

# **Stability Analyzes and Evaluations in Drug Formulations**

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# STABILITY

The stability of a drug means that its production date characteristics during production, storage, transport, hospital and pharmacy storage and handling remain within predetermined limits.

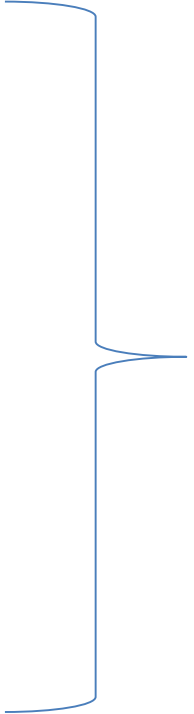
# Shelf life

- It is the time period for which an active substance or pharmaceutical product is expected to conform to the specifications made by the stability studies performed on a certain number of batches when stored in the recommended package in the recommended condition.

# Expiration date

- The expiry date on an active substance or label of a pharmaceutical product is expected to remain within the specification limits of the substance or the product if stored under appropriate conditions.

1. Chemical stability
2. Physical stability
3. Microbiological stability
4. Therapeutic stability
5. Toxicological stability



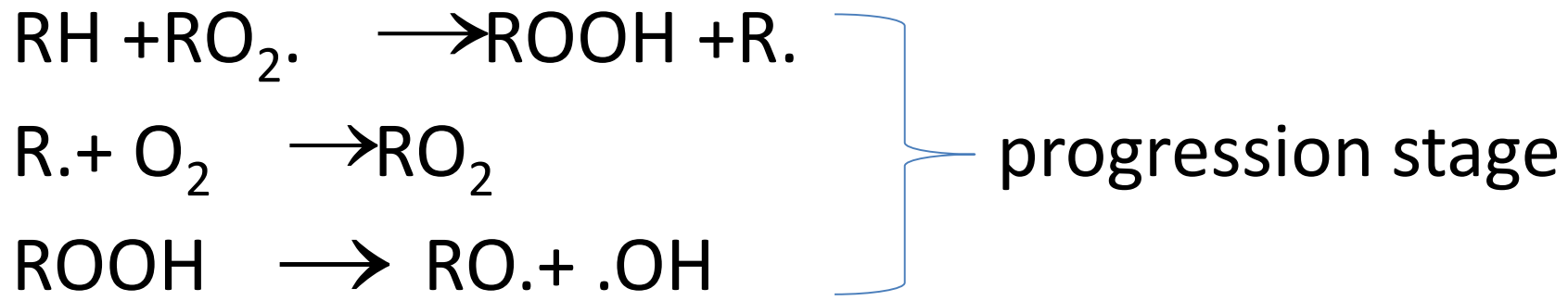
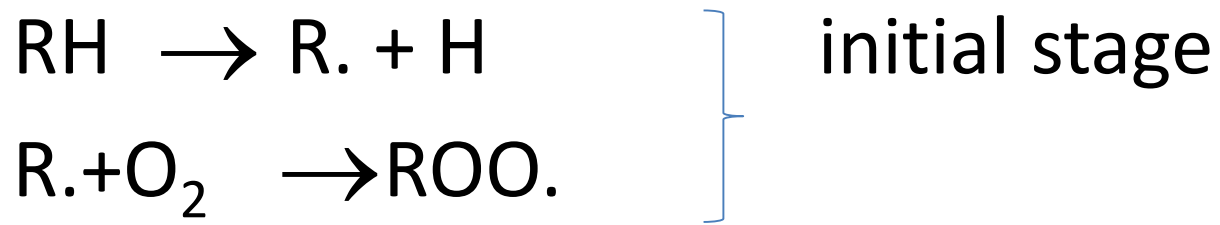
A drug should also fulfill these 5 stability properties during its shelf life.

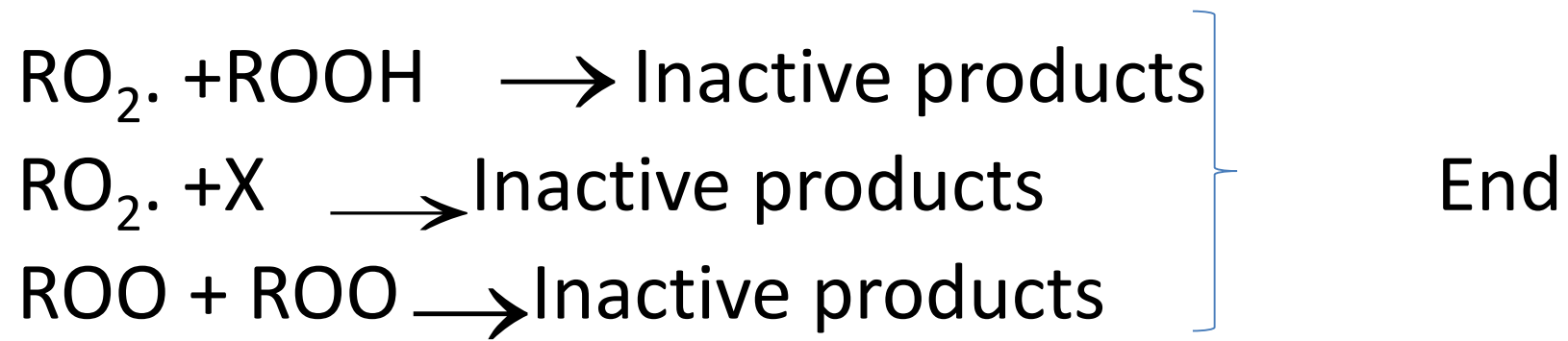
# Chemical stability and evaluations

- Oxidation reactions
- Hydrolysis reactions

# Oxidation reactions

- Examples are such as riboflavin, streptomycin, sulfadiazine, tetracycline, penicillins, novobiocin, norepinephrine, hydrocortisone, cyanocobalamin, chlorpromazine, ergometrine, A, B, C and E vitamins.





X: It is a free radical inhibitor.

It comes from the auxiliary substances in the environment.



- ❖ Self-initiated oxidation reactions without heat, light or heavy metal ions are called "auto-oxidation" reactions.
- ❖ Oxidation and reduction are reactions that move together.

Reduced state  $\longleftrightarrow$  oxidized state + n  $e^-$

It is called "redox" or  $e^-$  transfer reaction.

Functional groups exposed to autoxidation;

Phenols, catechols, ethers, thiols, thioethers,  
carboxylic acids, nitrites, aldehydes, amines.