Section A-Research paper

OPTIMIZATION SOFTWARE'S USED IN PHARMACEUTICAL MANUFACTURING INDUSTIRES

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Abstract:

These days the use of optimization software has become the most appropriate and realistically useful experimental designs and optimization approaches so to identify the different potential approach accessible to improve the quality, safety, and effectiveness of pharmaceutical products. To reach the optimal composition of formulation and process attributes under the predetermined set of conditions, we will discuss the most contemporary software, experimental designs, and optimization techniques. Different computer software plays a crucial function in keeping track of and maintaining the current pharmaceutical business processes. The methods that are simultaneously and systematically utilized to detect various types of issues that may affect pharmaceutical formulation research, development, and production include experimental designs and optimization procedures. Establishing the relationship between the influences on a process and its outcomes can be done systematically. To improve product quality by utilising the most appropriate facilities, various softwares has been employed in the implementation of optimization approaches in pharmaceutical products. The pharmaceutical industry can improve their cGMP practices and regulatory body compliance by installing software like design expert. This review focus on the different softwares available that can be used in many industries, also the major characteristics of the softwares will be discussed.

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KEYWORDS

Experimental design, Optimization, Regulatory body, Computer software's, Design expert, Pharmaceutical business, cGMP Practices.

INTRODUCTION:

We often employ a variety of optimization strategies to identify the solution because it is not always easy to do so instantly or directly. Even if optimization is not as straightforward as we initially thought, it will still lead to some conclusions. The verb "optimize," which meaning to make anything as good, practical, or effective as possible, is where the term "optimization" originates. The term "optimized" used to be used to describe pharmaceutical preparations or pharmaceutical procedures to signify that a formulation had been enhanced to suit the objective of a development scientist or researcher. Optimization is a method for determining the best experimental setup or composition for the target formulation or result. Optimization is the use of systematic methodologies to attain the optimum possible combination of product & process attributes within a given set of restrictions. Alternatively, it is possible to define optimization as the process of deciding which element, out of a range of choices, is best. The terms Formulation by Design and Quality by Design demonstrate how the primary objective of creating high-quality formulations may be accomplished by utilising various Experimental Design (ED) methodologies. Previously, any new pharmaceutical formulation was created by researching how composition and process variables affected the characteristics of the dosage forms, changing one distinct factor at a time while maintaining other factors at their original levels.[1] This approach was also referred to as adjusting one variable or element at a time. Problems may be resolved with this method, but it does not ensure that the concentration or procedure used will always result in the best product. Traditional approaches have certain drawbacks, such being unpredictable, uneconomical, time-consuming, and energy-intensive. They are also not suited for

detecting faults and only produce usable solutions. Therefore, a novel approach—an optimization method using systematic ED—was applied to address these problems.

The most recent methods of drug delivery system optimization in pharmaceuticals are represented by the following steps:

1. Nanoparticles in which the drug particles are delivered to certain cells or tissues in the body using these minuscule particles, which range in size from 1-1000 nm. Since they have a high surface area to volume ratio, the loading and distribution of drugs is improved. Dendrimers, polymeric nanoparticles, and liposomes are a few types of nanoparticles that are employed in medication delivery.
2. Delivering medications directly to the location of action, such as a tumor or inflammatory tissue, is known as targeted drug delivery. This can be achieved by using ligands that selectively bind to receptors on target cells or by using stimuli-responsive materials that release drugs in response to a specific trigger, such as pH or temperature. Combination treatments: In order to improve treatment outcomes, combination therapies give many medications at once. The utilization of drug-loaded nanoparticles, which combine many medications into single nanoparticles for simultaneous delivery, can be used to accomplish this.
3. Delivering genes to cells in order to treat or prevent illness is known as gene therapy. This may be done either by using non-viral techniques like electroporation or lipofection or by using viral vectors, which are modified viruses that can transfer genes to cells.
4. Drug Delivery based on Polymers: Drug delivery methods may be made using polymers, which are large chains of repeating units.[1] For sustained-release formulations, polymer-based drug delivery systems are the best choice since they can be made to release medications gradually over a set length of time.

5. Systems for the surgical implantation of pharmaceuticals into the body known as "implantable drug delivery systems" allow for the continuous supply of medications. Drugs may be released from them at a predetermined pace or in reaction to particular triggers.

The goals of optimization approaches include upholding public and industrial quality, economy, and safety. As opposed to this, optimizing a pharmaceutical product entailed identifying key factors, finding a more cost-effective way to make the formulation & enhancing the coherence and utility of the quality specifications in the product. Particularly, tools like experimental design are utilized to examine various problems that emerge throughout production, development, and research. It goes without saying that random experimentation will produce random results. Therefore, it is crucial to design the tests such that the necessary data would be gathered.[2]

MATERIALS & METHODS

Important terminology used in optimization:

1. Objective function- The function that has to be optimized is this one. It stands for the performance metric that should be increased or decreased.

2. Constraints- Limitations or requirements that must be met in order to optimize the objective function are referred to as constraints. The input variables, the output variables, or other factors may be the subject of constraints.

3. Variables- These measurements or values define the data's qualities. Dependent and independent variables are two different sorts of variables.[2] Ingredients are directly regulated by

the formulator along with other process and formulation factors. The reactions of work-in-progress or the final medication delivery system are dependent or secondary factors; they are the outcome of independent variables. The goal function can be optimized by changing these variables. The kind and quantity of the medication, the type and quantity of the delivery vehicle, and the mechanism of distribution are all potential factors in drug delivery systems.

4. Optimization algorithm- This approach is used to look for the objective function's best solution given the restrictions. Gradient-based techniques, evolutionary algorithms, and simulated annealing are examples of optimization strategies that can be either deterministic or stochastic. Pharma Technology is rife with optimization algorithms, which look for the mathematical functions' minimal values. They are used, among other things, to analyze control systems, evaluate design choices, and look for patterns in data.

5. Sensitivity analysis- Sensitivity analysis is a method for determining how little changes in the input variables will affect the output variables. Sensitivity analysis may be used to fine-tune the optimization process and assist in determining the most crucial input variables.[2] Its main goal is to ascertain if factors causing uncertainty in a model's input may also be utilized to account for uncertainty in the model's output.

6. Factor- An assigned variable is known as a factor, and grade, temperature, lubricant, drug-to-polymer ratio, polymer-to-polymer ratio, and concentration are a few examples of factors that can be allocated. You can employ a qualitative or quantitative component. A numerical value is assigned to quantitative aspects like concentration (1%, 2%, and so on), drug to polymer ratio, and so forth (1:1, 1:2, etc.). Qualitative elements are those that cannot be quantified numerically, such as the types of equipment, humidity levels, and polymer grades. They are distinct in nature.

Table no.1 Table of required softwares for respected working area

Working area's	Requirements
competent to promise and willing to pledge	Available to promise (ATP) and competent to promise (CTP) are two metrics for manufacturing capacity. For every stock item, the systems must compute the ATP & CTP, taking into account any ingredients on hand and any work that is currently being done.
Recall management & lot tracking	Every lot has to be tracked and recognized.[3] The components of the lot must also be linked to their unique batch numbers.
Formulating & sizing	The program should involve formulation control, such as component substitution & batch scaling. Batch sizes and product quantities can be matched by modern technologies. The system's need to offer formulas with different strengths.
Recall management	The recalls are being implemented for two reasons. First, a process mistake makes it possible for a product to be contaminated or tainted. Second, a component may be contaminated or diseased. In any instance, the system must disclose all impacted batches, & the consumers who bought these batches are must.
Hazard analysis critical control points compliance (HACCP)	Hazard Analysis Critical Control Points (HACCP) Principle 7: Establish record-keeping and documentation requirements should be reflected in the system's reporting

	for HACCP.
FDA Compliance	Both conventional and homoeopathic medicines are subject to FDA regulation; the labeling specifications are the same but differ in specific ways. The program should accurately designate normal and homoeopathic products as necessary.[3]
Quality assurance	Its structure will support quality assurance checks. The protocols should be systematized, documented, and then put into use. For testing, samples will be randomly assigned to categories, and test outcomes will be compared to expectations. Dashboards in more advanced systems will notify administrators of quality problems.
Process analytical technical support	As part of testing for quality assurance, the system should identify crucial process variables and specify how they affect crucial quality attributes.

The assigned and independent variable has an impact on the process's output or product:

The factor is often regarded as an independent variable that can impact the results of an experiment or procedure. Depending on the type of factor and the research issue being examined, factors might be given quantitative or qualitative values.[4]

For instance, in a study on plant development, variables like the quantity of sunshine, water, and fertilizer given to the plants may be given numerical values (e.g., hours of sunlight per day, milliliters of water per week, grammes of fertilizer per month). On the other side, qualitative

values may be attributed to elements like the type of soil, the presence of pests or diseases, and the genetic make-up of the plants (e.g., sandy or clay soil, presence or absence of aphids or fungus, genetically modified or non-modified plants).

In order to derive meaningful and trustworthy conclusions regarding the link between the elements and the process' result, it is important to assign values to the components in order to make sure that they can be precisely monitored and controlled in the experimental way.

These are the optimization parameters:

There are two different categories of optimization parameters:

- Problem type & Variables.

1. Problem type- This problem type is again grouped into two types which are;

- **Constrained type**: Systems that have limitations placed on them because of physical restrictions or perhaps just pragmatic concerns are referred to as constrained types.[5] Comparing the hardness of the pill to how rapidly it dissolves in less than 15 minutes to make this concept clearer.

- **Unconstrained type**: When a system is unconstrained, it is not restricted by practical restrictions or even by physical ones. But in the realm of drugs, there is always a limitation that the formulator wants to or needs to place on a system, whether it be a physical limitation or simply a practical one.

2. Variables- Although there are many factors involved in the formulation and manufacturing of pharmaceuticals, most variables may be classified into two categories:

- **Independent variables**: They are directly under the formulator's command. For example, mixing time.

- **Dependent variables**: They are not directly managed by the formulator. For example, homogeneity of mixed particles.

➢ **Factorial designs**

John Bennet Lawes and Joseph Henry Gilbert employed factorial designs (FD) for the first time in the nineteenth century. A factorial design enables the same number of trials to be used to assess the effects of several factors and even their interactions as are required to determine each factor's influence independently and to the same degree.[6] These patterns are among the most popular ones for response surfaces. In a factorial experiment, every level of a certain element is paired with every level of every other factor. These often have first-degree mathematical models as their foundation. Factorial designs firstly need to be the go-to design anytime we're interested in looking at treatment variances. Furthermore, factorial designs are productive. We may effectively merge these investigations into one rather than doing a number of distinct ones. Last but not least, this is the only practical approach to look at interaction effects. Ibuprofen fast-dissolving tablet optimization is the most recent FD application.

➢ **Fractional factorial design**

A fractional factorial design is typically used for factor screening. There haven't been as many runs, therefore the resolution is weak. Despite the fact that these designs are cost-effective in terms of the number of trials, the ability to discriminate some of the factor effects is slightly compromised by the decrease in testing. In a fractional factorial design, a small subset of possible factor and level combinations are looked at. As a result, fewer tests are needed, which enables a more efficient use of resources. Additionally, it suggests that not all possible interactions between factors are amenable to investigation.[6]

In scientific and industrial investigations where it is unfeasible or too expensive to examine every potential combination of elements, fractional factorial designs are frequently utilized. They are especially helpful when there are plenty of variables at play or a finite number of runs

(experiments) that may be carried out. The precise fractional factorial design used depends on the experiment's goals and the resources at hand. There are many distinct designs available, including the Taguchi, Plackett-Burman, and 2-level fractional factorial designs. Each design has certain advantages and disadvantages and is appropriate for various kinds of studies.

- **Full factorial design (FFD)**

A statistical experimental design technique known as the full factorial design is used to examine the impact of several factors on an interest response or outcome. The levels of all conceivable combinations of the independent variables are evaluated in this design, allowing for the detection of both main effects and inter-variable interactions. A full factorial design would test all four conceivable combinations, such as A-low/B-low, A-low/B-high, A-high/B-high, for example, if a research is looking at the impacts of two components, A and B, each having two levels (low and high). This enables the analysis of the interaction between each element and its combined effects on the end variable. Full factorial designs may be quite effective at revealing significant correlations between variables, but they are also time and resource-consuming and may need several experimental runs. The number of experimental runs required can be decreased by using partial factorial designs, which only test a portion of all potential combinations.

It is an experimental design that takes use of the design space's corner's dimensional component. The effects of several factors and their interactions are simultaneously assessed in studies using factorial designs (FD).[7] They are also employed in research to ascertain the results of various circumstances or elements. Since just two factors are included at each of its two levels, the two factorial designs (FD) are the simplest factorial designs. Four trials are produced as a consequence, which are then positioned at the four corners of a rectangle in two-dimensional factor space. If there are three components, each at two levels, then eight experiments are needed, distributed at the four corners of an orthogonal cube in three dimensions. The number of experiments is given by 2, where 'n' is the number of components. If there are several

components and levels, a factorial design necessitates the completion of a substantial number of experiments.

- **Central composite design (CCM)**

In order to determine the estimated optimum direction in RSM because the optimization and ideal position are unknowns, central composite design is employed. Additionally, CCD has readability, therefore by doing this, the value of (y (x)) at point x, which is at the same distance, will remain constant. The test points in the CCD are chosen based on the test limit values specified to each study component.[7] The response data is modeled using an appropriate mathematical framework. Mean, linear, quadratic, 2FI, and cubic models are among those used in Central composite design (CCD). The criteria for choosing models for mixed designs are the same as those for choosing the response model. The value attractiveness obtained allows us to observe the resolution of the optimal location.

- **Response surface methodology (RSM)**

The Box-Wilson Methodology is another name for the technique called response surface methodology (RSM). In modeling and analyzing issues where the answer is affected by numerous variables, surface methodology replies are a combination of statistical and mathematical methodologies. The input data that impact a response or result variable (output) are linked together using the response surface approach. If an area with the best reaction is identified, a model is built to link to that region so that the study may be done to locate the best location.[7] According to the protocol, RSM usage must be done in the correct order. Equation (1) is employed when a physical event is distant from its ideal state.

$$y = \beta_0+\beta_1x_1+\beta_2x_2+\ldots+\beta_kx_k+\varepsilon \ldots\ldots (1)$$

Equation represents a multivariate regression model with two independent variables. (1).

The regressor or predictor variable is the name given to this independent variable. A fixed intercept value is 0 (zero). A partial regression coefficient of 1 and 2 quantifies the change in y for each change in x1 units and the change in y for each change in xunits2, respectively. Through the optimization process, this equation will help scientist & researchers get close to the ideal region. Second model, or equation (2), is used once the optimal region has been identified.

$$y = \beta_0+\beta_1x_1+\beta_2x_2+\beta_{11}x_{12}+\beta_{22}x_{22}+\beta_{12}x_1x_2+\varepsilon\ldots\ldots (2)$$

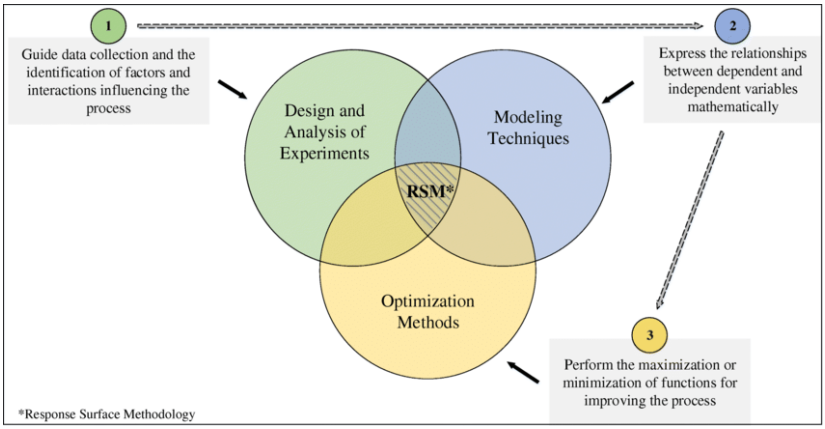

Figure no. 01 Optimization process using (RSM) Response surface methodology.

- **Box-Bhenken design (BBD)**

Three distinct aspects are used for optimization using Box-Bhenken Design (BBD). Since it requires less run/experimental units, the Box-Bhenken Design (BBD) trial and Central Composite Design (CCD) comparison are more efficient than Central Composite Design. Box-Bhenken can precisely predict the best value for both linear and quadratic functions despite the fact that there are fewer trails.[8]

Various softwares used in pharmaceutical manufacturing industries:

1. Design expert-

The software design Expert was developed by the State Ease. This was originally made available in 1996 to assist with the execution of experimental designs, such as figuring out the best preparation recipe. In addition to optimization, this program can understand the experimental variables. Depending on the experimental design to be used, there are three options for research directions in software. Options include screening, characterizing, and optimizing. The least quantity of information is provided yet the least amount of run is needed for screening. The number of experiments known as a run must be performed in accordance with the chosen experimental design. If there are more than six potential causes, but it is unclear which one will really have an impact, screening is utilized. Several significant factors were identified utilising only two levels of each component and main effect estimates (interaction was not present). Follow-up with the second DOE is necessary to estimate interactions and future requirements. The characterization yields more information but requires more runs per component.[8] It is used with a small number of variables (Around 10). Fit a two-factor interaction model to identify the factors and their interactions that significantly affect the answer.

To find non-linear interactions, consider adding a midpoint to this design if the components are decreased. The midpoint can be used as a starting point to find a factor value that maximizes or minimizes responsiveness when no curves are visible. The greatest information will be provided via optimization, but it will also take the most runs per element. After reducing the number of elements (Around 6) that are known to be significant and whose optimal probability is in the area being tested, optimization is utilized. It may be used to identify factor settings that either increase or decrease the response of the three possible experimental design options, each of which has three employable techniques: factorial/response surface, mixed, and combination.

2. Process pro-

ProcessPro's ERP system offers comprehensive production, stock, and economic integration and is a complete system from order input to production and accounting. The programme takes care of the essential needs for batch processing, such as complicated operations, ingredients management, on and reverses lot quality control, and on-and-reverse lot quality assurance.[9] The firm can instantly and reliably see income, production, and inventory thanks to the centralised database, and re-entering data is no longer necessary thanks to the better integrated quality control capabilities.

Power & baking of Microsoft

The enterprise resource planning (ERP) solutions from ProcessPro are built particularly for flexibility to meet the individual demands of your particular organisation while remaining current with the most recent standard update. These systems are built specifically on Microsoft's cutting-edge technologies, including.NET, SOA, and SQL Server.

Warehouse Management, Enforcement, Point of Sale, Direct Store Supply, Maintenance and Repair, Field Service, Fixed Assets, Project Costing, Payroll, Human Resources, EDI, and much more are added to Development, Stock, Performance, Financials, and Sales.[9] The software solution incorporates the essential business requirements of process users.

3. ProcessPro's comprehensive analytics and reporting software-

ProcessPro is software that provides dynamic views "on-the-fly" with countless reporting options. Users may easily access the data and manipulate and visualise the information by being able to record, scan, filter, and query as necessary. Key business information is provided on predetermined, editable dashboards, boosting out-of-the-box management capabilities. It is an advanced analytical tool that allows interactive data visualisation, reporting, and analysis from any desktop or mobile device, wherever in your organisation. Advanced Analytics also includes a powerful data reporting warehouse.[10] In any case, a crucial tool for your company analysis is

provided by charting, sorting, and delving into the crucial business data in conjunction with thorough pre-constructed reports, metrics, and KPIs, scheduling, and warnings. The organisation of the data and predefined relationships enable the research to be expanded to include other pre-built business resources.

4. BatchMaster ERP-

The creation and delivery of software solutions for the food, chemical, nutraceutical, and pharmaceutical sectors is the only focus of BatchMaster Software. The application enables R&D, formulation, packaging, costing, production, QC, QA, inventory, compliance, and traceability. It is based on formulas and is used in process manufacturing. Optional modules include sample management, preparation (MRP), scheduling (MPS), warehousing, alert management, and exchange of EDIs. Such technologies enable companies to quickly simplify and expand their operations, save expenses, and easily comply with today's more onerous regulatory regulations.

5. S2K enterprise software-

The joint strategy between VAI and IBM, the technology roadmap, provides companies with a business that depends on industry best practises and uses technology to improve quality and increase performance.[10] Distribution, manufacturing, retail, utilities, and leasing solutions are all part of the S2 K product family, which also has features tailored to the pharmaceutical, apparel, and durable goods industries.

6. S2K Analytics-

A strong business intelligence platform like VAI S2 K Analytics can assist you in managing efficiency, having a clear understanding of sales and productivity, tracking costs, and effectively managing scattered and dynamic suppliers. The workforce may get information from S2 K Enterprise using this straightforward yet practical solution, enabling them to make wiser decisions.

7. ResponsePro-

The pharmaceutical, medical, food, and chemical sectors use the ResponsePro ERP (Enterprise Resource Planning) system from 2 M Technologies, Inc. Since 1987, 2 M has assisted companies in making the most of their technological investments. ResponsePro gives you a competitive advantage to boost productivity and profitability and is accessible in both Linux and Windows platforms.[11-34]

It includes features, including publishing reports to secure websites and powerful search capabilities for any query or entry page to enable quicker action or entry.

CONCLUSION

We may draw the conclusion that these factors are extremely significant in boosting the quality, safety, and efficacy of pharmaceutical goods after having a full research on the influence of OT, experimental designs, and much other software in pharmaceutical formulations. By lowering the number of experimental trials conducted throughout the formulation development process, optimization approaches can also assist to lower the cost of the product. In addition to analyzing precise quality guarantees for regulatory bodies indicating improved product quality, optimized experimental designs are also beneficial in this respect. According to the study mentioned above, FD, CCD, FFD, and RSM are the most popular designs for optimization. An emerging area of research is the optimization of pharmaceutical formulations by various experimental designs, or other software's.

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