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## Optimization Technique in Pharmaceutical Formulation and Processing – Review Article



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**Dhaneshwar Vishwakarma\*, Ravi Prakash Chaudhary, Vikas Kumar, Naveen Shukla, Vinay Gupta**

*Kailash Institute of Pharmacy and Management, Plot No. BL 1 &2, Sector 9, Gida Gorakhpur, U.P.- 273209 India.*

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### ABSTRACT

This review article aims to understand about optimization technique which is made easy the pharmaceutical formulation and process. Information about terminology used in optimization technique, need of optimization, parameter, classical optimization, advantage, limitation of optimization. In this article also mentioned about quality by design, and different experimental designs. That explains about what is the quality by design and experimental design that used in optimization techniques. This article describes about future scope of an optimization technique in the pharmacy-related formulation and process. Thus, the optimization techniques play the most important role in various pharmaceutical process and formulation that gives profits and minimize the period of the pharmaceutical industry.



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## INTRODUCTION

Optimization term is defined as “to make perfect” which means to make the perfect anything using different techniques and processes. Optimization techniques are used in the different formulations of drugs which help to make good products. It involves in the various form of drug product and their process. Optimization technique are used in the finding solution of a slew of issues relating to the pharmaceutical process and product such as new drug development selection of excipients, formulation, manufacturing and other pharmacy-related problems. Due to the optimization technique we examine the various problems that occur during research. Optimization technique are helpful to make easy the process and formulation of pharmaceutical products and processes. It provides diverse design quality of formulation and experiment design, as well as systemic and mannered strategies and performance, which are investigated by changing the experimental variable to assess the effect on the specific response. The optimization strategies aid in the development of safe, effective, low-toxicity, and low-adverse-effect drug products, as well as cost effective products that are accessible to everyone. Nowadays the pharmaceutical industry are working on novel idea by using different optimization techniques, which the main aim to improve public health.

“It is not a screening technique”.

### 1. TERMINOLOGY USED IN THE OPTIMIZATION TECHNIQUE -

**Factor** –The variable which is affect the process and pharmaceutical product such as concentration, temperature, pH, and environmental factors.

**Level**- Values assigned for the factors are level.

**Variable** – The value that are characteristics of the data.

**Response Surface**- The relationship between the independent and dependent variables is represented by the response surface.

**Screening**- To separate something from the given mixture.

**Response**- Outcomes of any experiment.

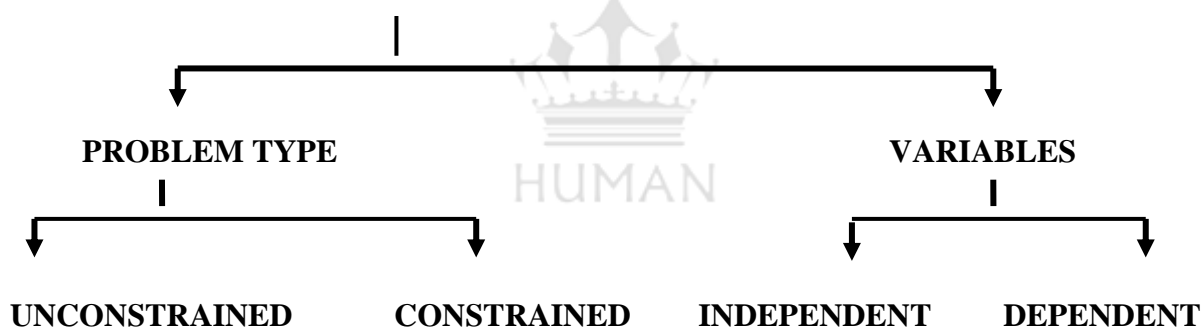
**Effect**- The effect is the change in reaction generated by the level variable, and it describes the link between numerous elements and the level.

**Interaction-** It is a term that refers to the combined effect of two or more elements. Variable mean lack of additivity of factor effects.

## 2. NEED FOR OPTIMIZATION TECHNIQUE-

- To improve the quality, and quantity of formulation.
- To find out the solution to the pharmaceutical problems.
- To improve the productivity of the product.
- To make the easy the process of formulation and its process.
- To save time.
- Reducing the cost of formulation and process.
- To decrease the chance of error.

## 3. OPTIMIZATION PARAMETER



**Unconstrained-** In this system, the restriction is not based on physical limitations. For example, one might want to make an uncoated tablet possible for a specific pharmaceutical system.

**Constrained-** In this system the restriction is based on physical limitations. As a result, the constrained challenge is to make the uncoated tablet but it should not be disintegrate in the stomach.

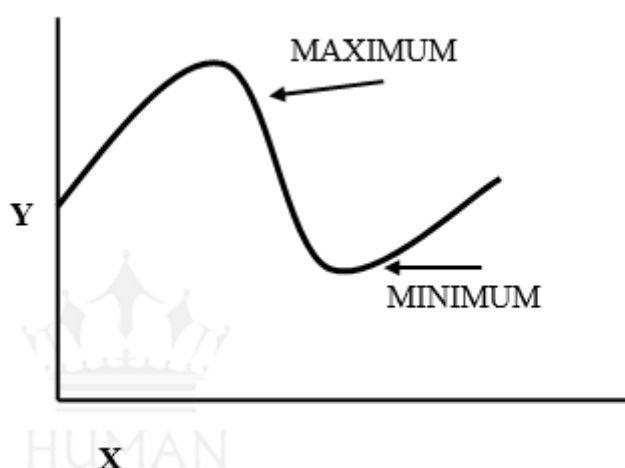
**Independent-** This type of variable are come under the supervision of a formulator like the force of compression, lubrication level, binder level etc.

**Dependent** -The formulator has no direct control over this type of variable. They are reliant on an unrelated variable. These are responses like hardness, flow property, and friability, among others.

**4. CLASSICAL OPTIMIZATION** - It is accomplished by applying calculus to a basic problem to determine the maximum and lowest values of a function.

The curve depicts the relationship between a single independent variable X and the response Y, from which we can derive the maximum and minimum functions. If the equation for Y as a function of X is –

$$Y=f(X)$$



**Fig. No. 1-** Classical Optimization Curve

#### **5. APPLICATION-**

- It is used in formulation and processing.
- It is used in clinical chemistry and Medicinal chemistry.
- It is used in HPLC analysis.
- It is used in the formulation of culture medium in the virological study.
- It is also used in the pharmacokinetic parameter.

**6. QUALITY BY DESIGN (QbD)** - QbD is the systemic process for the development and manufacturing, that ensures that the final product is according to our expect such as quality, the efficacy of the drug product.

Quality by design is done through an understanding of the technical process, variables and the effect of the variable on the process to achieve the goal. The benefit of the quality by design to both consumer (since the product is more consist, safe and effective) and manufacturer (since quality and costs will be controlled, known, and reliable). The quality of the product can be evaluated by in vivo and in vitro test. QbD give information about in vitro performance and in vitro study informs about in vivo performance of the drug product.

#### **7. ADVANTAGE OF QUALITY BY DESIGN-**

- It gives better understanding of the manufacturing process.
- Decrease the chance of batch failure.
- It gives more quality product.
- It gives safer and more effective product.
- It helps to understand the cost and need of the manufacturing process.
- It improves the consistency of the drug product.

**8. EXPERIMENTAL DESIGN-** An experimental design is a statistical design that informs a set of variables. Different experimental designs are used based on the model's factor, level, interaction, and order.

**9. FACTORIAL DESIGN-** A factorial design allows researchers to examine the effect of multiple elements, as well as their interactions, using the same number of trials. These are some of the most commonly utilised design response surfaces.

**10. FRACTIONAL FACTORIAL DESIGN-** This method is commonly used for factor screening. The fractional factorial design reduces the number of experiments, resulting in lower resolution and thereby saving money.

**11. FULL FACTORIAL DESIGN-** It uses dimensional factor space at corner of the design space. In which the effect of different factor leads to the determination of the effect of several factors and their interactions.

**12. PLACKETT-BURMAN DESIGN (HADAMARD DESIGNS)** - These are two-level Fractional Factorial Designs that are used for factor screening. Plackett-Burman designs are also known as saturated designs because they identify big main impacts while ignoring other interactions.

**13. CENTRAL COMPOSITE DESIGN (CCD) (BOX-WILSON DESIGN)**– It was created for nonlinear reactions that required the use of second modals.

**14. TAGUCHI DESIGN**- t provides the best results in the creation of processes and products, which is why Taguchi design is referred to as off-line quality control.

**15. MATURE DESIGN**- In this design, the quantity of each component is represented, but not their portions, because excipients are all one.

## **CONCLUSION-**

Optimization techniques the technique which make the easy the formulation and processing. It is the part of the development process and it help to understand the problem are rise during the experiment of the formulation. It aids in the manufacture of a high-quality product with the desired bioavailability. If product is optimum and good then the profit of the company is increases. Due to the optimization technique the quality, quantity, efficacy, and production are improving.

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