iJRASET
International Journal For Research in Applied Science and Engineering Technology

INTERNATIONAL JOURNAL FOR RESEARCH

IN APPLIED SCIENCE & ENGINEERING TECHNOLOGY

Volume: 11 **Issue:** I **Month of publication:** January 2023

DOI: https://doi.org/10.22214/ijraset.2023.48651

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International Journal for Research in Applied Science & Engineering Technology (IJRASET)
ISSN: 2321-9653; IC Value: 45.98; SJ Impact Factor: 7.538
Volume 11 Issue I Jan 2023- Available at www.ijraset.com

Review: Formulation Development Studies

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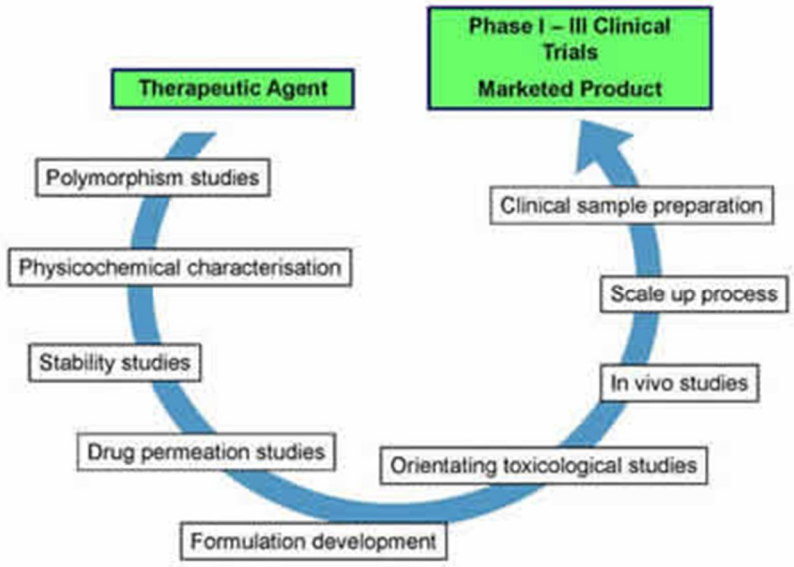
Abstract: ***The formulation development is crucial component of pharmaceutical development and important for therapeutic and commercial acquirement of product by delivering quality, safety and efficiency. The main parts of formulation development are product development methods like drug discovery, research etc. It is an essential factor not only in the starting stage of drug development, but also in later marketing success of drug product. It ties the exploration of a new drug substance to the successful development of a drug product. Formulation can determine patentability, lifecycle the success of a pharmaceutical product.***

I. PHARMACEUTICAL FORMULATION

Pharmaceutical formulation is the multistep process where the active drug is mixed with all other components by considering the factors of particle size, polymorphism, pH, and solubility and becomes the final beneficial medicinal product. Pharmaceutical formulation is the formation of a pharmaceutical product, including a drug's chemical properties, formulation, and details of the treatment protocol to be implemented in the clinical application [1, 2]



II. STEPS IN FORMULATIONS DEVELOPMENTS

A. Validation and Characterization of Drug

The validation & characterization of drug is so much important because it affect the final product.

B. Drug Additive Compatibility Study

More the additive compatible with drug more the chances of drug formulation success and effect of drug is also increase.

C. Formulation Development

The next stage is formulation development in which chemicals goes with excipient and forms drugs.

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D. Formulation Optimization

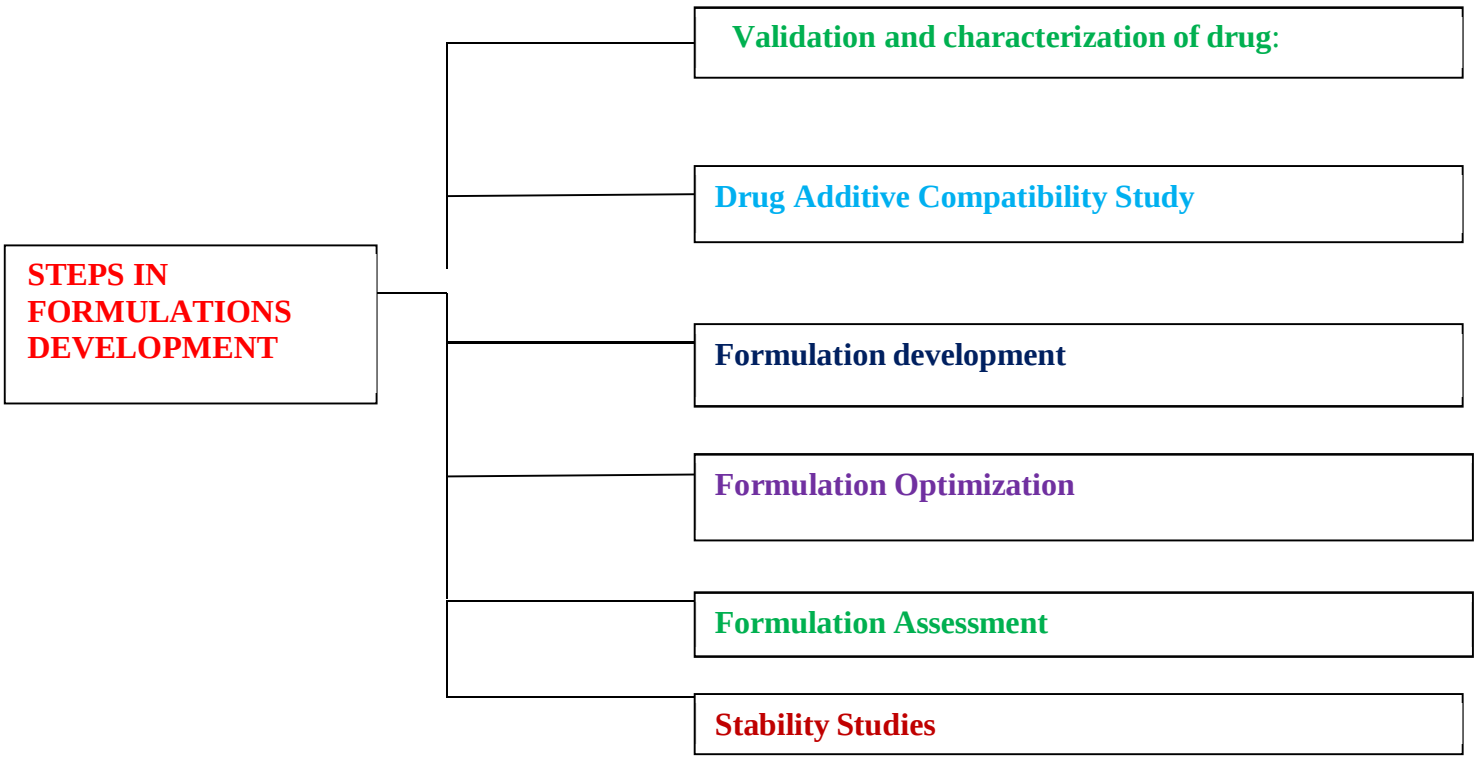
In this stage formulation like vaccine are produces this type of formulation have lots of studies than normal formulation and large amount of the knowledge needed

E. Formulation Assessment

The assessment studies help to enhance the already accomplished formulation by substitute the part of formulation like the solvent types

F. Stability Studies

It includes the stability of the formulation by performing tests so that the stability of formulation increase it also helps to improve the shelf life of formulation [3, 4 ,5].



III. PRE-FORMULATION STUDIES

Pre-formulation studies can defined as Laboratory studies to determine the characteristics of active substance and excipient that may influence formulation and process design and performance The pre-formulations is group of studies that emphasize the physicochemical properties of new drug candidate and combination with the excipient that affect drug performance.[6,7]

IV. OBJECTIVES

1) To develop the stable, effective and safer dosage form.
2) To provide useful information to design a new drug delivery system with better Bioavailability
3) To establish the physicochemical parameter of new drug.
4) To generate useful data needed in developing safe dosage forms that can be manufactured on a commercial scale.

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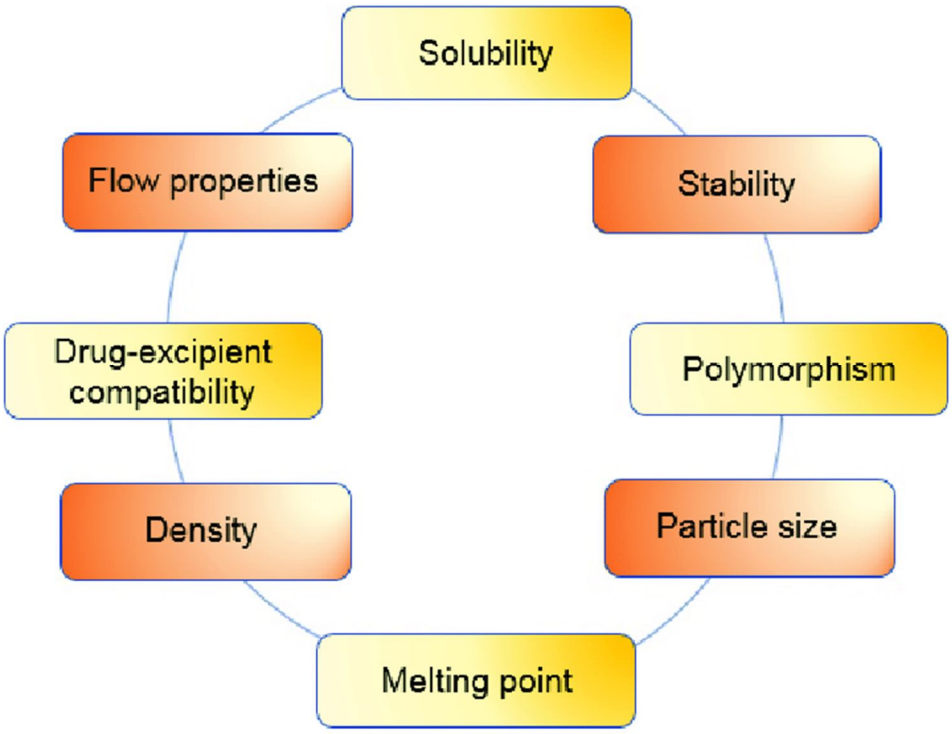
V. PRE-FORMULATION PARAMETER



VI. CONCLUSION

The formulation development studies along with the pre-formulation studies include the various tests, research & the S.O.P handling. These are the important parameter of the pharmaceutical industries without this pharmaceutical industries does not conduct properly and the quality efficiency. New problems arise during development and it cannot be solve until required efforts with knowledgenot met.

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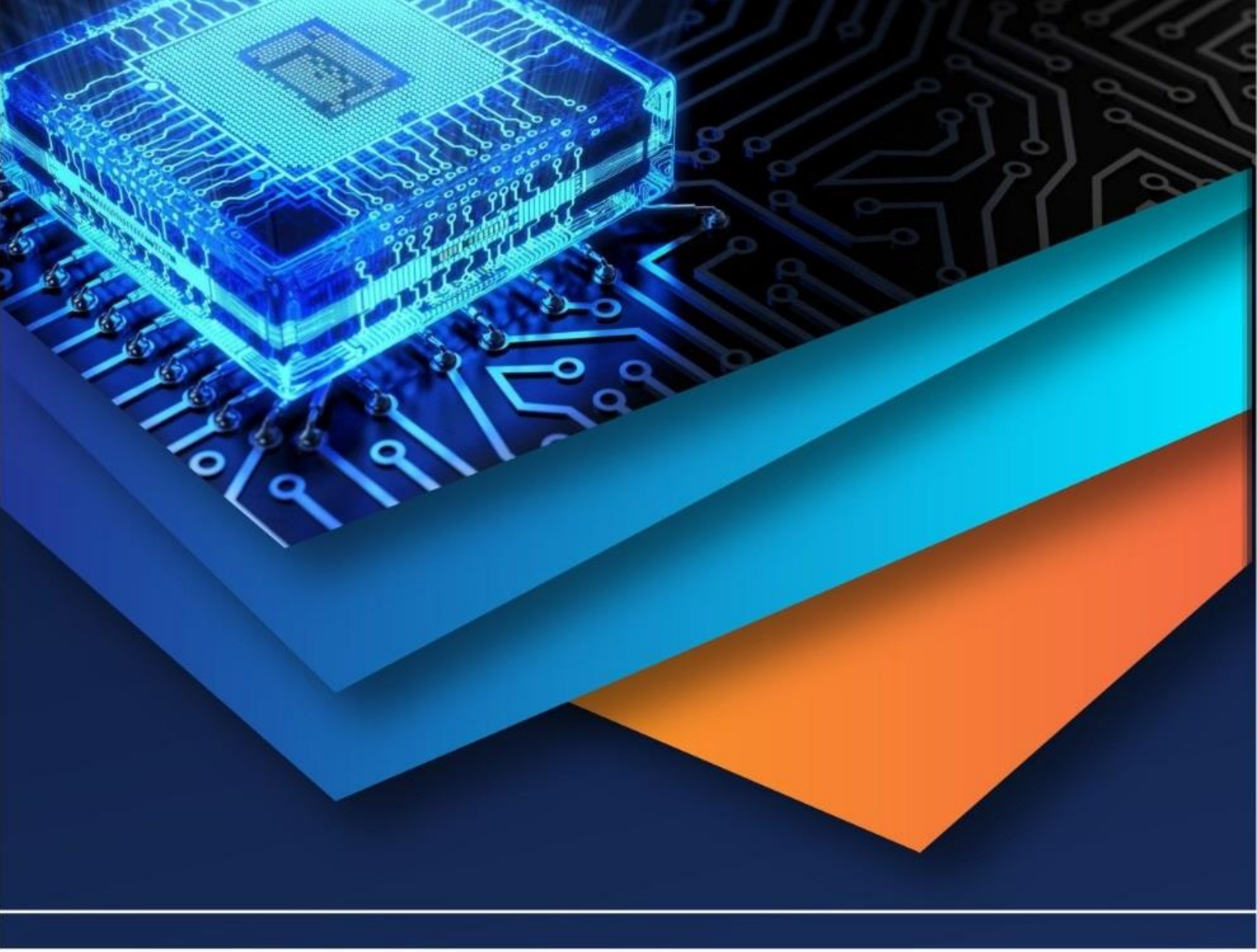

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