

Stability Management

Improving Efficiency and Compliance

Novatek Stability Features

Novatek Stability manages the day-to-day activities of the stability department within either quality control or R&D environments. The application can be run standalone or integrated to compliment existing LIMS or ERP/MES functionality.

Support for 21 CFR Part 11 and other key regulatory requirements including the ICH Q1 Stability Testing guidelines

Flexible design easily accommodates Accelerated or Long Term studies and incorporating both Bracketing and Matrixing of Protocols.

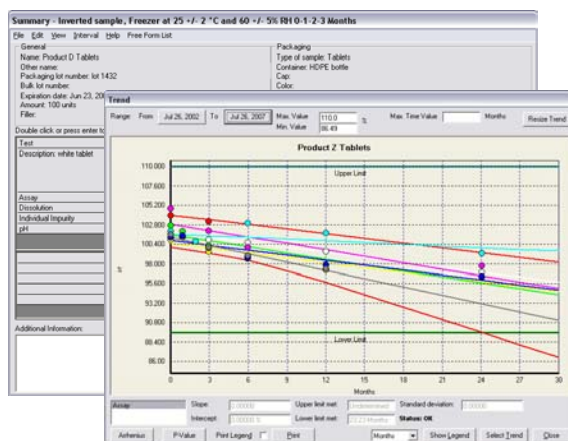
Inventory management of Stability chambers with Barcoding for easy storage, retrieval and monitoring of large volumes of samples.

Easy interface for entering, verifying and approving result data, and if appropriate modifying a study to add additional testing or time points.

Multi level specifications can be managed with automated Investigation of OOS/OOT results

Built in Statistical analysis with linear regression, user defined confidence limits, p-value and Arrhenius calculations to ensure the manufacturing process is under control.

Configurable reporting & query tools for data retrieval and knowledge management.



Novatek Stability Benefits

Fast implementation and validation, ease of upgrade and support

Accelerated laboratory turnaround

Workflow management from study design to ongoing Stability Batches

The screenshot shows the 'Product Registration' window. It has a search bar for 'Traching Number' and 'Formal Amount'. Below is a list of registered studies with columns for 'Name', 'Location', and 'Other'. The list includes various study types like 'Upright sample, Incubator at 25 +/- 2 °C and 60 +/- 5% RH 0-3-6-9-12-18-24-36 Months' and 'Inverted sample, Freezer at 25 +/- 2 °C and 60 +/- 5% RH 0-3-6-9-12-18-24-36 Months'. There are buttons for 'Add', 'Edit', and 'Delete'. At the bottom, there are fields for 'Date stability initiated', 'Row', 'Full date tolerance', 'Col', and 'Qty replicate Comment'. There are also buttons for 'Modify Cytion Lab', 'Print Product Registration', 'Save', 'Sign and Close', and 'Cancel'.

Reduced costs associated with Stability & Inventory management

Improved operational efficiency

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