

LABS Suite



01 Stability tests – the challenges and the solution

Stability tests are performed for a wide range of products both early on, during the development stage, and further down the line as part of quality assurance. The results are often used as the basis for determining the stability of a product and for arriving at an expiry date for a packaged batch of material.

The storage conditions for batches of material stored during stability testing, such as the medium, temperature and relative humidity, are selected based on the requirements that will be placed on the product in its target climate zone(s).

In the pharmaceutical industry, the procedure for performing stability tests is prescribed for pharmaceutical manufacturers, for example through the guidelines of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).



The challenges

Stability testing performed as part of routine quality monitoring or during development necessitates extensive planning for the batches of material to be stored, comprehensive storage documentation, continuous monitoring of schedule compliance, recording of items removed from storage, the acquisition and measurement of data, and graphical and statistical evaluation as part of the reporting process. Particularly within regulated environments, the outlay on follow-up, record-keeping and documentation is always very high.

The solution

The stability testing modules provided with the LABS Suite with LABS/Q® LIMS offer the user the ideal tool for testing the interaction of development and production batches, their primary packaging and climatic conditions, the influence of new materials or manufacturing conditions, the stability of newly developed products or those already on the market, and much more.

The LABS Suite helps you to plan by identifying the necessary quantities of test material and the climatic conditions in which they are to be stored and by highlighting any possible bottlenecks. Potential errors are avoided, for example as a result of definable consistency rules. Comprehensive processing is ensured thanks to the automatic monitoring of climatic chambers (repositories) and schedule compliance (e.g. scheduled times for removal from storage) and the issuing of corresponding reminders (e.g. via email). The automatic processing of the removal and the test orders is simplified thanks to a connection to the relevant measuring instruments. Analysis, graphical and statistical evaluation (regression for extrapolation, Arrhenius equation for recalculation, etc.), the creation of reports and the archiving and distribution of reports are key features of the LABS Suite.

You too can benefit from our many years of experience in supporting you in achieving your goals. Our LABS Suite helps you to automate your processes within a reliable and professional GxP-compliant system and thereby save time and money. The LABS Suite also assists you with internal quality assurance by providing the necessary capacity monitoring and monitoring of schedule compliance.

02 Study templates – templates for recurring tests

Templates can be predefined for studies. These templates enable you to create frequently recurring stability checks with minimum effort. These templates make performing stability studies much easier – not just for routine follow-up or ongoing checks but also for recurring tests when developing new products.

Both the **scope of the investigation** (based on saved test plans) and tailored specifications and methods for each **material**, **primary packaging material**, **climate zone** and **scheduled time** can be stored with the templates.

The details from the methods and a **reserve quantity** or a quantity factor are used to calculate the quantity to be stored.



Recalculation of the required quantity and the primary packaging (e.g. lozenges and blisters) is also supported here.

These templates also make planning stability studies/stress tests significantly easier for recurring checks when developing new products.

Stability templates

- Templates
- Scope of investigation
- Materials
- Primary packaging materials
- Climate zones
- Scheduled times
- Reserve quantities
- Additional master data

Example: study template with different climate zones and details of the reserve

Additional master data is provided to enable the study templates to be created with ease. This may include, for example, materials, primary packaging materials, test plans or methods, features, schedule, climate zones/repositories.

03 Study management – flexible tool for mapping studies

Stability studies

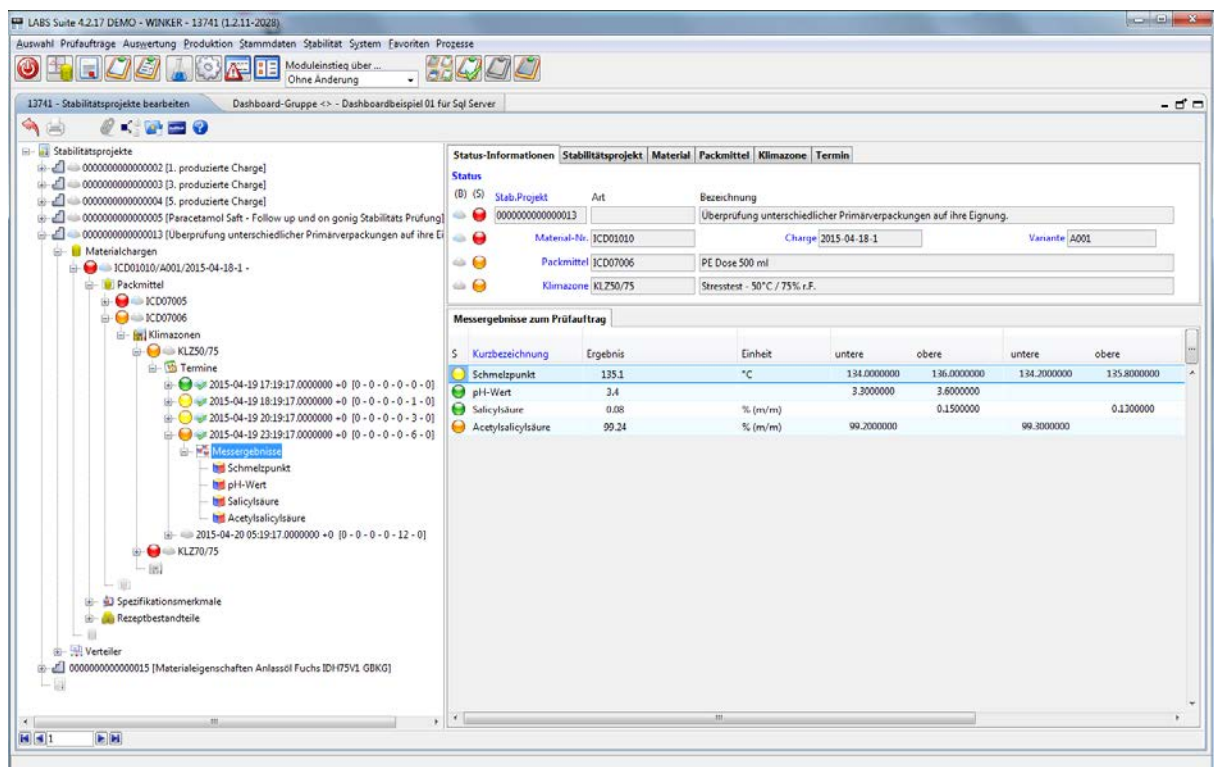
- Version check
- Study templates
- Follow-up / ongoing
- Climate zones
- Scheduled times
- Scope of investigation
- Reserve / sample quantity
- Additional master data

The study management module in the LABS Suite is used to manage the manually or automatically (e.g. based on a new batch from production) created studies. Every change or extension of the study is logged via a **version control**. The creation of new versions of a stability study means that in the event of system-related changes during the course of the study you always benefit from security and verifiability. The associated test orders and their results can also be looked at in this context. The study management function therefore offers you a comprehensive overview of the studies with the available results, reports and evaluations.

The integrated stability study management feature provides you with a flexible tool for mapping follow-up, ongoing and development stabilities. You can work with pre-made **study templates**, test plans and schedules or put together highly individual studies with one to any number of batches of material, packaging materials, climate zones, scheduled times, methods and specifications.

The user of the LABS Suite is automatically informed that a **follow-up or ongoing** check is required and the recommendation is made that they store the batch currently being processed. When this option is selected, a study is then automatically recreated or extended. If the batch is not selected, then a reminder is issued once again at the next batch release.

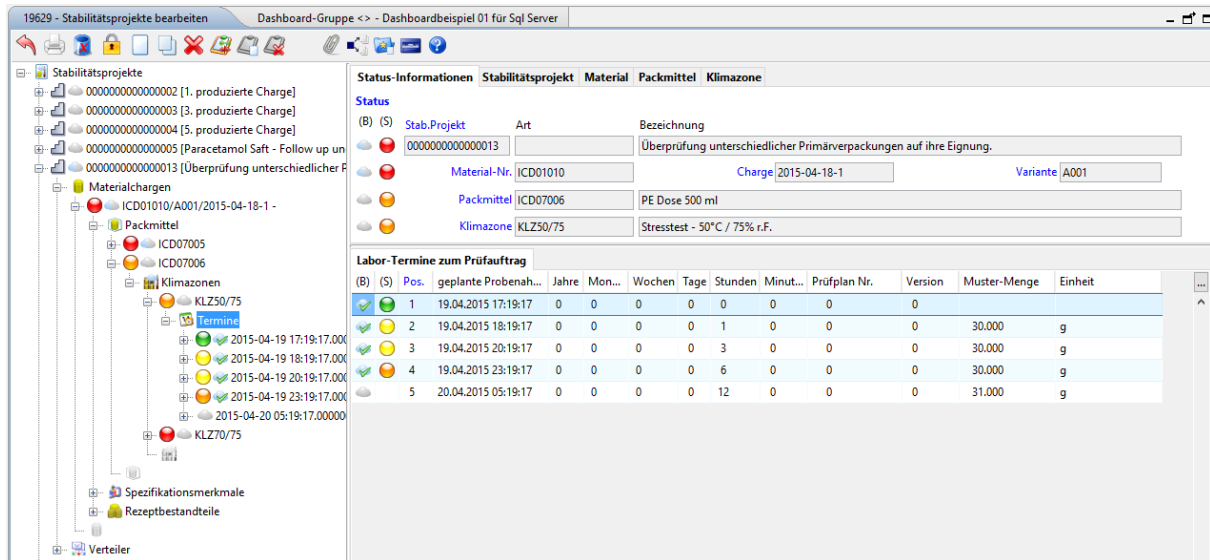
Example: project/materials/batch/packaging material/climate zones/scheduled times/specification/results



A number of different **climate zones** can be determined within a stability study. The possible climate zones are described in the LABS Suite via the available climatic chambers or repositories with its capacities (storage spaces).

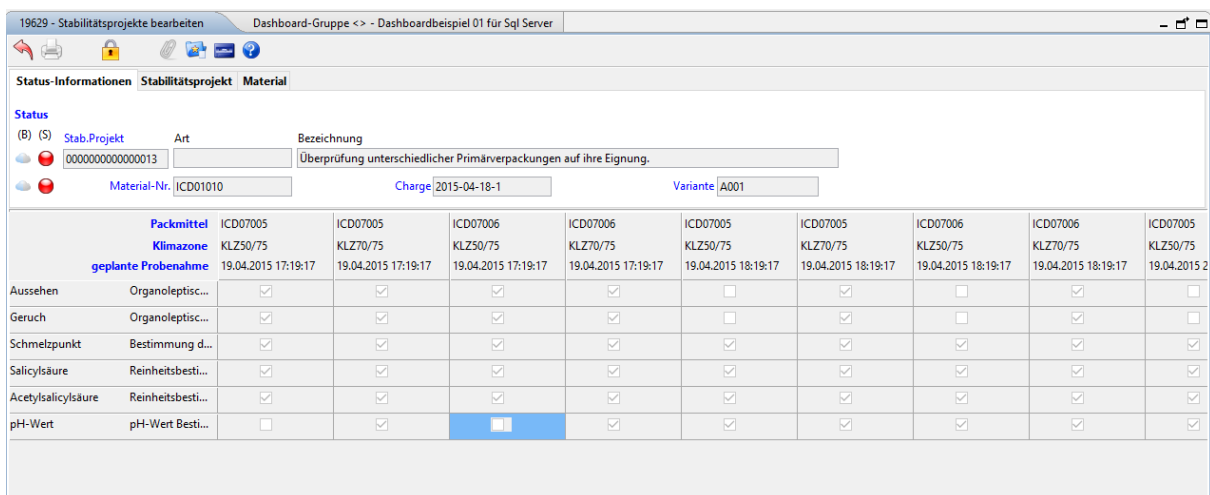
The **scheduled times** for storage up to the last removal can then be defined for each climate zone, either manually or based on the schedules stored in the LABS Suite.

Example: project/materials/batch/packaging material/climate zones/scheduled times



The **scope of the investigation** for the individual scheduled time is then determined based on a test plan or individually based on the methods. The version can be specified with the test plan. If this is not done, the current version is used subsequently in the test orders. It can also be specified individually for each scheduled time whether a check-out is necessary.

Example: matrix for determining the scope of the investigation



Depending on the scope of the investigation (methods) and a specified **reserve** (set quantity or factor), the system automatically calculates the necessary **sample quantity** per scheduled time. A recalculation of the amount and packaging (e.g. lozenges to blisters or g to containers) is supported. The **sample quantities** automatically suggested by the system can, however, still be manually adjusted.

Stability tests

Example: matrix with the required quantities per scheduled time and climate zone

	01.07.2012 16:34	01.07.2012 19:34	01.07.2012 22:34	02.07.2012 01:34	02.07.2012 04:34	02.07.2012 10:34	02.07.2012 16:34	03.07.2012 04:34
70001 ST-25°C/60	Menge	Menge 1.240	Menge 1.200	Menge 1.240	Menge 1.200	Menge 1.240	Menge 1.200	Menge 1.440
70002 ST-25°C/60	Menge	Menge 0.620	Menge 0.600	Menge 0.620	Menge 0.600	Menge 0.620	Menge 0.600	Menge 0.720
70003 ST-25°C/60	Menge	Menge 0.124	Menge 0.120	Menge 0.124	Menge 0.120	Menge 0.124	Menge 0.120	Menge 0.144

The following [additional master data](#)/modules are used to assist with the creation of stability studies and their templates:

Storage management:

The storage management function enables the different repositories/climatic chambers with their various climatic conditions to be defined and described and also enables the description of repositories/storage spaces. Based on these details and the current occupation of available spaces, capacity monitoring is possible even as early as the planning stage for further studies.

Schedule:

Templates for frequently recurring scheduled times can be stored in the LABS Suite by managing schedules.

Materials management:

The materials and packaging materials are stored in the LABS Suite using materials management. The time intervals at which ongoing and follow-up stability studies are to be performed and the frequency of these are also defined for the material and prescription. The study template to be used can also be specified.

Partner management:

If the stability studies are also processed in the service, the partner (client) for the study can be stored. The agreed price list and the agreements on discounts and payment are then stored for the partner.

Terminraster	Bezeichnung	Anzahl Termine	letzte Änderung
12MO	12 Monate (0, 6, 9, 12)	4	14.12.2011 15:42:18
18MO	18 Monate (3, 6, 9, 12, 18)	6	05.11.2003 14:35:13
30TAGE	30 Tage für den TOC-Abbau	30	07.04.2003 15:37:02
36 MONATE	36 Monate	7	15.04.2003 13:46:35
36MO-1	36 Monate (3, 6, 9, 12, 24, 36)	7	05.11.2003 14:31:39
48 MONATE	48 Monate	8	15.04.2003 14:03:11
60 MONATE	60 Monate-Raster	13	29.04.2002 14:04:57
60MO-1	60 Monate (0, 12, 24, 36, 48, 60)	6	11.03.2009 16:23:11
60MO-2	60 Monate (0, 3, 6, 9, 12, 18, 24, 36, 48, 60)	10	14.12.2011 15:40:19
60STUNDEN	60 Stunden	9	18.06.2009 19:53:09
6MO	6 Monate (3, 6)	3	05.11.2003 14:36:08
6MO-1	6 Monate (0, 3, 6)	3	14.12.2011 15:43:20
90TAGE	90 Tage-Raster	7	26.03.2002 16:04:05
WEATHERING	Weathering	14	15.08.2013 14:56:12

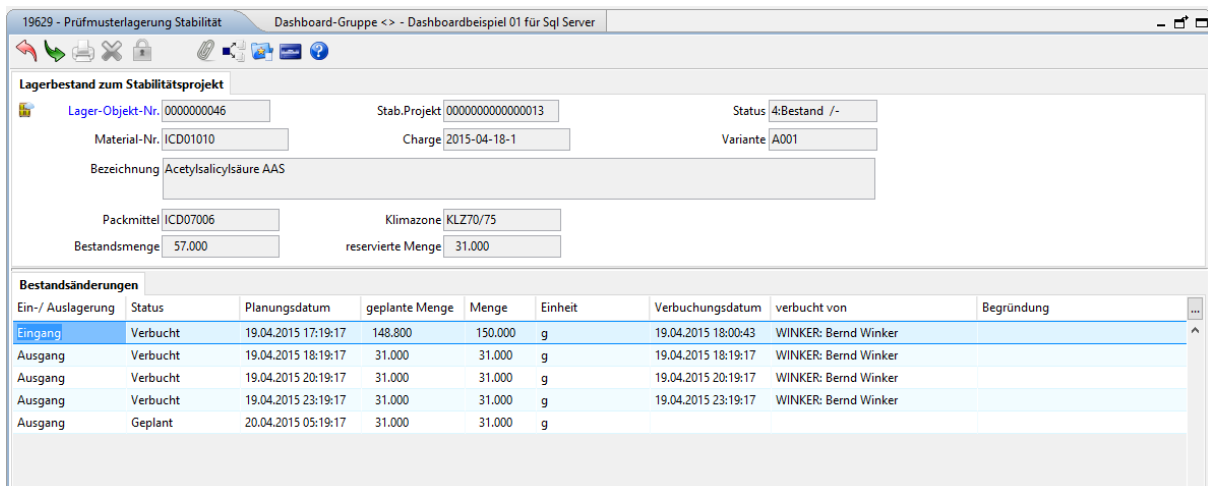
04 Storage of stability samples in inventory management

The LABS Suite inventory management feature is also used to manage the **inventory** of stability samples. With this function, scheduled times for storage and removal are automatically planned based on released and active stability studies.

The **storage** of the stability templates can be performed and logged with the actual scheduled time. Any labels required are created as a matter of course.

Automated functions in the system prevent scheduled times for **removal** being forgotten. A number of days in advance, corresponding test orders are automatically scheduled and the affected individuals are informed by e-mail. If desired, a list of upcoming removals can also be created, filtered according to a schedule.

Example: list of changes to the inventory for a study, climate zone, material/batch and packaging material



The screenshot displays the 'Lagerbestand zum Stabilitätsprojekt' (Inventory for Stability Project) window. It shows details for a project with 'Lager-Objekt-Nr.' 0000000046, 'Stab.Projekt' 0000000000000013, and 'Status' 4:Bestand /-. The material is 'Acetylsalicylsäure AAS' (Material-Nr. ICD01010, Charge 2015-04-18-1, Variante A001). The packaging material is 'ICD07006' and the climate zone is 'KLZ70/75'. The current inventory is 57,000 units, with 31,000 units reserved.

Below the overview is a table titled 'Bestandsänderungen' (Inventory Changes) with the following data:

Ein- / Auslagerung	Status	Planungsdatum	geplante Menge	Menge	Einheit	Verbuchungsdatum	verbucht von	Begründung
Eingang	Verbucht	19.04.2015 17:19:17	148.800	150.000	g	19.04.2015 18:00:43	WINKER: Bernd Winker	
Ausgang	Verbucht	19.04.2015 18:19:17	31.000	31.000	g	19.04.2015 18:19:17	WINKER: Bernd Winker	
Ausgang	Verbucht	19.04.2015 20:19:17	31.000	31.000	g	19.04.2015 20:19:17	WINKER: Bernd Winker	
Ausgang	Verbucht	19.04.2015 23:19:17	31.000	31.000	g	19.04.2015 23:19:17	WINKER: Bernd Winker	
Ausgang	Geplant	20.04.2015 05:19:17	31.000	31.000	g			

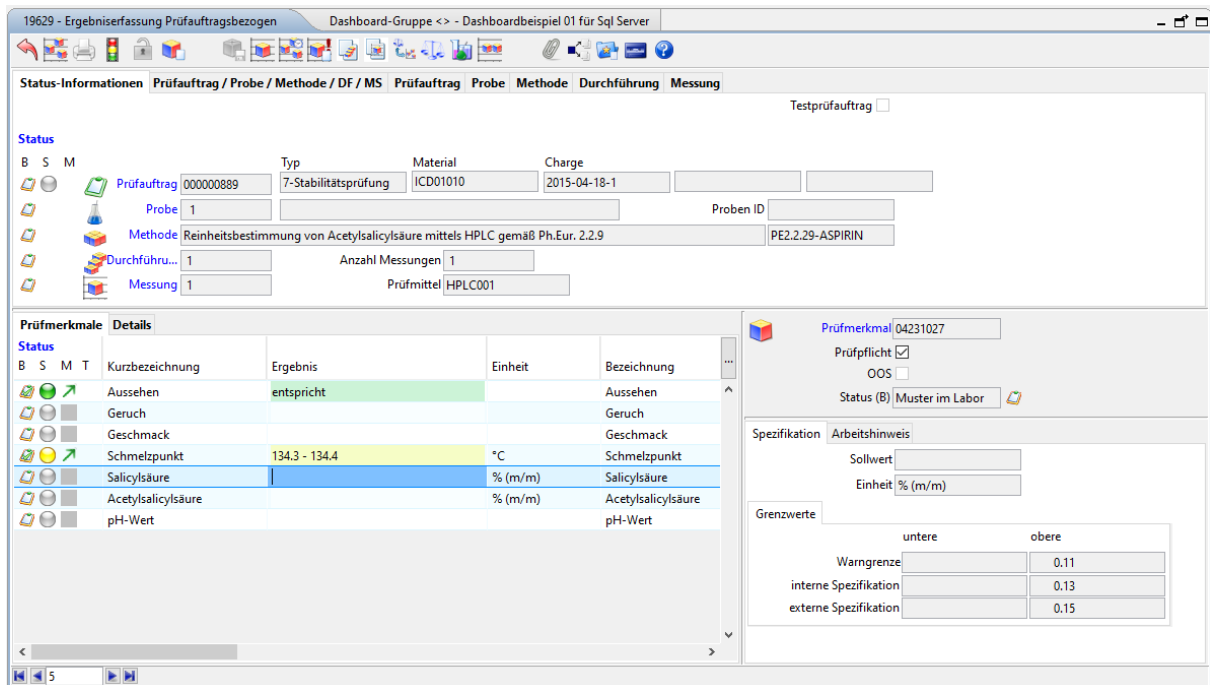
If the removal is then booked in the inventory management function with the actual scheduled time and the quantity removed, the corresponding test order is then automatically transferred to the status "pre-registered" (sample taken). It is naturally still possible for barcode labels to be created following this.

05 Processing of test orders for stability tests

Once the laboratory has received the stability templates, the status of the corresponding test orders is transferred to "Registered – template has reached laboratory". These are then provided to the laboratory staff or the measuring instruments for processing.

Processing can then proceed with the support of the various modules and functions of LABS/Q® LIMS and the app for recording results. The measured values can be imported from the measuring instrument both manually and automatically. Once they have been recorded, the measured values and, for example, the calculated results are automatically evaluated.

Example: manual recording of measured values via LABS/Q®



Example: recording of measured values via tablet app



Once the test order has been processed, the results are assigned to the study and are then available for the creation of reports and for graphical and statistical evaluation.

06 Creating reports

The LABS Suite offers a wide range of options for the manual and automatic creation of reports. Automatic report creation takes place based on the results (e.g. test order was concluded) and on the basis of schedules (e.g. daily lists of planned removals from storage). The report templates can be created based on [Jasper Reports](#), [Crystal Reports](#) and HTML-based [FreeForms](#) and stored in the LABS Suite.

Example: report with and without graphics

Stab.Projekt 0000000000000003 **Version** 1
Material-Nr. 50001 **Acetylsalicylsäure**
Charge 1/2011 **Variante** A001
Packmittel 70001
Lager ST-25°C/60
Merkmal SCHMELZPUNKT
PE2.2.14 Methode

Schmelzpunkt

[Tage]	[°C]
01.07.2012 16:34	~134.5
1	~134.2
2	~134.0

Merkmal PE2.2.29-ASS-B **C9H8O4**
PE2.2.29-ASS-B Methode
Acetylsalicylsäure

[Tage]	[%(M/M)]
01.07.2012 16:34	~99.85
1	~99.55
2	~99.40

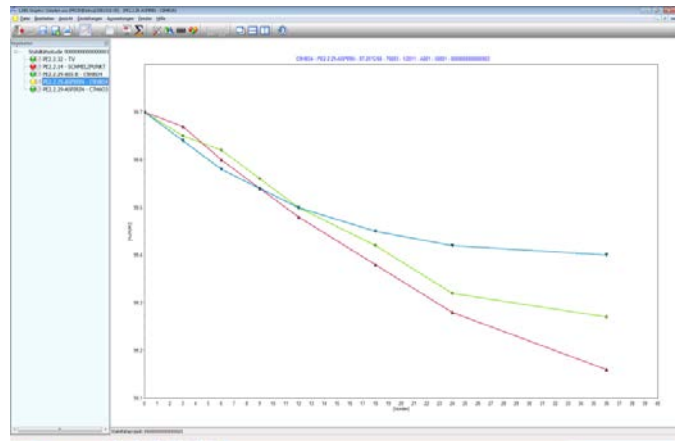
Parameter	Start Spezifikation	aktuelle Spezifikation	Termin Stunden	9:00	12:00	18:00
Schmelzpunkt	134.0 - 136.0	134.0 - 136.0	°C	entspricht	entspricht	entspricht
Identität	entspricht	entspricht		entspricht	entspricht	entspricht
Salicylsäure	max. 0.15	max. 0.15	%(M/M)	0.06	0.07	0.08
Acetylsalicylsäure	min. 99.00	min. 99.00	%(M/M)	99.70	99.65	99.62
Acetylsalicylsäure	min. 99.3	min. 99.3	%(M/M)	99.9	99.9	99.9
Trockenverlust	max. 0.5000	max. 0.5000	%(M/M)	0.1750	0.2000	0.2100
Restlösmittel	entspricht	entspricht		entspricht	entspricht	entspricht

07 Tailored graphical evaluations supported by LabsGraphic

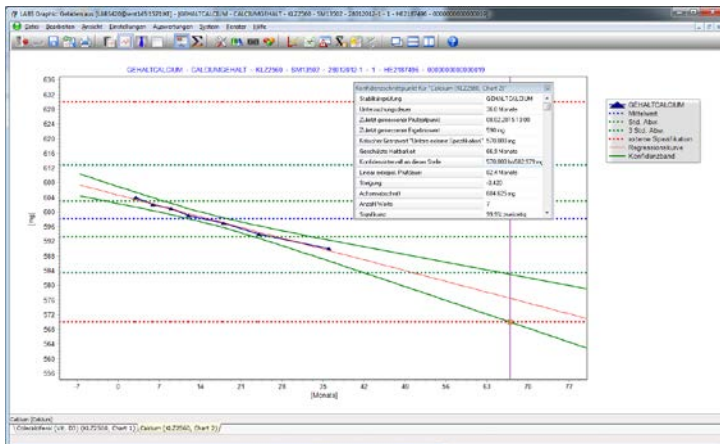
In connection with LabsGraphic (details: see product description), tailored evaluations of the study and results data can be performed.



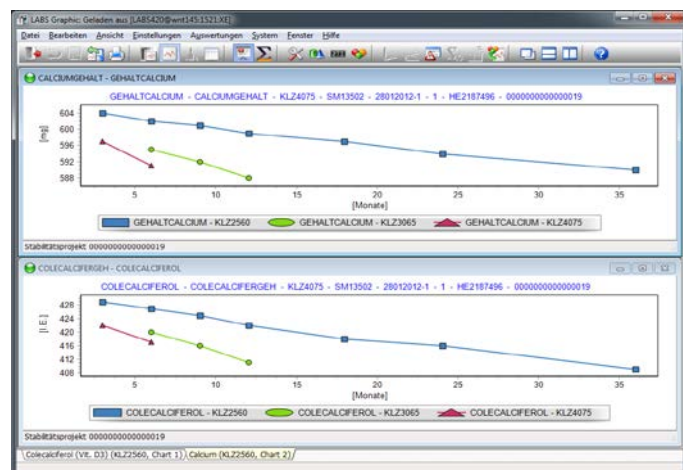
Example: Comparison of different stabilities



Example: Stability predictions/trends



Example: Stability extrapolation / Arrhenius



08

The benefits for you at a glance

iCD. has been well-known internationally for outstanding laboratory software solutions and associated consulting services since 1986. The software products are developed in accordance with the quality management system of iCD., which has been certified to [EN DIN ISO 9001](#) since 1994 and conforms to [GAMP5](#). We offer a high level of investment security thanks to our many years of continuously developing and maintaining products. More than 300 large and medium-sized businesses from different fields, some operating globally, trust in our software solutions. You can have confidence in our expertise.

We will support you through every phase of your project to ensure that you successfully implement the best possible software solution for your company.

As your platform for processing stability studies, the LABS Suite with LABS/Q® LIMS helps you to plan, implement and report on such studies and to perform graphical and statistical evaluations. This is carried out based on studies created manually or automatically from study templates, the calculation of the necessary sample quantities and their storage details and the monitoring of compliance with schedules for removal and investigation. The automatic creation of reports and also the options for graphical and statistical evaluation enable studies to be stopped in good time when required. These features also allow capacity to be generated for storage and equipment and personnel to be provided for additional studies. A wide range of evaluation options is provided for the final evaluation of the data. It is easy to incorporate the results into final evaluation reports and to store them in the integrated document management system (DMS).

At every work step, any missing or incomplete information is brought to the attention of employees. Forgetting to remove items from storage or perform tests will be a thing of the past thanks to monitoring of compliance with schedules. You can say goodbye to time spent searching for documents, the laborious process of compiling measurement results, and errors resulting from the manual transmission and evaluation of measurement data.

We are on hand to help and look forward to hearing from you!

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