East and Central African Journal of Pharmaceutical Sciences
Vol. 25 (2022) 1-2

EDITORIAL

THE INTERPLAY OF PHARMACEUTICAL ANALYSIS, DELIVERY SYSTEMS AND BIO-EVALUATION IN PHARMACEUTICAL PRODUCT DEVELOPMENT

The development of new products for pharmacology-based therapies relies to a great extent on three key interrelated areas, namely: pharmaceutical analysis and characterization of the active principle; use of a suitable dosage form for administration and delivery of the active component; and bio-evaluation of the active prior to clinical trials. These areas are also the focus of much of research work in pharmaceutical sciences.

An unmet therapeutic need is the basis for the identification, discovery and development of new pharmacologically active ingredients. The active ingredient may be described as a molecule that elicits pharmacological action which leads to a desired therapeutic effect. The term active ingredient is used here to also include natural and herbal ingredients that may not be today classified as drugs despite possessing pharmacological activity. Ironically, although naturally derived actives were the basis for several modern medicines, they have been largely surpassed by synthetic molecules for a number of reasons, predominantly because the latter have easier control of production consistency (reduced variability) and perhaps controversially, intellectual property ownership advantages.

In contrast, the delivery system (or dosage form), is a product designed to administer the active in a reliable manner and comprises of: 1) active ingredient; 2) additional ingredients (excipients) that enable manufacturing, stability and *in-vivo* delivery of the active; and 3) manufacturing process that incorporates the active into a product that can be administered reliably to the patient.

In many cases, existing active ingredients show improved efficacy when formulated with alternative or more advanced delivery systems. This is especially relevant for actives which have issues with limited bioavailability due to unfavorable pharmacokinetic or biopharmaceutical properties.

For any active ingredient, the first step in its utilization is identification and quantification which requires suitable analytical methods. Characterization may also address purity, chemically modified derivatives, isomers, solid state properties, particle size, solubility, dissolution rate and membrane permeability. Another important part of analysis is monitoring the stability of the active ingredient, especially regarding the means by which it is processed during manufacturing and subsequent storage prior to use.

In addition to establishing the basis for quality control, analysis and characterization of active ingredients form the rational basis for the development of suitable products that permit delivery to the target therapeutic sites in the patient. In some cases, there may be different dosage forms for the same active designed to meet specific customized patient requirements such as specific age groups or patients benefiting from modified release profiles.

Since any processing of the active into a dosage form may affect its stability and performance, further analysis and characterization in the finished product is required. In some cases, stability aspects may be addressed by appropriate packaging systems while in others specific formulations may be necessary.

The final step in the development process of healthcare products is their evaluation in patients in order to ensure that they meet safety and efficacy criteria. In order to reduce development costs various chemical, physical and biological tests may be conducted in a range of models prior to clinical testing in humans. An increasingly important part of this development is evaluation of the active's safety, efficacy and biopharmaceutical performance using non-human biological systems or surrogate models – termed "bio-

evaluation". Therefore, methods that can provide predictions of whether or not a product will be safe, effective and bioavailable prior to clinical trials are of immense value.

If bio-evaluation does not meet the desired preset targets, chemical or physical modifications may be made to the active to address its limitations. Alternatively, the delivery system may be modified or changed entirely to improve the active's bioavailability or pharmacokinetic profile. Analysis provides critical measurements and quantification of the active in these areas thereby permitting evaluation of results and product performance.

The papers published in this issue of the journal are drawn from the fields of analysis, drug delivery and bio-evaluation. The reader is invited to appreciate the interplay and relevance of each field towards the development of new products.

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