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Opinion Article

Analysis of Drug Stability and Chemical Degradation

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DESCRIPTION

The drug discovery and development process can be divided into two main phases. This includes separation, purification and standardization of the active ingredient. The second major phase, drug development, begins with a single compound. At this point, various studies designed to support approval as a new drug are underway. The new drug is then prescribed in the appropriate pharmaceutical form.

Pharmaceutical stability is defined as the ability of a product to maintain its potency, properties, and properties throughout its shelf life within a particular container. The recommended shelf life (expiration date) of over-the-counter medicines is 3 to 5 years. During this time, the concentration of the drug should not drop more than 95% of the value of the original formulation.

There are five types of stability that concern the pharmacist in the manufacturing of drugs: Chemical (including photochemical), the product retains its chemical integrity and potency. Physical, the conformity of the pharmaceutical product (color, appearance, dissolution, etc.) does not change upon storage or handling. Microbiological, sterilized products should remain sterile (no pyrogenicity). In therapeutic, the therapeutic effect remains unchanged within the specified dosage regimen. In toxicological, no significant increase in a predetermined toxicity effect is noted.

The type of stability (therapeutic, microbiological, and toxicological) basically depends on the chemical and physical properties of the drug. Knowledge of the chemical stability of a drug is very important for selecting appropriate storage conditions for the effects of light, temperature, humidity, etc. and predicting drug interactions or interactions with excipients. Stable medicines are very important to pharmacists (from a marketing, storage and distribution perspective). For physicians and patients (in terms of safety and efficacy); to regulatory agencies and quality control analysts (in terms of quality, strength, purity and identity).

Many tablets are derivatives of carboxylic acid or comprise purposeful companies primarily based totally in this moiety, as an instance esters, amides, lactones, lactams, imides or carbamates. Accordingly, diverse chemical reactions can bring about the degradation of the drug. These reactions encompass hydrolysis, oxidation, photochemical reactions, polymerization, isomerization, racemization and dehydration.

Hydrolysis bureaucracy is maximum not unusual place pathway through which pills turn out to be degraded due to the fact many pills include hydrolysable purposeful groups. It may be described because the method through which drug molecules have interaction with water to yield breakdown merchandise of various chemical constitution. Hydrolysis happens greater with no trouble in liquid kingdom than within side the stable kingdom. It can also additionally arise in aqueous suspensions of sparingly soluble pills. In pills and different stable dosage bureaucracy, there can be enough water to permit hydrolysis of the drug.

Oxidation involves the removal of electropositive atoms, radicals, or electrons, or the addition of electronegative atoms or radicals. When molecular oxygen (O═O) is involved in a reaction, it is commonly referred to as autoxidation and is the most common pathway for oxidative degradation of drugs. Oxidative decomposition by autoxidation may involve a chained process consisting of three simultaneous reactions: initiation, propagation, and termination. Initiation can occur *via* free radicals formed from organic compounds by light, heat, or exposure to transition metals such as copper and iron. These are present in trace amounts in almost all buffers.

Drug molecules that are unstable to photolysis, many medicines have been tested for their photo stability. Carbonyls, aromatic nitro compounds, and N-oxide functional groups, aryl halides, alkenes, polyenes, and sulfides are specific chemical functional groups that are expected to induce photo reactivity. If the compound absorbs light above 300 nm and photo degradation becomes apparent in a short period of time, photo degradation of the drug is considered to be practically important.

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Factors that determine the photochemical reaction rate include aerobic (most reactions occur in the presence of oxygen) and anaerobic (N_2) conditions, solvents (H_2O), organic solvents), buffers, temperatures, metals, irradiance and Optical spectrum distribution, drug concentration, and amount of sample.