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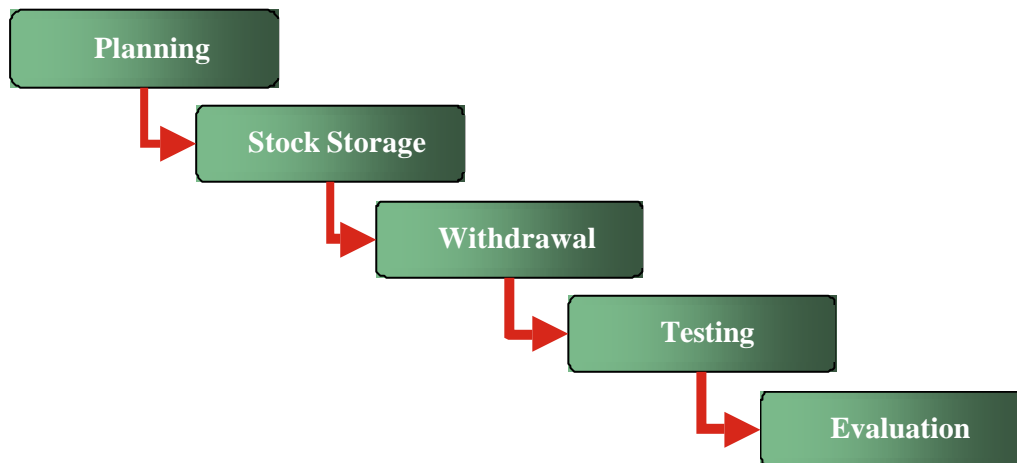
Stability Studies

Which opportunities will provide a LABS/Q[®] integrated solution for durability and stability studies?

The Module

The module of stability studies as an integrated solution in the LABS/Q[®] system offers all necessary features for planning, stock storage and storage periods of stock withdrawal, testing and evaluation of test samples with regard to stability or durability studies.

Consequently, this module offers you the ideal tool for representing the interaction of product, packing and its climatic conditions, the influence of novel raw materials or production conditions, the durability of products in trade and much more.



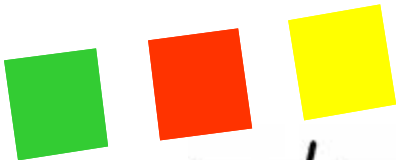
The Features

In a stability study you can represent all relevant information like details according to the product, packing, climatic conditions or the scope of inspection. These details can be combined either in a very flexible way or by using predefined templates.

Based on this study the corresponding stock storage and withdrawal dates will be planned and monitored.

The stock storage quantities will be planned according to the scope of inspection, the packing size and additionally taking into account the backup quantity. At any time you can extend or reduce the study.

Modifications of stability data will be documented definitely by a version control system. Thus, changes of stability data can be identified easily at any time.



43918 - MODULE 195

Inventory Stability Project

Storage Cond: KLZ2560 STAB Project: ASS-EXAMPLE Stock Object No: 000002001 Status: 4

Material No.: ASS Description: Acetylsalicylic acid

Variant: MM1 Batch ID: 2003-08-13

Pack Type: PE-BH 100 Inventory: 30.000 Reserved Quantity: 18.000

Stock Entries / Removals

E/R	Status	Planned Date	Planned Quantity	Quantz	Unit	Date booked	Booked by	Cancellation
I	0	13.08.2003 14:05	27.000	30.000	g	14.08.2003 11:17	SYLVIA, Sylvia Schri	
O	0	13.11.2003 14:05	3.000	3.000	g	14.08.2003 13:03	SYLVIA, Sylvia Schri	
O	1	13.02.2004 14:05	3.000	3.000	g			
O	1	13.05.2004 14:05	3.000	3.000	g			
O	1	13.08.2004 14:05	3.000	3.000	g			
O	1	13.08.2005 14:05	3.000	3.000	g			
O	1	13.08.2006 14:05	3.000	3.000	g			

Bundles as well as sample labels and advice notes can be printed automatically by the system. The actual withdrawal dates will be taken into account during the evaluation of the study. The possibility of booking the withdrawals ensures a clearly arranged sample stock. At any time evaluations in consideration of the actual withdrawal dates and the already accomplished tests can be compiled by the system. These evaluations may be performed even if the study was modified or extended individually.

43918 - MODULE 190-1

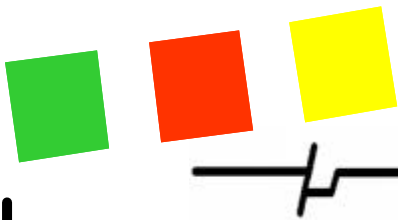
Stability Project Details

STAB Project: ASS-EXAMPLE Version: 2 Type: ONG

Description: Presentational example for stability study in pharmaceutical industry - product ASS

Material No.: ASS Variant: MM1 Batch ID: 2003-08-13

Pack Type	PE-BH 100	PE-BH 100	PE-BH 100	PE-BH 100	PE-BH 100	PE-BH 100
Storage Condition	KLZ2561	KLZ2560	KLZ2560	KLZ2560	KLZ2560	KLZ2560
Planned Sample Time	13.08.2003 14:05	13.11.2003 14:05	13.02.2004 14:05	13.05.2004 14:05	13.08.2004 14:05	13.08.2005 14:05
Identity ASS	ASS-Identity	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Appearance of solution	ASS-Purity	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Heavy metals	ASS-Purity	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Loss on drying	ASS-Purity	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Similar substances	ASS-Purity	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Sulfate ash	ASS-Purity	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Content of ASS	ASS-Content det	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>



Taking the integrated stability module you will receive a flexible tool, which offers you various possibilities of monitoring Follow-Up-, On-Going- or development stabilities.

You can either use predefined time patterns or compose individual studies.

The version control of the stability module ensures at any time transparency and traceability according to situational modifications during the course of study. The system reminds you automatically of current withdrawal dates, so you won't forget any date. Evaluations of the study may be performed anytime regarding to various aspects of the stability investigation. The evaluation can be started either manually just at the push of a button or automatically on the basis of system events. The graphical representation of the study results can be included in the evaluations and reports. This will help you for your decision making in case unexpected events occur during the further course of the project.

