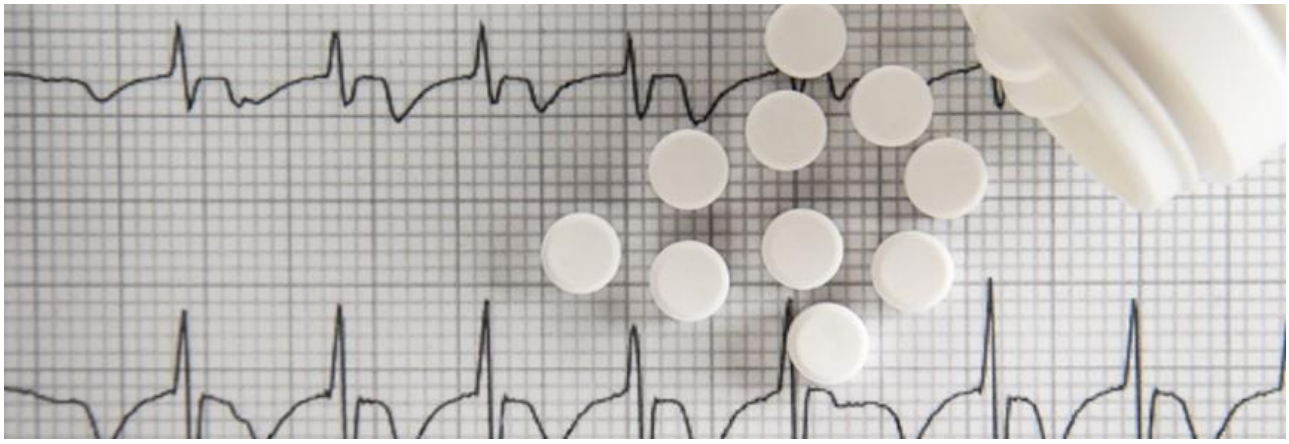
STABLUS® Predictive Shelf Life Simulation



Simulator for Shelf Life Predictive Calculation

Pharmaceutical stability and shelf life are dependent on optimal packaging. Choosing protective packaging can be expensive and time consuming. STABLUS® predictive shelf life simulation is a service for packaging conditions that helps our customers determine optimal solutions for shelf life protection.

Optimal desiccant dosage or required barrier protection: This may not be immediately known for a given application.

Stablus: Evaluates the shelf life of packaging using predictive simulation for packaging materials, packaging permeability, drug moisture isotherm, anticipated environmental conditions and oxygen permeation, etc.

$$\frac{Q}{t} = \frac{P \cdot A \cdot (\Delta p)}{X}$$

Science based: STABLUS provides recommendations based on proven formulas to optimize the compatibility between the drug isotherm and the packaging.

Why use STABLUS?

- Evaluates the relative humidity (RH) level and oxygen concentration inside the packaging during the shelf life depending on the environmental conditions and the packaging barrier properties.
- Guides development for an optimal packaging configuration, taking into consideration the container (bottles, tubes, container closure system, aluminum bags, dispenser, and inhaler) and functional agent (desiccant, oxygen scavenger, etc.).
- Reduces time to market and testing resources by streamlining the choice of packaging configurations required for stability testing.
- Determine technical and/or cost-saving improvements for existing drug packaging.
- When marketing a drug product in a different climatic zone, STABLUS can evaluate requirements for alternative packaging configurations (i.e., more or less desiccant, blister packaging, etc.).

Climatic Zone	Definition	Criteria Mean annual temperature measured in the open air/mean annual partial water vapor pressure	Long-term testing conditions	
I	Temperature climate	≤15°C / ≤ 11 hPa	21°C / 45% RH	The climatic zones in which the product will be manufactured are essential to shelf life predictive calculations. [1]
II	Subtropical and Mediterranean climate	> 15 to 22°C / > 11 to 18 hPa	25°C / 60% RH	
III	Hot and dry climate	> 22°C / ≤ 15 hPa	30°C / 35% RH	
IV	Hot and Humid climate	> 22°C / > 15 to 27 hPa	30°C / 65% RH	
V	Hot and very humid climate	> 22°C / > 27 hPa	30°C / 75% RH	

1. WHO, Stability Testing of Active Pharmaceutical Ingredients and Finished Pharmaceutical Products, Technical Report Series 953, (2009) Annex 2. http://apps.who.int/medicinedocs/documents/s19133en/s19133en.pdf

Regulatory compliance may vary depending on the country and end-use application, please contact your Colorcon representative for more information.

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