to calculate the structures and properties of molecules and solids. Computational approaches are help in the efficient synthesis of compounds by predicting the molecular structure of molecules by the use of the simulation of forces, or more accurate quantum chemical methods, to find stationary points on the energy surface as the position of the nuclei is varied. It also helps to identify the correlations between chemical structures and properties for the efficient synthesis of compounds. Computational chemistry is useful to design molecules that interact in specific ways with other molecules.These studies can be carried out to find a starting point for a laboratory synthesis, or to assist in understanding experimental data, such as the position and source of spectroscopic peaks. Thus, computational chemistry can assist the experimental chemist or it can challenge the experimental chemist to find entirely new chemical objects. But in under graduate level the students are not provided with software packages and also not included in the syllabus. In post graduate level the Quantitative structure-activity relationship (QSAR) theory is incorporated in syllabus but they lack in practical approach.

IMPURITIES

The impurities are the major problem in bulk drug production. The impurities found in the pharmaceuticals are identified in different sources. Medicines are formulated forms of active pharmaceutical ingredients. There are 2 types of impurities in medicines: (1) Impurities associated with active pharmaceutical ingredients and (2) Impurities that are created during formulation or with aging or that are related to the formulated forms.According to ICH guidelines [2], impurities associated with active pharmaceutical ingredients **(**APIs) are classified into organic impurities (process and drug-related) , inorganic impurities and residual solvents. Organic impurities may arise due to starting material, reagents, ligands, catalysts, heavy metals and solvent residues. They also arise during the manufacturing process like degradation products, exposures to adverse temperatures, light-especially UV light , humidity, mutual interaction amongst ingredients, ester hydrolysis , hydrolysis , oxidative degradation photolytic cleavage drying, decarboxylation, decarboxylation and/or storage of the drug substance.According to ICH guidelines on impurities in new drug products [3], identification of impurities below the 0.1% level is not considered to be necessary unless the potential impurities are expected to be unusually potent or toxic. The knowledge about the impurities is low in under graduate level students.

CLEANING VALIDATION

Cleaning validation is a documented process that proves the effectiveness and consistency in cleaning pharmaceutical production equipment [4]. It is necessary to validate cleaning procedures for the following reasons [5] (1). It is a prime customer requirement since it ensures the purity and safety of the product. (2). It is a regulatory requirement in Active Pharmaceutical Ingredient product manufacture. (3). It also assures the quality of the process through an internal control and compliance. Cleaning validation should contain the assessment of equipment and products, assessment of the impact of aprocess on routine process, determination of an appropriate cleaning agent and method, determination of acceptance criteria for the residues, determination of a degree of evaluation required to validate the procedure, decisive on the residues to be tested based on solubility and toxicity, development of sampling and analytical methods for recovery and detection of residues, acceptance criteria for the validation, compilation and approval of the validation protocol, scope for the validation studies to be performed in accordance with the protocol, compilation and approvals of validation reports, documented studies, conclusions, recommendations and revalidation policy. The above mentioned topics are not at all included in under graduate level syllabus either in theory or practical.

Conclusion

The syllabus is based on only theory basis it does not cover the needs of industry. The under graduate students after the completion of the course can directly join in industries in production department, quality assurance department, Research and development with lack of practical knowledge. This is a big challenge to train the fresh employees and it causes some struggle to them also. The students retain a greater degree of background when the theoretical and experimental subjects were associated to the day-to-day act of the pharmaceutical profession. The topics like green chemistry, computational chemistry, bulk drug impurities, cleaning validation should be included in the theory and practical syllabus to improve the knowledge of under graduate students.

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AUTHORS' CONTRIBUTIONS

Athors contributed equally to all aspects of the study.

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CONFLICTS OF INTEREST

The authors declare that they have no competing interests