Opinion

Preformulation studies: commercial and regulatory strategy for the pharmaceutical industry

Volume 10 Issue 5 - 2022

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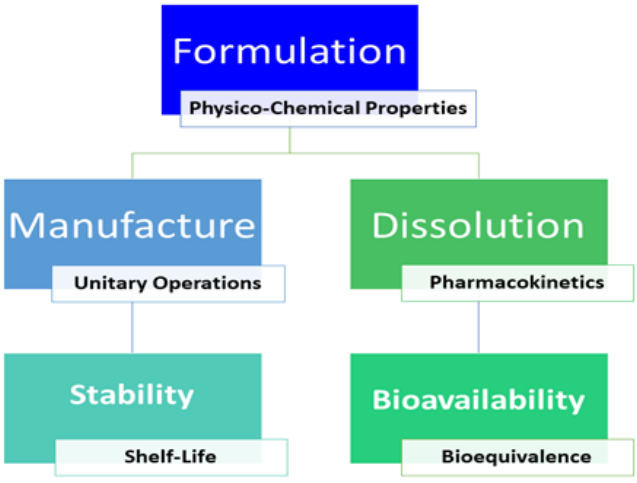
Received: August 19, 2022 | **Published:** September 05, 2022

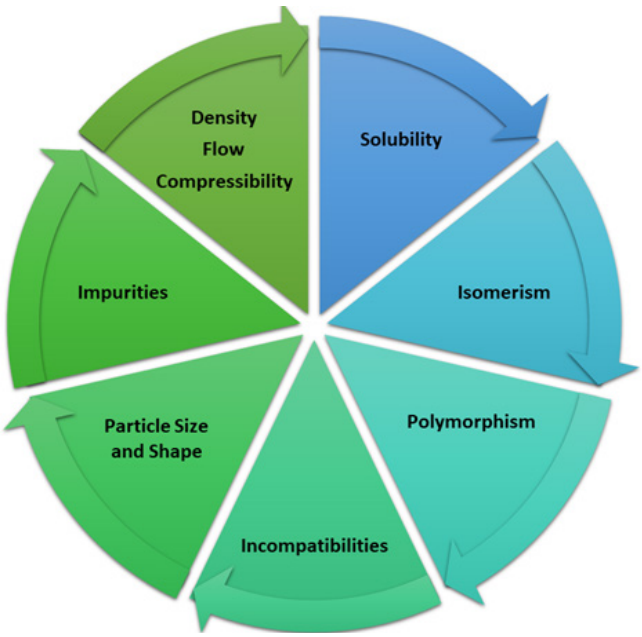
Background

The introduction of a critical scientific sense contributing to the development of pharmacy and medicine began in ancient Greece with Hippocrates. He rationalized and systematized medical knowledge and placed the practice of medicine on a high ethical standard.[1] His works included descriptions of hundreds of drugs, and it was during this period that the term "pharmakon" came to mean a purifying remedy only for good, transcending the previous connotation of drug for good or ill, so Hippocrates came to be considered the Father of Medicine.[1] Dioscorides became the pioneer in dealing with botany as an applied science of pharmacy, through his work, "On Medical Material", which is considered a milestone in the development of pharmaceutical botany in such a way that it gave rise to what is now consolidated as product chemistry and/or pharmacognosy.[1] Claudius Galen, through his studies, originated so many plant drug preparations by mixing or melting the individual ingredients that the field of pharmaceutical preparations was commonly referred to as "Galenic pharmacy".[1]

It is estimated that approximately 90% of all drugs used in clinical medicine are administered orally, with capsules and tablets being the most commercialized.[2] The oral forms have the advantages of greater dose precision, content uniformity, large-scale production and lower cost in the packaging process, the possibility of modulating drug release (gastro-resistant tablets and delayed release), in addition to providing greater adherence to the drug treatment due to ease of swallowing.[2] The research and development process of oral solid forms is fraught with challenges that involve the difficulty of achieving adequate bioavailability and stability.[2]



The characterization of the solid state as a tool for physical-chemical, physical-mechanical investigation of drugs, excipients and final formulation has become essential to obtain adequate physical and chemical stability of the drug during its shelf-life.[3] This concept called Preformulation emerged in the late 1950s and early 1960s as a result of a change in emphasis in pharmaceutical product development.[3]



Compatibility studies between actives and excipients allow the choice of the most stable components, avoiding undesirable surprises during stability studies and also make it possible to reduce the number of pilot batches produced until the selection of the final formulation, in addition to contributing to the optimization of resources and time.[4]

The RDC N° 361/2020 (ANVISA/Brazil), which establishes the criteria and minimum documentation necessary for granting and renewing the registration of drugs with synthetic and semi-synthetic active principles, classified as new, generic and similar, in order to

guarantee the quality, safety and efficacy of these drugs, included as a requirement the assessment regarding the compatibility of the API with the excipients of the formulation, in addition to the physico-chemical characterization of the drug such as polymorphism, particle size distribution, morphology, solubility, isomerism, as they can have a direct impact on the performance and quality of the finished product.[5]

Summary

The preformulation studies carried out during the development of pharmaceutical products present as a strategy from a commercial point of view the optimization of time and resources while from a regulatory point of view harmonization with Good Manufacturing Practices, applicable current legislation enabling providing scientific knowledge for the establishment of a robust and quality formulation and production process throughout the product life-cycle.

Acknowledgments

None.

Conflicts of interest

Authors declare that there is no conflict of interest.

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Citation: Dezena RMB, Rosa PCP. Preformulation studies: commercial and regulatory strategy for the pharmaceutical industry. *Pharm Pharmacol Int J.* 2022;10(5):149–150. DOI: 10.15406/ppij.2022.10.00377