Ind. J. Res. Methods Pharm. Sci. 2022; 1(4):10-13
ISSN (Online): 2583-3804

MINI REVIEW ARTICLE

REVIEW ON INHALATION FORMULATION DEVELOPMENT

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Received: 7 Aug 2022/ Accepted in revised form: 15 Aug 2022 / Published online: 20 Aug 2022

ABSTRACT:
Inhalation drug delivery via inhalation is a well-established and widely used method for delivering drugs to the lungs. Inhalation developers work to ensure that the drug is effective when inhaled and that it does not cause any adverse effects. The goal of inhalation formulation development is to produce a formulation that will be safe and effective for the intended patient population. Inhalation formulation development is a complex process that involves many different factors. Particle size is one of the most important considerations in this process, as it can impact both the efficacy and safety of the final product. There are a variety of methods available for particle size analysis, each with its own advantages and disadvantages. The GSD is a unitless quantity that provides a measure of how widely dispersed the particles are in terms of their sizes. It can be used to compare different particle size distributions or to track changes in the dispersion of a particle size distribution over time. The GSD can be affected by many factors, including changes in temperature, humidity, and pressure.

Key words: *Formulation development, Inhalation, Pulmonary Drug Delivery, Geometric Standard Deviation.*

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INTRODUCTION:

Inhalation formulation development is a complex procedure that involves numerous steps. It is important to consider the properties of an inhalation formulation in order to develop a successful and effective product [1,2]. In this article, we will explore the key elements of inhalation formulation development, including the physical characteristics, chemical interactions, and dosage forms. We will also discuss some of the tools available to assist with inhalation formulation development. Finally, the authors provide a review of several existing products on the market today to help guide prospective researcher's decision on which product may be right for the intended purpose.

PULMONARY DRUG DELIVERY:

Pulmonary drug delivery via inhalation is a well-established and widely used method for delivering drugs to the lungs. Inhalation formulations are designed to deliver the drug to the lungs in an aerosable form, such as an aerosable powder or liquid [2].

Inhalation formulation development must consider several factors, such as the physical and chemical properties of the drug, the device used for administration, and patient characteristics. The goal of inhalation

formulation development is to produce a formulation that will be safe and effective for the intended patient population [3].

There are many challenges associated with inhalation formulation development, but significant advances have been made in recent years [4]. With a better understanding of these challenges and continued research, it is possible to develop safe and effective inhalation formulations for a variety of drugs.

INHALATION FORMULATION DEVELOPMENT

Inhalation formulation development is a process in which the active ingredient of a drug is delivered to the lungs in aerosable form. Inhalation formulation developers work to ensure that the drug is effective when inhaled and that it does not cause any adverse effects [5]. The process of inhalation formulation development includes preclinical testing, clinical trials, and regulatory approval [3].

When developing an inhalation formulation, developers must consider the physicochemical properties of the active ingredient, as well as the delivery device. The goal is to develop a formulation that will be effective when delivered to the lungs and that can be easily inhaled by the patient [1,3].

Preclinical testing is essential to determine the safety and efficacy of an inhalation formulation. animal studies are conducted first, followed by human clinical trials. These studies help to identify any potential side effects and to determine the optimal dose for humans [2].

After preclinical testing is complete, clinical trials are conducted to assess the safety and efficacy of an inhalation formulation in humans. These studies are conducted in phases, with each successive phase building on the data from previous phases. Phase I trials are typically small and involve healthy volunteers. Phase II and III trials are larger and involve patients who suffer from the condition that the inhalation formulation is intended to treat [3,4]. After completing clinical trials, manufacturers submit their data to regulatory agencies for approval. In order for an inhalation formulation to be approved for use, it must be shown to be safe and effective in humans [1,5].

PARTICLE SIZE ANALYSIS:

Inhalation formulation development is a challenging process due to the wide range of particle sizes that need to be considered. Particle size analysis is an important tool in understanding and optimizing this process [3]. There are a variety of methods available for particle size analysis, each with its own advantages and disadvantages. The most common methods are laser diffraction, dynamic light scattering, and electron microscopy [2].

Laser diffraction is the most widely used method for particle size analysis. It is rapid, relatively inexpensive, and can be easily automated. However, it is limited in that it can only be used on dry powders and does not provide information on particle shape [3].

Dynamic light scattering (DLS) is another common method for particle size analysis. It has the advantage of being able to measure both dry and wet samples. DLS is also capable of measuring a wider range of sizes than laser diffraction. However, it is more expensive and slower than laser diffraction [1].

Electron microscopy is the most accurate method for particle size analysis but is also the most expensive and time-consuming. Electron microscopy can provide detailed information on particle shape as well as size. However, it is only practical for small samples sizes due to the time and expense involved [2].

MASS MEDIAN AERODYNAMIC DIAMETER (MMAD)

The mass median aerodynamic diameter (MMAD) is a measure of particle size distribution. It is defined as the particle diameter for which 50% of the particles by mass are larger and 50% are smaller. MMAD is typically expressed in micrometers (μm) [2].

Inhalation formulation development is a complex process that involves many different factors. Particle size is one of the most important considerations in this process, as it can impact both the efficacy and safety of the final product. The MMAD is a useful metric for characterizing particle size distribution and can help guide formulation development decisions [4].

GEOMETRIC STANDARD DEVIATION (GSD):

The geometric standard deviation (GSD) is a measure of the dispersion of a particle size distribution. It is a unitless quantity that provides a measure of how widely dispersed the particles are in terms of their sizes [1,3].

The GSD is calculated as the ratio of the geometric mean particle diameter to the arithmetic mean particle diameter. The GSD can be used to compare different particle size distributions or to track changes in the dispersion of a particle size distribution over time.

The GSD is often used in conjunction with the median particle diameter (MPD) to characterise the dispersion of a particle size distribution. The MPD is the point in the distribution at which 50% of the particles are smaller and 50% are larger. The GSD can be used to calculate the MPD, but it can also be used to assess whether a change in the MPD is due to a change in the dispersion or a shift in the entire distribution [3].

The GSD can be affected by many factors, including changes in temperature, humidity, and pressure. It is important to control for these variables when measuring or calculating the GSD [2].

IN VITRO DOSE UNIFORMITY (IVDU):

Inhalation formulation development is a process that involves many steps and requires a great deal of coordination between different departments within a company. One of the most important steps in this process is In Vitro Dose Uniformity (IVDU). This step is critical to ensuring that the finished product will be safe and effective for patients [1].

The IVDU step involves testing the uniformity of the dose delivered by the inhaler device. This is done by measuring the amount of drug that is deposited on a filter paper after each puff from the device. The results of these measurements are then used to calculate the delivered dose uniformity percentage (DUP) [3].

The FDA has established guidelines for acceptable DUP values for various types of inhalation products. For example, dry powder inhalers must have a DUP of at least 75%. metered-dose inhalers must have a DUP of at least 85%, and nebulizers must have a DUP of at least 90% [4].

It is important to note that even if an inhaler meets the FDA's minimum requirements for DUP, it does not guarantee that the product will be effective. There are many other factors, such as particle size and aerodynamic properties, that can affect the efficacy of an inhalation product [5].

IN VIVO DOSE UNIFORMITY (IVDU):

Inhalation therapy is an important part of many treatment regimens, and therefore, it is crucial that the inhaled dose is as uniform as possible. In order to ensure this, pharmaceutical companies conduct in vivo dose uniformity (IVDU) studies during the development process.

In a typical IVDU study, a group of subjects is recruited and each subject is given an inhaled dose of the medication under study. The doses are then analyzed to assess the degree of uniformity with which they were delivered [3]. There are several factors that can affect the results of an IVDU study, including the type of device used to deliver the dose, the particle size of the medication, and the breath pattern of the subject. Therefore, it is important to carefully consider all of these factors when designing an IVDU study. It is necessary ensure that any inhalation product will meet all regulatory requirements [4].

AERODYNAMIC PARTICLE SIZE DISTRIBUTION (APSD):

The aerodynamic particle size distribution (APSD) of an inhalation formulation is a measure of the amount of drug that is delivered to the lungs in each inhalation. It can be measured using a spirometer or a similar device [1]. The APSD is important because it determines the amount of drug that is available for absorption into the bloodstream. If the APSD is too low, then not enough drug will be delivered to the lungs and absorption may be insufficient. On the other hand, if the APSD is too high, then more drug may be delivered to the lungs than can be absorbed, leading to wastage [3].

CONCLUSION:

Inhalation formulation development is a complex and ever-evolving process due to the recent advancements in inhaler technology. By understanding the basic principles of this process, researchers can develop more effective drug delivery systems for various indications. Furthermore, by incorporating best practices throughout each step of formulation development, from material selection to product testing, companies can ensure that their products are safe and effective while complying with global regulatory requirements.

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