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MINI REVIEW ARTICLE

REVIEW ON IVIVC AND BIOEQUIVALENCE INDICATING DISSOLUTION SPECIFICATIONS

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ABSTRACT:
The *In Vitro In Vivo* Correlation (IVIVC) method is a useful tool for forecasting bioequivalence between multiple pharmaceutical dosage forms. The concept behind IVIVC is that the in vitro release profile of a drug from dosage form correlates with its in-vivo performance. It is the process of determining whether two or more formulations of the same drug have similar therapeutic effects. The in vitro-in vivo correlation (IVIVC) is a predictive calculation of relationship between the in vitro release of a drug from a dosage form and its in vivo performance. IVIVC can be applied as a tool to help with the development of dissolution specifications for bioequivalence studies. The US FDA defines bioequivalent as the extent to which two products produce the same pharmacologic effect when administered to humans. The IVIVC can be applied to help determine appropriate dissolution specifications for new drug products. In vitro-in vivo correlation (IVIVC) is an important tool in the development and regulation of drug products. The goal of IVIVC is to provide a link between the laboratory results and the performance of a drug product in humans. This can help forecast how changes in formulation or manufacturing processes may affect the product's performance.

Key words: *IVIVC, Dosage forms, US FDA, Convolution*

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INTRODUCTION:

When it comes to drug development and testing, bioequivalence is an important concept that must be taken into consideration [1]. It is the process of determining whether similar formulations containing a drug have similar effects. The In Vitro In Vivo Correlation (IVIVC) method is a forecastive tool for calculating bioequivalence between multiple pharmaceutical dosage forms. This blog post will review the IVIVC method and provide insight into how dissolution specifications can indicate bioequivalence. We will also discuss the advantages and limitations of this approach as well as provide some useful resources for further study.

WHAT IS IVIVC?

IVIVC is an abbreviated term for in-vitro in-vivo correlation. It is a forecastive scientific approach used to establish equivalence between two or more products, usually drugs or medical devices [2]. The concept behind IVIVC is that the in vitro release profile of a drug from

dosage form correlates with its in vivo performance. In order to generate an IVIVC, data on the in vitro release of a drug from its dosage form are collected and compared to corresponding in vivo pharmacokinetic data [3]. A mathematical model is then used to establish the relationship between the two sets of data. This relationship can be applied to forecast the in vivo performance of new or modified dosage forms.

There are several benefits of using IVIVC over other analytical methods, such as bioequivalence studies, when seeking to establish equivalence between products [4]. First, IVIVC can be applied to assess products that cannot be studied using bioequivalence methods, such as those that do not lend themselves to oral administration or have a short half-life. Second, IVIVC tends to be less expensive and time-consuming than bioequivalence studies. Finally, IVIVC can provide more information about a product's behavior in the body than bioequivalence studies alone [5].

When used correctly, IVIVC can be a valuable tool in demonstrating equivalence between products. However, it is important to note that there are some limitations associated with this approach.

WHAT ARE THE BENEFITS OF USING IVIVC?

There are many benefits of using IVIVC to help indicate dissolution specifications, including:

1. IVIVC can provide a more accurate forecastion of in vivo performance than in vitro methods alone.
2. IVIVC can help reduce the number of experiments needed to screen formulations and optimize process conditions.
3. IVIVC can provide valuable information on the effects of formulation and process variables on drug absorption.
4. IVIVC can help elucidate the mechanism(s) of drug release from solid dosage forms.
5. IVIVC can be applied to generate pharmacokinetic profiles forecasted for different formulations and/or manufacturing processes.

HOW DOES IVIVC HELP WITH BIOEQUIVALENCE?

The in vitro-in vivo correlation (IVIVC) is a mathematical relationship between the in vitro release of a drug from a dosage form and its in vivo performance. The IVIVC can be applied as a tool to help with the development of dissolution specifications for bioequivalence studies [6].

The US Food and Drug Administration (FDA) defines bioequivalence as "the extent to which the active moiety or therapeutic agent in pharmaceutical equivalents or pharmaceutical alternatives produces the same pharmacologic effect when administered to humans under similar conditions". In order for two products to be considered bioequivalent, they must have the same rate and extent of absorption of the active moiety.

Dissolution is one of the in vitro tests that can be applied to assess the release of the active moiety from a dosage form. The US FDA requires that all new drug products have dissolution specifications included in their approved labels. These specifications are generally based on the results of comparative bioavailability studies conducted using the FDA's standard 3-stage dissolution method [1,3].

The IVIVC can be applied to help determine appropriate dissolution specifications for new drug products. In general, an IVIVC exists when there is a direct relationship between in vitro drug release and in vivo pharmacokinetic parameters such as AUC or Cmax. This

relationship can be represented by a mathematical equation linking these variables. There are several advantages of using an IVIVC to help with bioequivalence

ARE THERE ANY LIMITATIONS TO USING IVIVC?

There are a few potential limitations when using IVIVC. First, in vitro data may not accurately represent in vivo conditions. This means that there is always the potential for some variability between the two. Second, it is important to have well-defined and reproducible in vitro methods. Without these, it can be difficult to interpret results and make meaningful comparisons. Finally, it is also worth noting that IVIVC should not be used as a replacement for clinical studies. While it can provide valuable information, it should be used in conjunction with other data to make decisions about bioequivalence and dissolution specifications [2].

CONCLUSION:

In vitro-in vivo correlation (IVIVC) is a statistical relationship established between the results of in vitro tests and in vivo bioavailability or bioequivalence studies. The goal of IVIVC is to provide a link between the laboratory results and the performance of a drug product in humans. This can help to forecast the performance of new formulations and to understand how changes in formulation or manufacturing processes may affect the product's performance. IVIVC can also be used to support the development of in vitro tests for bioequivalence and to help in the design of bioavailability and bioequivalence studies. Overall, IVIVC is an important tool in the development and regulation of drug products.

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