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# STABILITY TESTING AND ITS ROLE IN DRUG DEVELOPMENT PROCESS

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## ABSTRACT
One crucial factor in the creation of novel pharmaceuticals and formulations is the results of stability tests. Predicting how long a drug will keep in storage is an important component of creating any kind of pharmaceutical, as it helps with choosing the right environment for storage and coming up with helpful labelling recommendations. Stability studies are required for the acceptance and approval of any pharmaceutical product to ensure that the product quality, safety, and effectiveness are maintained throughout the shelf life of the product. These investigations must be carried out methodically, in accordance with the standards set out by ICH, WHO, or any other relevant regulatory bodies.

**KEYWORDS**: Stability Studies, Pharmaceutical Products and Stability Testing.

## INTRODUCTION
Physical, chemical, microbiological, and pharmacokinetic features and characteristics of a pharmaceutical product are said to be stable if they are maintained throughout the product's shelf life after its point of manufacturing. When the substance loses 90% of its initial concentration, the product has reached the end of its shelf life. As a technical phrase, "shelf life" refers to the length of time a product may remain unchanged before it spoils. Each pharmaceutical product has a unique expiration date. A pharmaceutical dosage form's shelf life is affected by numerous variables, including the formulation's physical and chemical active ingredients, the kind of container-closures employed, and the storage circumstances. Literature data on the breakdown and biodegradability of active compounds, together with suitable analytical techniques, are typically accessible. As a result, research of stability may be limited to the dose form. Pharmaceutical analysis and stability studies are essential throughout development because they establish and guarantee the identity, potency, and purity of materials and finished products.[1] Microbiological changes, such as microbial development in non-sterile goods and changes in the efficiency of preservatives, may also impact the stability of a pharmaceutical product. In addition, the information gathered during stability testing is crucial for obtaining regulatory approval of a medicine or formulation.[2] [3] 2. WHY STABILITY STUDIES ARE IMPORTANT Underdosing on an inactive drug's dosage form is only one of the potential consequences of a product's instability. Drug's physical qualities may be altered during shipment as part of the marketing strategy. The concepts of kinetics are used to the prediction of a drug's stability, however kinetics and stability studies look at the drug in distinct ways.[4]

## TYPES OF STABILITY STUDIES ON DRUG SUBSTANCES[4,5]
The guidelines for what constitutes sufficient physical, chemical, microbiological, therapeutic, and toxicological stability investigations are laid forth in the United States Pharmacopeia (USP). Durability in body and mind Appearance, colour, disintegration, palatability, and suspendability are all just as they were before. The homogeneity and release rate of the substance are dependent on its physical stability, which is why this property is crucial to the product's effectiveness and safety. Consistency in composition Resistance to deterioration or alteration as a result of exposure to air, atmosphere, temperature, etc. Immunity to microbes Medicines that are resistant to losing their sterility or growing bacteria are said to be microbiologically stable. The potency of the antimicrobials utilised in the formulation is maintained within the allowed parameters. Such microbial instability may threaten the sterility of the pharmaceutical product. Security in treatment There has been no change in the medicinal effect (Drug Action). Thermodynamic Stability in Toxicology There has been no appreciable rise in toxicity, hence the compound is considered to be toxicologically stable.

**Types of stability studies**

Long-term testing of a pharmacological product at a range of temperatures and relative humidities is known as a "stability study" (RH). Long-term stability studies are crucial if the medicine is to be disseminated across many locations, each of which may need separate shipment. Experiments on long-term stability involve repeatedly putting a sample through a battery of tests at regular intervals while varying various environmental factors. The main purpose of this research was to establish the stability of the medicinal product throughout time. There are essentially four distinct kinds of stability studies: in-use, accelerated, short-term, and intermediate.

## STABILITY TESTING METHODS

All pharmaceutical products go through a process called stability testing at different points in the development process. Accelerated stability studies, which are often conducted at high temperature and humidity, are used for stability testing in the early phases. Accelerated stability tests make it possible to foresee the drug's deterioration over a short time frame. In the accelerated stability tests principally the drug is done at long-term storage. The duration of the product at high temperatures is measured. The major purpose for the stability testing is to supply the acceptance level of fitness/ quality throughout the duration during which they are available for the patience and should be fit for the acceptance of the medicine by the patient. As a result, it is simpler to treat the patient, the treatment is more likely to be widely accepted, and more people benefit from the pharmaceutical goods that have been developed.[6] The stability testing processes have been broken down into four distinct classes based on their intended use and the methods they employ: 1. Two, speeded-up stability tests 3. Stability testing with retained samples The fourth kind of stress test is the cyclic temperature test. Stability testing in real time In order to simulate considerable product deterioration under the circumstances of suggested storage, real-world stability testing often takes a very long period. The length of time needed to conduct tests on the product is based on its stability, which indicates that the product has not been significantly deteriorated or decomposed throughout the course of several assays. The samples are taken at regular intervals throughout testing, allowing the analyst to detect gradual deterioration on a daily basis as a result of the high frequency with which the data is gathered. You may get further information by adding in the one batch of standard material for which stability parameters have been defined. Stability testing requires uniformity in the use of reagents and equipment. Reagent and instrument modifications should be monitored for drift and discontinuity so that they may be corrected.[7] Two, speeded-up stability tests For this purpose, the product is subjected to elevated temperatures in order to ascertain the point at which it begins to decompose. This data is then utilised for either shelf life prediction or stability comparison between different formulations. The time it takes to learn how stable a drug is may be cut significantly with the use of rapid stability tests. A variety of stresses, including temperature, humidity, light, pH, and gravity, are applied. The time needed to evaluate instability is less than half that required for real-time testing. Projections of stability are carried out at four distinct stress temperatures for the accelerated stability investigations. When denaturing stress temperatures are not present, however, predictions are produced.

## GUIDANCE OF STABILITY STUDIES

The pharmaceutical preparation of the drug to be administered for the patient's wellbeing should be optimised for stability, and products are manufactured in accordance with the standard guidance proposed by the World Health Organization, the Food and Drug Administration, and the International Conference on Harmonization. When it comes to making and selling these medicines, ICH is a major player. The International Conference on Harmonization (ICH) is the system used to keep track of medicines intended for human consumption. Since its founding in 1991, the International Council for Harmonization (ICH) has developed several standards for drug substances and drug products with regards to their quality, safety, effectiveness, and interdisciplinary nature (also known as Q, S, E, M). Geneva, Switzerland is home to the ICH's headquarters and secretariat. Included in these instructions are the fundamentals of stability, the necessary stability data for the application dossier, and the procedures to be followed. The International Council for Harmonization (ICH) issued recommendations in 1996, and the World Health Organization (WHO) amended and published updated guidelines for stability studies in a global setting in 2004.[6] The ICH did not take into account the harsh weather conditions that exist in many nations, and it mainly addressed the development of new pharmacological ingredients and the revision of already existing medicines. Similar but unofficial rules were given by the US Food and Drug Administration (FDA) in Silver Spring, Maryland, in June 1997. New Delhi is home to India's drug regulatory agency, the Central Drug Standards Control Organization (CDSCO). Different countries have different regulations. Thus, arranging the data and evaluating the application got challenging. Hence, there was an urgent need to simplify and unify the rules. In this meeting, the ICH Steering committee was formed, and it was decided that they would meet at least twice yearly to make a decision. Series of recommendations relating to stability testing have also been established by the Committee for Proprietary Medicinal Goods (CPMP) within the European agency for the Evaluation of Medicinal Products (EMEA) to aid the seeking marketing products. Reference to ICH[1,3] and CPMP's Codes and Titles.

## CONCLUSION

Predicting the shelf life of pharmaceutical products, including the effect of environmental factors on the degradation of the product, has become straightforward

thanks to stability studies, which make a significant procedural contribution to the development programme for new drugs and new formulations. The product's quality, safety, and effectiveness might be compromised if it deviates from its defined stability profile. To verify that a drug remains safe and effective beyond its labelled shelf life, stability tests are conducted. Therefore, the stability tests should be carried out following good scientific principles and after comprehension of the present regulatory needs and as per the climatic zones.

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