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Editorial

Where Drug Shelf Life is Valid but Performance Life Crosses

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Abstract

The properties and life of flower may not be equal when it stays on tree comparable to when it is plucked. It is heavily impacted by the influence of environment and disassociation from its origin. The degree of impact varies with the type and kind of flower and environmental conditions. The same is with protein when used as a drug. It's not easy but sometimes so complex to understand because protein molecule likes to live in its system. As soon as it is removed from its original biological system (plucked like flower) it by default inclines towards coagulation, agglomeration, precipitation or denatures and thus lose its activity as it was inside its original system.

Keywords

Drug, Pharmaceutical marketing, Life Affects, Impact.

Introduction

Pharmaceutical Manufacturing is a complex science that integrates multiple systems and elements to build quality in the end drug product. To maintain the quality, safety and efficacy of drug, patient needs to understand the appropriate and careful storage inside the home. It becomes critical generally in the products that are multi dose, used after reconstitution or subject to dilution and particularly in biological products. Shocks of environmental factors may impact irreversibly on the product's efficacy and safety in many cases. The risk of instability in biological drugs is much higher and special attention is required at the end of consumer, whereas, stringent practices to maintain stability throughout the manufacturing, transportation, distribution and storage are the obligatory requirement of the manufacturer.

Drug product stability means the ability of product to deliver same performance throughout the specified period under prescribed environmental conditions as claimed & promised on the label by the manufacturer with the approval of regulatory authority. The manufacturer has to perform stability studies to demonstrate acceptable shelf life within specified environmental conditions. The product can safely be used during shelf life that is often indicated on label as expiry date. These studies require regulatory compliance and much attention. Maintaining and monitoring of conditions constantly in the stability studies is the biggest challenge because of limited excursion zone particularly in biological drugs. Controlling the condition of transferring sample from stability chamber to the testing bench has its own impact in determining the shelf life. Different approaches are used in early stage of development to see & understand the degradation pathway upon stress conditions that help in calculation of shelf life.

Sometimes, useable period is also indicated on the label beside the expiry date. Expiry date indicates its shelf life under specified conditions if product is not opened for use or container is not damaged for its integrity. Useable period tells about the period and conditions of storage after opening of the original product container on which stability study is performed. Product may not be used if it crosses the specified useable period after opening the product, no matter, how much shelf life remains because of absence of evidence required to demonstrate stability of the product. It means the shelf life of the product is independent, whereas, useable period after opening the product is dependent on the shelf life of product.

For e.g. a Product X has a shelf life of two years (Expiry Date: December 2020), but if it is opened, it may not be used after 10 days under specified environmental conditions. This product is opened on 1st January 2019, it may not be used after 11th January 2019 in this case. In another scenario for the same product, if it is opened on 26th December 2020, in this case it may not be used after 31st December 2020 because it is dependent on the product shelf life, no matter, useable period after opening is indicated as 10 days.

It is a hidden challenge for the manufacturer and regulatory authority to ensure that every consumer takes safe and effective dosage inside home and may not experience undesired or unreasonable adverse reactions. Understanding of protein chemistry and its markers that can indicate its performance are the real questions. One cannot assume a drug that is exposed in kitchen or exposed in dining room for the same period may have same effect, unless it is not studied and proven through qualified markers. Adherence with the conditions specified is significant, particularly in biological drugs and generally all drugs that require reconstitution or dilution in hospital settings. On the other hand, the control studies

and development of indicating markers to understand each biological product individually are becoming indispensable. The same way, enhancing the capacity of regulatory authority to understand the product and tendency to alter product therapeutic value is essential. Collaboration of manufacturing and regulatory sciences is the answer to advance public health.

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It is personal point of view written in best of professional knowledge and experience of regulatory sciences. It is not an obligation to agree by the organization or association to which I belong. The intent of writing is to sensitize culture of reading and learning. The author can be reached at obaidali1971@gmail.com & roohibanoobaid@gmail.com.