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A Short Review on Pharmaceutical Drugs Stability

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Abstract: *In Pharmaceutical Industry stability of Pharmaceutical product is as important as drug development in maintaining physical, chemical, microbiological, therapeutic and toxicological optimal condition till its shelf life under environmental factors specified in regulatory specifications (ICH Q1). In this article we try to understand the various factors causing drug instability and analytical testing procedures estimating degradation, with their mechanism and its preventive measures along with examples observed in Pharmaceutical Industries*

Keywords: drug stability, shelf life, accelerated stability testing, degradation mechanisms.

I. INTRODUCTION

Stability studies ensures maintenance of drug safety and efficacy till its expiry date and the testing studies explore the mechanism of drug degradation under various stress conditions checking three major domains namely physical, chemical[1] and microbiological[2]

In the chemical stability studies, we observe the active pharmaceutical ingredient undergoing covalent bonds breakage and new formation, resulting in loss of its efficacy and generating toxic products such as ester, amide, lactam hydrolysis, atmospheric oxidation.

In the physical stability studies: the pharmaceutical dosage form we observe the retention of physical properties like appearance, palatability, uniformity, dissolution rate and crystal morphology (as amorphous to crystalline and other polymeric transitions) noted.

In the microbiological stability study, we observe the efficiency of preservatives added in specified limits in retaining the sterility and resistance to microbials[3].

ICH guidelines as a Regulatory framework understood by following global acknowledged stability guidelines followed by various countries.

ICH (International Council for Harmonization) guidelines aligns with FDA-US (Food and Drug Administration-United States), EMA-Europe (European Medicines Agency) and PMDA-Japan (Pharmaceuticals and Medical Devices Agency) stability guidelines are given as follows

ICH Q1A-establishes core stability related protocols for setting up frequency of testing in temperature and humidity.

ICH Q1B-establishes a mandatory photostability testing of drug products.

ICH Q1C-establishes a stability setup for the newly developed dosage forms of approved drugs.

ICH Q1D & ICH Q1E-establishes a statistical framework to evaluate products shelf life data, proving with mathematical principles minimizing exhausting trials[4].

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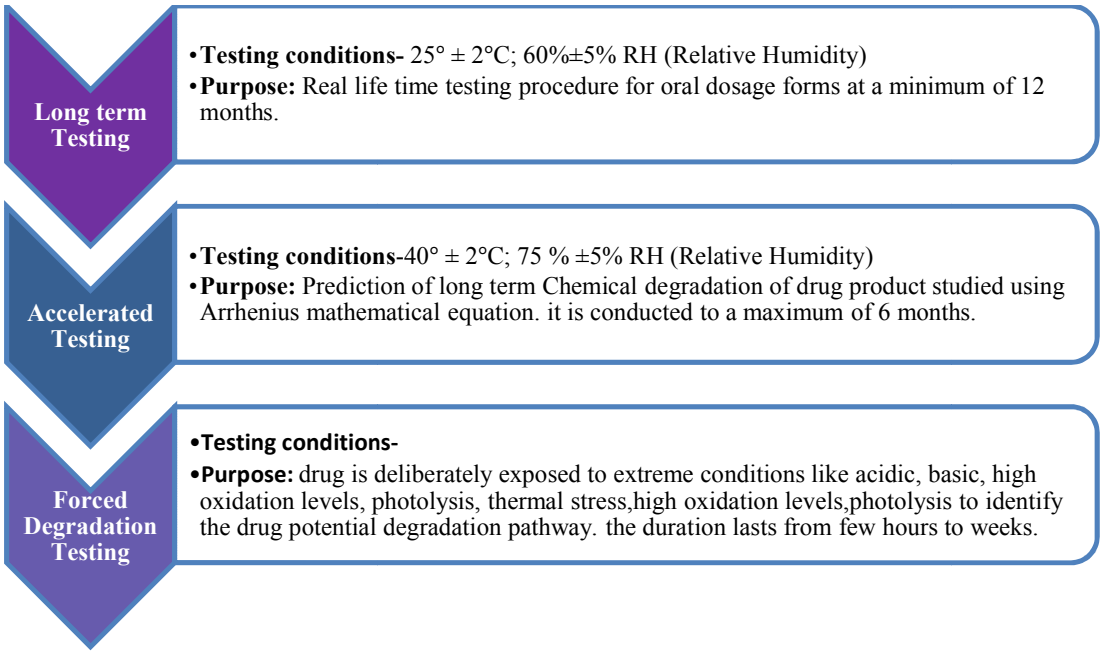

Figure 1: diagrammatic representation of stability testing conditions.

Analytical instruments and its application in stability studies

HPLC-High Performance Liquid Chromatography used for quantifying the drug as identification of drug potency.

Differential scanning calorimetry and powder X-Ray Diffraction used for identifying physical transformation from crystalline to amorphous and vice versa.

Dissolution studies used to study the drug release affected due to physical changes[5].

Table no.1 examples of drug Instability and its preventive measures.

Drug	Instability condition	Degradation pathway	Preventive measure
Aspirin	Chemical	Moisture causes Hydrolysis leading to breakdown of bonds in aspirin drug as acetic acid and salicylic acid	Package in ALU-ALU blister and formulate drug as solid oral dosage form and for liquid formulation use non-aqueous solvents.
Nitroglycerin	Physical	High pressure leads to volatization and the drug loss observed as sublingual tablets	Addition of micro-cellulose crystalline and packaging in dark containers Avoid plastic containers.
Epinephrine	Chemical	Oxidation and hydrolysis	Addition of antioxidants. Addition of chelating agents. Store in amber coloured glass bottles
Amoxicillin	Chemical	Hydrolysis causes breakdown of beta lactam ring causing drug losing its potency as antimicrobial agent.	Manufactured as dry powders with liquid for re-constitution available for use, avoiding degradation.
Tetracycline	Chemical and Physical	Polymorphism and observed due to	Store in < 65% RH and prior

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		humidity. Epimerization results in conversion to kidney toxic product 4-epianhydrotetracycline	dehumidification is done.

Pharmaceutical industries monitor the drug stability by following steps in protocols

Batch wise testing includes selection from three batches of final product ready for supplying commercial market with packaging tested according to the regulatory guidelines.

Testing frequency for long term stability studies time intervals are initial,3,6,9,12, 24 months and annually thereon. For Accelerated stability studies time intervals are initial,3,6,9 months.

Monitored parameters: these include three parameters

- Physical attributes are color, clarity, tablet hardness and dissolution rates.
- Chemical attributes are loss of drug, presence of toxic product and shift in pH.
- Microbiological attributes are sterility condition[6].

Preventive measures taken to prevent the drug degradation in Pharmaceutical Industry are discussed below.

As soon as the drug degradation pathway known the preventive measures at all steps of formulation stage, packaging stage and finally supply stage and storage conditions taken as follows[7].

In the formulation stage addition of

- antioxidants like ascorbic acid, Butylated hydroxy toluene and sodium metabisulfite.
- pH adjustment done with buffers agents adding citrates, acetates and phosphates preventing pH shifts of drug substance.
- Chelating agents EDTA addition give chemical inertness.
- Coating Process as protection for acid-sensitive and thermolabile and light sensitive drugs[8].

In the Packaging system protective enclosures used such as HDPE-High density polyethylene and ALU-ALU aluminum blister packaging used for moisture protection.

For photolytic degradation protection amber colored glass storage and packaged in cardboard cartons for preventing chemicals bonds break down induced by light.

Nitrogen purging to replace the oxygen in vials and containers before sealing[9-12].

In the environmental protection and supply chain drugs as biologics, vaccines and thermosensitive drug products strictly stored under controlled temperatures of cold 2-8° C and freezing conditions -80° C[13].

II. CONCLUSION

Pharmaceutical Industry efforts for safe guarding the drug products till it reaches patient and maintenance till its shelf life is challenging yet the solution lies in understanding the degradation pathway of the drug which helps in designing the right preservation process and suggesting the storage conditions. This topic is very interesting and research oriented as the stability testing is a continuous process of up-dation in developing new technologies for stability enhancement.

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