

## SOFTWARE

### PH21 Software

The Professional Data Management System for Solid Dosage Forms

The PH21 pharmaceutical quality assurance system enables you to control and evaluate your tablet testers, disintegration testers, friability testers, weighing machines and other devices centrally. Once it is stored in the central product database, you can use product-specific data for all tests on the connected devices.

The PH21 system supports the connection of more than 30 external pharmaceutical testing devices. Such devices include Kraemer Elektronik's well-known UTS tablet testing systems, tablet hardness testers, capsule testers and automatic disintegration testers as well as weighing machines for Production, In-Process Control, R&D and QC laboratories.

For larger applications, the PH21 system can be installed and operated as a client-server application. The entire software is 100% compliant with FDA 21 CFR Part 11 and allows you to use a wide scope of evaluation options for completed tests. Automatic backups in the background guarantee failsafe in-process control.

Numerous interfaces are available for communication and data exchange with external software applications.

#### PARAMETERS

-  WEIGHT
-  THICKNESS
-  HARDNESS
-  LENGTH / WIDTH / DIAMETER
-  DISINTEGRATION
-  FRIABILITY
-  POWDER ANALYSIS

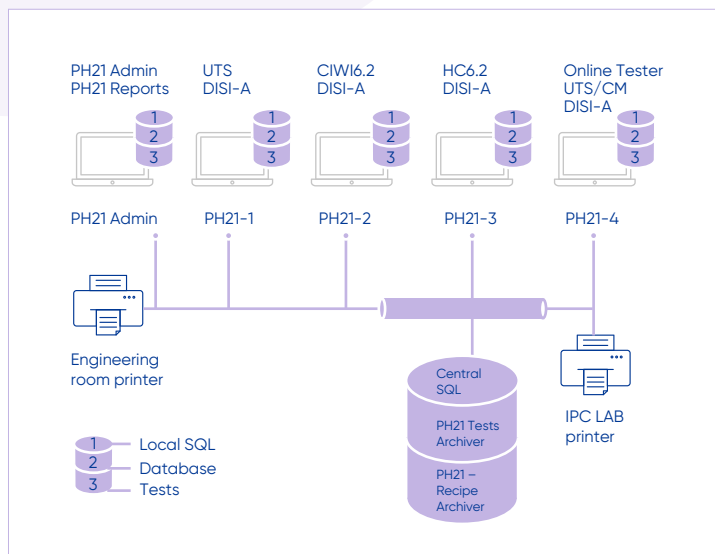
#### ADVANTAGES

- + Advanced functionality
- + Various Export possibilities
- + Modularly expandable
- + Fully 21 CFR Part 11 compliant
- + Networked environment
- + Unlimited number of workstations
- + Unlimited number of testing devices

#### OPTIONAL ADD-ON'S

- + OPC-Server
- + Listening Device
- + Batch reporting tool
- + LIMS, MES
- + Admin station
- + Windows-Authentication
- + Virtual Test Equipment
- + Eye (video supervision)
- + Sample collecting (at tablet press)
- + Barcode
- + ODT data transfer
- + Powder AnalysisQ

Networking example:



## The Product Catalog (Methods/Recipes Catalog)

- virtually unlimited number of product specifications (methods, recipes) can be stored
- one product specification contains all test methods for all available test devices, stored in a single place
- products can selectively be filed to and retrieved from archive

## Test Standards

- Ph-Eur and USP test standards for tablet weight and disintegration time are already preinstalled
- expandable by unlimited number of user-specific standards
- standards are applicable besides of weight and disintegration time also to any other type of values (e.g. tablet hardness, any manually acquired values)
- standards may not only be applied to measured values but also on statistical values (e.g. mean values, standard deviation)
- batch/test results which do not confirm to the applied standard cannot be confirmed/signed off
- Pass/Failed evaluation is available

## Batch Management

- a virtually unlimited number of batch records can be handled by the system
- Ph21 provides an active and an in-active batch record repository, this reduces the size of selection lists of actual data
- batches which comply to the applied standards can electronically be confirmed/signed-off
- batches can selectively be filed to and retrieved from archive

## Alarm Functions & Control Charts

- comprehensive support for in-process-control systems is provided like:
  - support for automatic sampling devices
  - user definable alarm control functions supported
  - online control charts provided
  - continuous integrity monitoring for 7/24 lights-out operation provided
  - support for external switching devices (for additional alarm actions)
- alarm trail with alarm confirmation function provided
- special sorting divider control is supported for separation of bad objects from a batch

## Reporting Functions

- embedded batch and test reports are available, printout in tabular and graphical presentation
- reports are configurable by user definable 'layouts' (standard layouts are pre-installed)
- an external program for batch long-term and batch-trend analysis is provided

## Operator Account Management

- all operators are assigned to dedicated operator groups
- unlimited number of operator accounts and operator groups supported
- a variety of access control properties can be assigned to operator groups
- operator management is only allowed by authorized users

## The Ph21 Archive Functions

- products and batches can selectively be archived to or retrieved from an archive
- Ph21 archives are self-contained SQL-Server databases
- any number of archives can be created by the user of the system
- Ph21 provides an 'auto-archive' function which automatically archives in-active/outdated batch records

## Audit Trail & Alarm Trail

- all relevant actions and events are logged in the audit trail
- all relevant alarm conditions and confirmations are logged in the alarm trail
- audit and alarm trail are protected to manipulations by users of the system
- batches carry their audit and alarm trail with them when archived

## Master Data Change Control Features

- creation and alteration of master records (products, standards, user accounts) are recorded in a change control record.
- any previous instance of these records can be restored at any time (requirement of 21 CFR Part 11)

## Configurability

- the complete 'appearance' of the Ph21 system can be configured by the user of the system with the help of Ph21's unique access control feature
- specifically configured user interfaces can be stored as so-called Ph21 user 'profiles'
- special reduced functionality versions (e.g. 'light' versions) can be configured with the help of Ph21's access control feature and user profiles
- special device-specific versions can be configured

## The Ph21 fine-grained User Access Control System

- access down to every single Ph21 checkbox and text item is access controllable and configurable by the user (administrator) of the system
- handling of unlimited number of user groups with dedicated access control rights
- advanced password features available
- users may temporarily be suspended

## Supported Test Devices

- Charles Ischi/Kraemer Elektronik/other brands
- UTS tablet testers
- CIW tablet weighing and weight sorting systems
- OZB oblong positioning add-on for UTS or CIW tablet testers
- HC6.2 hardness testers
- IP54-LR tablet testers
- IP65i tablet testers
- Fette Checkmaster(R) listening device (passive data acquisition)
- 'disi' fully automatic tablet disintegration testers (with realtime remaining height acquisition)
- Mettler and Sartorius laboratory balances
- Mitutoyo calipers and height gauges
- Other brands and instruments on demand
- manually acquired test results via Ph21's virtual test device (VTE)
- Ph21 supports multiple test devices of the same type or a mix of them at the same time

## System Integration Features

- Ph21 proprietary solutions for integration into MES/LIMS systems provided
- Data exchange via OPC server provided
- Data exchange via SQL database
- plain textfile exports of test results provided
- several Ph21 systems may share a single Sql Server database
- Ph21 database may be hosted on a customer's corporate Sql Server system
- several Ph21 systems may exchange data via Ph21's proprietary online data transfer (ODT)
- dedicated Ph21 'administration' system provided in order to separate administrative from tablet testing tasks
- support of data collection systems intended for long-term storage and data analysis

## Barcode Operation

- barcode scanner can be connected for signing onto the system, identifying product and batch barcodes on sample containers, setting up tablet tests.

## Other Options

- selectable, if one or two independent tolerance sets (QC / IPC limits) are to be applied to a single type of value (a 'pre-warning' before batch becomes bad can be accomplished)
- selectable user profiles (user interfaces) for simplified operation
- manual or automatic export of batch/test results is provided
- user-defined additional values (in conjunction with virtual test devices) provided
- definable calibration validity interval (testing will be prevented when interval is expired)
- extensive data and error logging facilities provided

## System Validation and other Support Services

- validation support for all system components is provided
- an extensive quality documentation package (QDP) is provided
- support service for automated system migration from older PH21 installations is provided

## TECHNICAL DATA

<b>Supported SQL editions</b>	All editions starting from 2005 SQL express version supplied for local database installation SQL full version required for centralized database on network
<b>Supported Windows OS</b>	Windows 10 & 11
<b>PC requirements</b>	>2Ghz quad core >8Gb RAM >256Gb SSD / HDD >1280 x 1024 RS232 or converter 100MB / 1GB LAN