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Review Article

A Review on Importance of Stability Testing in Pharmaceutical Development

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ABSTRACT

The main purpose of the stability testing in pharmaceutical development is to ensure that a drug or cosmetic product remains safe and effective for patients by stablishing its shelf life and storage conditions. Stability testing are regarded as a must for the acceptance and approval of any pharmaceutical product since they guarantee the stability of product quality and safety during the shelf life. ICH, WHO, ASEAN and separate agencies issued the guidelines for stability testing which are required for regulatory fill and approval of any medicinal product. The shelf-life prediction is major role for the pharmaceutical product development of all the dosage form and also it is utilized to determine the particular storage condition and to suggest the label instructions. This article will help the researcher or the developer who is developing a formulation by providing a complete information about drug stability, principle of drug degradation, force degradation studies, stability testing, factors affecting the drug stability and different ways to increase the drug stability. Stability testing is not only the regulatory requirement but it is an integral part of ensuring that pharmaceutical product are safe and effective for use of patient over the time and ultimately protects the public health by reliable medicine product.

INTRODUCTION

Stability testing in pharmaceutical development is a complex set of procedure wich involves the considerable cost, time consuption and scientific enperties in order to build a quality ,effective and safe formulation determination of the products shelf life is the goal of the stability testing. The term stability refers to the amount of time that can pass before a dosage form start to degrade. The shelf life (expiry date) of a product is calculated based on this period.

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Expiration date in marketed medicine is affected by the variety of factors counting by all physical, chemical and biological like the interactions between ingredients used in a formulated product, type of dosage form, light and packaging system, temperature and humidity in the environment encountered during storage and shipment. In addition to, solvolysis, oxidation, reduction, racemization and other chemical mechanism are associated to the drug deterioration which is accelerated by a subsequent condition like a concentration of reactants, pH, radiation etc., additionally the starting materials used and time period from the time of manufacturing to the consumption of the product. Such degradation is measure by physical, chemical, and biological stability assessment such as changes or non-compliance in appereance, content uniformity, colour, organoleptic characteristic, hardness, friability, disintegration, dissolution, sedimentation and resuspendability, weight, moisture content, particle shape and size, package integrity, loss of potency(active ingredient), loss of excipient (antimicrobial preservations, antioxidants), microbial growth in non-sterile products, preservation of sterility, preservative efficacy changes etc.

In the present review importance of various method followed for stability testing of pharmaceutical products, guidelines issued for stability testing and other aspects related to stability of pharmaceutical products have been presented in a concise manner.

Histological Background:

Jordan was the one to give the name for stability testing in the pharmaceutical companies. The need arose when regional office organized a workshop for validation of expiry dates of drug in Amman. The workshop ordered every medical authority to collaborate with every pharmaceutical company to guide them about the importance of drug stability and expiry date.

Thus International Conference on Harmonization thus took a step to implement these guidelines. FDA issued its first stability guidance in 1987. Considerable efforts were taken, to harmonize the stability practices within the ICH region then after in the early 1990. As a result to the efforts, International Conference on Harmonization (ICH) was established in 1991 and various guidelines for drug substance and drug product came into existence regarding their quality, safety and efficacy. These guidelines are called as quality, safety, efficacy and multi disciplinary (also called as Q,S,E and M) guidelines. Work on stability of pharmaceutical products was initiated by the WHO in 1988 and the WHO guidelines on stability testing for well established drug substance in conventional dosage forms were adopted in 1996 by the WHO expert committee on specifications for pharmaceutical preparations following extensive consultation. In 2000, discussions began between the International Conference on Harmonization (ICH) expert working group Q1 (stability) and the WHO to harmonize the number of stability tests and conditions employed worldwide.

Stability Testing Method:

Stability testing is a routine procedures performed on drug substances and products and is employed at various stages of the product development. In early stages, accelerated stability testing (at relatively high temperatures and\or humidity) is used in order to determine the type pf degradation products which may be found after long-term storage. Testing under less rigorous(rigid) condition i.e. those recommended for long-term shelf storage, at slightly elevated temperature is used to determine a products shelf life and expiration dates. The major aim of pharmaceutical stability testing is to provide reasonable assurance

that the products will remain at an acceptable level of fitness/quality throughout the period during which they are in market place available for supply to the patients and will be fit for their consumption until the patient uses the last until of the product (Kommanaboyina et al., 1999). Depending upon the aim and steps followed, stability testing procedures have been categorized into the following four types.

Real-Time Stability Testing:

Real-time stability testing is normally performed for longer duration of the test period in order to allow significant product degradation under recommended storage conditions. The period of the test depends upon the stability of the product which should be long enough to indicate clearly that no measurable degradation occurs and must permit one to distinguish degradation from inter-assay variation. During the testing, data is collected at an appropriate frequency such that a trend analysis is able to distinguish instability from day-to-day ambiguity. The reliability of data interpretation can be increased by including a single batch of reference material for which stability characteristics have already been established. Stability of the reference material also includes the stability of reagents as well as consistency of the performance of the instrument to be used throughout the period of stability testing. However, system performance and control for drift and discontinuity must be monitored (Anderson et al., 1991).

Accelerated Stability Testing:

In accelerated stability testing, a product is stressed at several high (warmer than ambient) temperatures and the amount of heat input required to cause product failure is determined. This is done to subject the product to a condition that accelerates degradation. This information is then projected to predict shelf life or used to compare the relative stability of alternative formulations. This usually provides an early indication of the product shelf life and thus shortening the development schedule. In addition to temperature, stress conditions applied during accelerated stability testing are moisture, light, agitation, gravity, pH and package. In accelerated stability testing the samples are subjected to stress, refrigerated after stressing, and then assayed simultaneously. Because the duration of the analysis is short, the likelihood of instability in the measurement system is reduced in comparison to the real-time stability testing. Further, in accelerated stability testing, comparison of the unstressed product with stressed material is made within the same assay and the stressed sample recovery is expressed as percent of unstressed sample recovery. For statistical reasons, the treatment in accelerated stability projections is recommended to be conducted at four different stress temperatures. However, for thermolabile and proteinaceous components, relatively accurate stability projections are obtained when denaturing stress temperatures are avoided. For statistical reasons, the treatment in accelerated stability projections is recommended to be conducted at four different stress temperatures. The concept of accelerated stability testing is based upon the Arrhenius equation (1) and modified Arrhenius equation

$$\mathbf{k = Ae\text{-}Ea/(RT)}$$

$$\mathbf{\ln(k) = -Ea/R\ 1/T + \ln(A)}$$

Where, K = degradation rate
A = frequency factors/s,
E = activation energy (kJ/mol)
R = universal gas constant (0.00831kJ/mol) T = absolute temperature (K)
As modified.

k =A (T/T0)ne-Ea/(RT)

These equations describe the relationship between storage temperatures and degradation rate. Using Arrhenius equation, projection of stability from the degradation rates observed at high temperatures for some degradation processes can be determined. When the activation energy is known, the degradation rate at low temperatures may be projected from those observed at "stress" temperature.

Retained Sample Stability Testing:

For all marketed medicine whose stability data is essential, the manufacturer commonly practices of selecting a minimum one batch per year as stability sample for retained storage and those for new product, stability sample of every batch is taken which on later stage might be reduced to only 5% to 2% of marketed batches. When more than 50 batches are marketed, then stability sample from 2 batches are suggested to be taken. In this study, frequency of testing ought to be enough to set up the stability profile of the retained product and testing interval should be every three months over 1st year , every six months over 2nd year and annually thereafter throughout the estimated expiry date. i.e. sample will be tested at 3,6,12,18,24,36,48 and 60 months for a product having a shelf life of 5 year. This typical method for determining stability profile on retained samples is termed as constant interval method. Since in this study, samples are subjected to storage under ideal condition because of which they never experience the stressful situation in the market during shipping and storage. Thus to make the quality of the product modified method known as stability testing by evaluation of market sample was used, which involve assessing quality attributes of that product available in the market place.

Cyclic temperature stress testing:

This is not a routine testing method for marketed products. In this method, cyclic temperature stress tests are designed on knowledge of the product so as to mimic likely conditions in market place storage. The period of cycle mostly considered is 24 hours since the diumal rhythm on earth is 24 hour, which the marketed pharmaceuticals are most likely to experience during storage. The minimum and maximum temperatures for the cyclic stress testing is recommended to be selected on a product-by-product basis and considering factors like recommended storage temperature for the product and specific chemical and physical degradation properties of the products. It is also recommended that the test should normally have 20 cycles (Kommanaboyina et al., 1999; Carstensen et al., 2000).

Guidance Of Stability Studies:

The drug to be administered for wellbeing of the patient the pharmaceutical preparation should be optimally stable and products are manufactured according to the standard guidance which are proposed by WHO, FDA, ICH. ICH plays a key role in the preparation and marketing of the preparation. ICH stands for "International Conference of Harmonization" which is used for the register of the pharmaceutical products for human use. The ICH was established in 1991, was a consortium formed inputs from both regulatory and industry from European commission, Japan, USA, and various guidelines for drug substance and drug product came into existence regarding their quality, safety, efficacy and multidisciplinary(also known as Q, S, E, M). The secretariat of ICH is situated at Geneva, Switzerland. These guidelines include basic issues related to stability, the stability data requirement for application dossier and the steps for execution. Later in the year 1996 WHO (world health

organizations) has modified the guidelines proposed by ICH and WHO, in 2004 released the guidelines for stability studies in global environment. As the ICH did not assess the extreme climatic conditions found in many countries and it only covered new drug substance and the product which were earlier established. In 1997 , June the United States Food and Drug Administered (US FDA) situated at Silver Spring also issued the guidelines but they were not entitled. The CDSCO (Central Drug Standards Control Organization) is a drug regulating authority for India situated at New Delhi. The regulatory requirements vary from country to country. Thus, organizing the data and scrutinizing the application became difficult. Hence, there was an urgent need to rationalize and harmonize the regulations. The ICH steering committee was established at the meeting and A decision was to be taken at least twice a year. Series of guideline related to stability testing have also been issued by the Committee for Proprietary Medicinal Products (CPMP) under the European agency for the evaluation of medicinal product(EMEA) to assist the seeking marketing products. The codes and titles used in ICH and CPMP. Guideline were tabulated in Table 1 and Table 2 respectively.

Table 1: Codes and Titles used in ICH Guidelines

ICH Codes	Guideline titles
Q1A	Stability testing of new drug substances and products(second revision)
Q1B	Photo stability testing of new drug substances and products
Q1C	Stability testing of new dosage form
Q1D	Bracketing and Matrixing designs for the stability testing of drug substances and products
Q1E	Evaluation of stability data
Q1F	Stability data package for registration applications in climatic
	zones 3 and 4
Q5C	Stability testing for biotechnological/biological products
Q6A	Specifications: Test procedures and acceptance criteria for new drug substances and new drug products: Chemical substances
Q6B	Specifications: Test procedures and acceptance criteria for new drug substances and new drug products: Biotechnological/Biological products

Table 2: CPMP Guidelines for stability studies

CPMP Codes	Guidelines Titles
CPMP/QWP/576/96 Rev.1	Guideline on stability testing for application for variations to a marketing authorization
CPMP/QWP/6142/03	Guideline on stability testing for active substances and medicinal products manufactured in climatic zones 3 and 4 to be marketed in the EU

CPMP/QWP/609/96 Rev.1	Note for guidance on declaration of storage condition for medicinal products particulars and active substances
CPMP/QWP/122/02 Rev.1	Note for guidance on stability testing of existing active substances and related finished products
CPMP/QWP/072/96	Note for guidance on start shelf life of the finished dosage form
CPMP/QWP/2934/99	Note for the guidance for in-use stability testing of human medicinal products
CPMP/QWP/576/96	Note for guidance on stability testing for a type 2 variation to a marketing authorization

Climatic Zones for Stability Testing:

For the purpose stability testing, the whole world has been divided into four zones (1-4) depending upon the environmental conditions the pharmaceutical products are likely to be subjected to during their storage. These conditions have been derived on the basis of the mean annual temperature and relative humidity data in these regions. Based upon this data, long-term or real-time stability testing conditions have been derived.

The standard climatic zones for use in pharmaceutical product stability studies have been presented in the table 3. The break-up of the environmental conditions in each zone and also the derived long-term stability test storage conditions, as given by WHO have also been presented. The stability conditions have also been harmonized and adjusted to make them more practical for industry application and rugged for generalized application (Singh et al., 2000; ICH Q1A(R2),2003).

Table 3: ICH Climatic zones and long term stability conditions.

Climatic Zone	Climatic/ Definition	Major Countries/Region	MAT*/Mean annual partial water vapour pressure	Long-term testing conditions
1	Temperature	United Kingdom Northern Europe Russia United state	<15ºC/<11hPa	21ºC/45%RH
2	Subtropical and Mediterranean	Japan Southern Europe	>15-22ºC />11-18 hPa	25ºC/60%RH
3	Hot and dry	Iran India	>22ºC/<15hPa	30ºC/35%RH
4a	Hot and humid	Iran Egypt	>22ºC/>15-27hPa	30ºC/65%RH
4b	Hot and very humid	Brazil Singapore	>22ºC/>27hPa	30ºC/75%RH

*MAT= Mean Annual Temperature measured in open air.

Protocol for Stability Testing:

The stability testing protocol is a requirement for preliminary stability testing and is a written document which portrays the necessary part of stability study like-tests to be performed and planned schedule of testing. The protocol is required for batches of clinical, formulation development, registration and marketed product to develop a stability profile of the product. The protocol depends on types of dosage form and proposed container closure system.

As well as protocol depends on the drugs formulated newly or is already is in the market. The protocol should also include the regions where the medicine is planned to be marketed that are proposed by ICH, namely climatic zones 1-4 and extreme tropical zones, 4b by ANSEAN. A well-designed stability study protocol should include the following information:

Batches:

Stability studies at developmental stages are generally carried out on a single batch while studies intended for registration of new product or unstable established product are done on first three production batches, while for stable and well-established batches, even two are allowed. If the initial data is not on a full-scale production batch, first three batches of drug product manufactured post-approval should be placed on long-term studies using the same protocol as in approved drug application. Data on laboratory scale batches obtained during development of pharmaceuticals are not accepted as primary stability data but constitute supportive information. In general, the selection of batches should constitute a random sample from the population of pilot or production batches(Singh et al.,2000).

Container and Closures:

containers-closures system intended for marketing. The packaging materials include aluminum strip packs, blister packs, HDPE bottles etc. which may also include secondary packs except for shippers. Products in all different types of containers/closures, whether meant for distribution or for physician and promotional samples, are to be tested separately. If bulk containers stimulate the actual packaging, then testing in prototype containers is acceptable.

The Orientation of Storage of Containers:

To permit for the full interaction of the product with the container-closure, samples of liquid or semisolid form like a solution, suspension, emulsion etc. are kept upright and placed either inverted or titled. This orientation helps to know when the drug comes in contact with the containers and the closure consequences in the leaching of chemical substances from the closure components or adsorption of product components into the container-closure system.

Testing Time Point:

Testing frequency should be enough to establish the stability profile of drug product where the testing point interval at the long-term storage condition should be each three months over the 1styear, every six months over the 2ndyear and yearly thereafter throughout the estimated expiration date. But for the accelerated storage conditions, at least 3 testing points, including the initial and ending points, for e.g. initial, three, and six months are suggested. If the accelerated stability data show a trend toward a significant failure, then the testing frequency should be amended to include more frequent testing either by adding samples at the last time point or by counting a 4thtime point in order to determine the actual failure occurring time period, in the stability study design.

Sampling Time Point:

Frequency of testing should be such that it is sufficient to establish the stability profile to the new drug substances. For products with a proposed shelf life of at least 12 months, the testing frequency at the long-term storage condition should be every 3 months over the first year, every 6 months over the second year and annually thereafter throughout the proposed shelf life expiration date. In the case of accelerated storage conditions, a minimum of three time points, including the initial and end points, for example, 0,3 and 6 months is recommended. When testing at the intermediate storage condition is necessary as a result of significant change at the accelerated storage condition, a minimum of four test points, including the initial and final time points, is recommended, for example, 0,6,9 and 12 months. This test schedule for stability testing of a new product has been presented in table 4 (Cha et al.2001).

Table 4: Test Schedule for stability testing of new products.

Environmental	Sampling Time Points (months)	Method & Climatic zone
25ºC/60%RH	3, 6, 9, 12, 18, 24, 36	Long term for zones 1 and 4
30^{O}C/35%RH	3, 6, 9, 12, 18, 24, 36	Long term for zones 3
30^{O}C/65%RH	3, 6, 9, 12, 18, 24, 36	Long term for zones 4a, or intermediate condition for zones 1 and 2
30^{O}C/75%RH	3, 6, 9, 12, 18, 24, 36	Long term for zones 4a, or intermediate condition for zones 1 ans 2
40^{O}C/75%RH	3, 6	Accelerated condition for all zones

Test Storage Conditions:

The storage condition to be selected are based upon the climatic zones in which the product is intended to be marketed or for which the product is proposed to be filed for regulatory approval. General recommendations on the storage condition have been given by ICH, CPMP, and WHO. The indicative ICH and WHO storage conditions for drug products have been given in table 5.

Table 5: Stability test storage conditions for drug products.

Intended storage condition	Stability test Method	ICH Test temperature and humidity (period in months)	WHO Test temperature and humidity (period in months)
Room temperature	Long term Intermediate Accelerated	25±2ºC/60±5%RH (12) 30±2ºC/65±5%RH(6) 40±2^{O}C/75±5%RH(6)	25±2^{O}C/60±5%RH or 30±2ºC/65±5%RH 30±2^{O}C/75±5%RH(12) 30±2^{O}C/65±5%RH(6) 40±2^{O}C/75±5%RH(6)
Refrigerated	Long term Accelerated	5^{O}C/ambient (12) 25±2ºC/60±5%RH(6)	5±3^{O}C 25±2^{O}C/60±5%RH OR

			30±2^{O}C/65±5%RH
Freezer	Long term	-20^{O}C/ambient (12)	-20^{o}C±5^{O}C

Test Parameter:

The test parameter used in the stability studies must be evaluated of the stability samples. The test of sample mainly includes the quality, purity, efficacy, and identity which can be depending upon the climatic conditions. Therefore appearance, assay, degradation products, microbiological test include sterility, preservatives measures etc. The stability testing batches should also reach the testing parameters including the heavy metals, residue of ignition, residual solvents etc. These test are also been discussed in the ICH guidelines(QA6).

Expiration Date/Shelf Life:

An expiration date is defined as the time up to which the product will remain stable when stored under recommended storage conditions. Thus, an expiration date is the date beyond which it is predicted that the product may no longer retain fitness for use. If the product is not stored in accordance with the manufacturer's instructions, then the product may be expected to degrade more rapidly. Shelf life is the time during which the product, if stored appropriately as per the manufacturer's instructions, will retain fitness for se. The expiration date is also defined as the date placed on the container/labels of a drug product designating the time during which a batch of the product.

Estimation of Shelf life:

The shelf life is determined from the data obtained from the long term storage studies. The data is first linearized and test for goodness of fit is applied. The linearized data is then analyzed to see that the slope and the intercepts are matching.

Table 6 gives the different possibilities in the pattern of the concentration-time data of the three batches. are also been discussed in the ICH guidelines(QA6).

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Table 6: Pattern of concentration-time data and pooling decision.

Slope	Intercept	VariationFactors	Pooling
Identical	Identical	Nil	Yes
Identical	Different	Batch e.g. unequal initial drug concentration	No
Different	Identical	Storage e.g. difference in the rate of drg loss	No
Different	Different	Interactive forces-both batch and storage factor	No

For determination of significance of difference in case of slope or intercept, stastical tests like t-test should be applied. The data is available in the form of only five data points i.e.0,3,6,9 and 12 months, either pooled from the three batches or from the three individual batches if they are not fit for pooling. Most pharmaceutical products are characterized by only one shelf life. However, in some cases a product may have two e.g. a freeze-dried(lyophilized) protein product may have only 1 shelf life, say 2 years, for the product stored in the dry condition and a 2nd shelf life, say 2 days, for the product when it has been reconstituted with the appropriate vehicle and is ready for the injection (Carstensen et al., 2000).

Stability studies and their classification:

Stability studies are the essential criteria for assuring the quality efficacy and integrity of the final product.

Physical stability studies:

For intrathecal, ocular and intra-artetial routes, the physical evaluation of the solution is of particular importance. The physical changes can have deleterious effects too. Physical stability studies are also essential because tablet may become soft and ugly or it may become very hard and show very slow dissolution time as a result of which bioavailability may not be good.

Chemical stability studies:

Many chemical reaction involve moisture as a reactant and play the role of the solvent vector in many reactions. Molecules have more kinetic energy and more decomposition is observed because moisture has better thermal conductivity than solids which allow better heat transfer. The common cause in all these, hydrolysis or oxidation or fermentation is moisture. The HPLC, HPTLC or capillary electrophoresis methods are widely for evaluation of chemical instability.

Microbiological stability studies:

Microorganism not only contaminate the formulations containing moisture but also solid dosage forms containing natural polymer because many natural polymers are the source of microorganisms.

Factors Affecting Stability of Drug:

Temperature:

Changes in temperature have an impact on a pharmacological substance's stability; higher temperatures speed up the rate at which medicines are hydrolyzed.

Moisture:

When the water-soluble solid done is absorbed into any moisture surface and loses its qualities, several physical and chemical dosage changes.

pH:

The rate of medication deterioration in hydrolyzed solutions is affected by pH, which lowers the potency of pharmaceuticals manufactured with buffers at the pH where stability is greatest.

Excipient:

Because of their higher water content than other excipients, starch and povidone have an impact on stability. Additionally the chemical interactions between excipient and medication reduce instability.

Oxygen:

Some products oxidation is facilitated by the presence of oxygen. When exposed to oxygen, products with a greater rate of breakdown are stabilized by replacing the oxygen in the storage container with carbon dioxide and nitrogen.

Light:

The rate of breakdown accelerates in light-exposed materials. Because some medications are photosensitive, it is possible to compare how well they hold up when stored in the dark vs exposure to light.

Mechanism of drug degradation:

Oxidation:

The most significant drug breakdown pathway is oxidation. Oxygen is present everywhere in the atmosphere and exposure to oxygen will decompose drug substance that are not in their most oxidized state through auto-oxidation. There are two main categories of oxidative degradation of pharmaceuticals: reaction with molecular oxygen and reaction with other oxidizing agents present in the formulations.

Hydrolysis:

Hydrolytic reactions are among the most common pathway for drug breakdown. The medication in solution is subjected to nucleophilic attacks by water on labile bonds during hydrolysis events.

Microbial Instability:

Product contamination can result in significant product damage or, in certain cases, no damage at all. For instance, mould spores may exist in a latent state and never create spoilage or affect the patient who takes the medication.

Temperature:

Temperature has a significant impact on a wide range of processes, and an increase in temperature typically speeds up these reactions.

pH:

Acidic and alkaline pH levels affect how quickly most medications breakdown.A pH increse or drop might harm the formulations of a medicinal product.

Stability testing:

Stability tests are a standard procedure used in the various stages of medicinal substances and product development. Accelerated stability tests are used in the early phases to assess the kind of deteriorated goods discovered after extended storage.

Importance of stability testing:

- The breakdown of active medications may result in the formation of toxic compounds.

- Ensuring that the brand is appropriate for usage for the duration that it is on the market and that it has all functionally acceptable features to preserve the manufacturers good name.
- To confirm that no adjustments to the manufacturing process or formulation.
- It provides a database that might to be used for selecting, excipients, formulations, and container closing strategies for growing current products.
- It is the only way to know for sure whether a drug meets the requirements for acceptance or not.

Current trends in stability studies:

The current trends in stability studies are the multinational pharmaceutical companies, is to define conditions for stability testing for global marketing. For this the companies are orienting their protocols to single set of conditions that covers extreme environmental conditions. The specific changes for global testing include increase in duration of accelerated testing period from 6 to 12 months and conduct of additional tests at 50oC/75% RH for 3 months. The concept behind this change is to avoid repetition of stability testing for other regions and efficient and optimum use of resources as all tests are done in laboratory.

CONCLUSION:

Stability testing in current time is most important procedural component in the pharmaceutical development of new drug as well as new formulation. Stability testing all the key practical technique that is capable in distinguishing active drug substance from any degraded products as well as estimate the shelf life under defined storage condition. The degradation studies should be conduct during the development of drug product to gain enough information about the stability profile of the molecule. This information in term helps to improve formulation manufacturing process and determine the storage condition. Over a period of time and increasing experience and attention , the regulatory requirements have been made increasing by stringent to achieve the above all goal in all possible conditions to which the product might be subjected during its shelf life. Therefore the stability test should be carried out with proper scientific principles and after under standing of the current regulatory requirement and as per climatic zone.

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