ISSN: 2321-3760

Review Article

International Journal of Current Trends in Pharmaceutical Research

IJCTPR, 2014, Vol. 2(3): 491-493

www.pharmaresearchlibrary.com/ijctpr

Optimization Techniques : A future of Pharmaceutical Product Development

Suhas.S Siddheshwar*, Prajakta.S. Varpe, Ganesh.A. Waghmare, Prashant.B. Wadghule, Dattaprasad.N. Vikhe

Pravara Rural College of Pharmacy, A/P-Loni, Tal-Raiatea, Dist.Ahmednagar, India-413736

Received: 15 March 2014, Accepted: 28 April 2014, Published Online: 15 May 2014

Abstract

Optimization of product or process is determination of experimental conditions resulting in its optimal performance. Optimization has been defined as the implementation of systemic approaches to achieve the best combination of product and process characteristics under a given set of conditions. In today's pharmaceuticals optimization is emerged as a technique for the best compromising answer to a particular question. The term optimization means to optimize something, or use something at its best. Optimization is finding a perfect, effective or functional answer. There is no single solution to design optimization tasks. Many techniques are available for this.

Key words: Optimization, problems, variables, experimental designs

Contents

***Corresponding author**
Suhas.S Siddheshwar
Pravara Rural College of Pharmacy,
A/P-Loni, Tal-Rahata, Ahmednagar, India
E-mail: ssiddheshwar@gmail.com
Manuscript ID: IJCTPR2052

PAPER-QR CODE

1. Introduction

Definition:

The term optimization is often used in pharmacy related to formulation to processing. Optimization is not a screening process. In developmental projects one generate experiments by series of logical steps, carefully controlling the variables & changing one at a time until a satisfactory system is produced. To make as perfect, effective or functional as possible

Terms used in Optimization:

Variables: These are the measurements, values, which are characteristics of the data. There are two types of variables, dependent and independent variables. Independent variables are the variables, which are not dependent on any other value Eg: concentration of lubricants, drug to polymer ratio, etc.

Dependent variables are dependent on the concentration of independent variable used.

Factor:

Factor is an assigned variable such as concentration, temperature, lubricating agent, drug-topolymer ratio, polymer-to-polymer ratio or grade. A factor can be qualitative or quantitative. A quantitative factor has a numerical value to it e.g., concentration (1%, 2% so on), drug to polymer ratio (1:1, 1:2 etc). Qualitative factors are the factors, which are not numerical.

E.g: Polymer grades, humidity condition, type of equipment etc. These are discrete in nature.

Levels:

The levels of a factor are values or designation assigned to the factor, e.g., concentration (factor) 1% will be one level, while 2% will be another level.Two different plasticizers are levels of grade factor. Usually levels are indicated as low, middle or high level. Normally for ease of calculation the numeric and discrete levels are converted to -1 (low level) and +1 (high level)

Response: Response is mostly interpreted as the outcome of an experiment. It is the effect, which we are going to evaluate i.e., disintegration time, duration of buoyancy, thickness, etc.

Effect: The effect of a factor is the change in response caused by varying the levels of the factor. This describes the relationship between factors and levels.

Interaction: It is also similar to the term effect, which gives the overall effect of two or more variables

Factors of a response:

For example, the combined effect of lubricant (factor) and glidant (factor) on hardness (response) of a tablet. From the optimization we can draw conclusion about. Effect of a factor on a response i.e., change in dissolution rate as the drug to polymer ratio changes.

2. Optimization parameters

The optimization parameters are classified into two types

A) Problem type B) Variables

A) Problem type:

The problem type of parameters again grouped

a) Constrained type:

Constrained types are, restrictions placed on the system by means of a physical limitations or perhaps by simply practical based. This can best explained by taking hardness of tablet and its disintegrating time in less than 15 min.

b) Unconstrained type:

In unconstrained type there are no restrictions placed on the system by means of a physical limitations or perhaps by simply practical based. But in pharmaceuticals, there is always alimitation of a means of a physical limitation or perhaps by simply practically the formulator wishes to place or must place on a System.

B) Variables:

There are several Variables in pharmaceutical formulation and processing but generally variables can be classified into, a) Independent variables b) Dependent variables

Independent variables:

These are the variables which are directly under the control of the formulator, such as mixing time etc.

Dependent variables:

These are the variables which are not directly under the control of the formulator, these variables are the responses or the characteristics of the in process materials or the results. These are a direct result of any change in the formulation or a process such as homogeneity of the mixed granules

3. Experimental Method

Experimental Designsinvolve:

a. Full factorial design
b. Plackett and Burman design
c. Fractional factorial design
d. Central composite design
e. Simplex lattice designs
f. Lagrangian method

Experimental design:

The concept of experimental design originated in the agricultural industry & was developed by Sir Ronald Fisher in 1926 followed by book “The Design of Experiments in 1935”. From 1990 design of experiment techniques were used for either formulation or process optimizations.

- Benefits of experimental design

- Saving time, money & drug substance.
- Identification of interactions effects.
- Characterization of response surface.

Forms of Optimization techniques:

There are three forms of systematic optimization techniques:-

1. Sequential Optimization
2. Simultaneous Optimization techniques.
3. Combination of both.

1. Sequential Methods:

This method is also referred to as the "Hill climbing method". As first of all a small number of experiments are done and further research will be done by using the increase or decrease of response. In this way a maximum or minimum will be reached2. Simultaneous Methods:-This method involves the use of full range of experiments by an experimental design and the results are than used to fit in the mathematical model. And maximum or minimum response will then be found through this fitted model.

Multi-modal optimization:

Optimization problems are often multi-modal, that is they possess multiple good solutions. They could all be globally good (same cost function value) or there could be a mix of globally good and locally good solutions. Obtaining all (or at least some of) the multiple solutions is the goal of a multi-modal optimizer.

Classic Optimization:

Classical optimization techniques due to their iterative approach do not perform satisfactorily when they are used to obtain multiple solutions, since it is not guaranteed that different solutions willbe obtained even with different starting points in multiple runs.

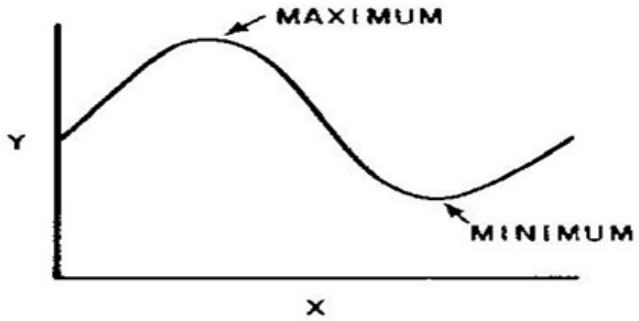

Figure.1 Classic Optimization

4. Conclusion

A pharmaceutical formulation is composed of several formulation factors and process variables. Several responses relating to the effectiveness, usefulness and stability, as well as safety, must be optimized simultaneously. Consequently, expertise and experience are required to design acceptable pharmaceutical formulations. Experimental design, including factorial design and response surface, is a multivariate approach recommended for the development of analytical methods. This approach is applied to (a) reduce large amount of data that could be easily interpreted, (b) examine main and interaction effects of experimental conditions on the efficiency of methods, and (c) optimize simultaneously experimental conditions regarding their interaction with each other by a minimum number of experiments.

5. References

1. Kuchekar, B.S., Badhan, A.C., Mahajan, HS. Mouth dissolving tablets: A Novel Drug Delivery System, Pharm Times., **2003**, 35: 7-9.
2. Corveleyn S., Remon J.P., Formulation & production of rapidly disintegrating tablets, **2001**, 1(2): 234-237.
3. Kwala, A., Vincent, H., Lee, L., Geaham, D. Mathew K .Fast disintegrating tablets, December 6, US Patent 6733781, **2000**.
4. Boltonn, S., Pharmaceutical Statistics. New York, NY Marcel Decker Inc, 2nd edition. **1990**, 532-570.
5. Parakh, S.R, Gothoskar, A. A review of Mouth Dissolving Tablets Technologies, Pharm. Technol., **2003**, 27(11), 92-100.
6. TakayamaK., Fujikawa M., Obata Y., Morishita M., Nagai T. Optimization ofpharmaceutical formulations based on artificialneural networks, Journal of Pharmaceutical Science and Technology, Japan, 2.