

iCD. GmbH
Augustinusstr. 9d
50226 Frechen / Germany
TEL +49-2234-96634-0
FAX +49-2234-96634-90
e-mail: info@icd.biz
web: http://www.icd.biz



Dissolution-Tests

In vitro dissolution is a central quality aspect for medicine. Those test allow to infer the bio availability of the compounds in the medicine form. The measured dissolution is an important criterion during the evaluation of the production process in the development and production of tablets and capsules. In vitro dissolution tests are e.g. a component of routine examinations of tablet charges in the pharmaceutical industry.

Dissolution-Systems

Typical systems for dissolution tests are computer-assisted systems consisting of the dissolution tester, an analytical device (UV, HPLC etc..) and a sampling unit (manual or automatic). A dissolution test report contains data from heterogeneous sources (reviewed manual inputs and/or data from software). Due to the official regulations for the tolerances of the dissolution parameters (dissolution quantity, temperature, stirring speed, drawing times, pH value of the dissolution medium, parameters of the analytic method etc..) a documentation obligation of these data exists. With multiple drawing times evaporation and/or active substance withdrawal must be considered when determining the dissolution behavior.

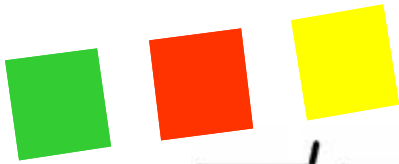
LABS/DS-Program

With the LABS/DS dissolution system dissolution runs can be planned, executed, evaluated and archived. The system consists of the following components:

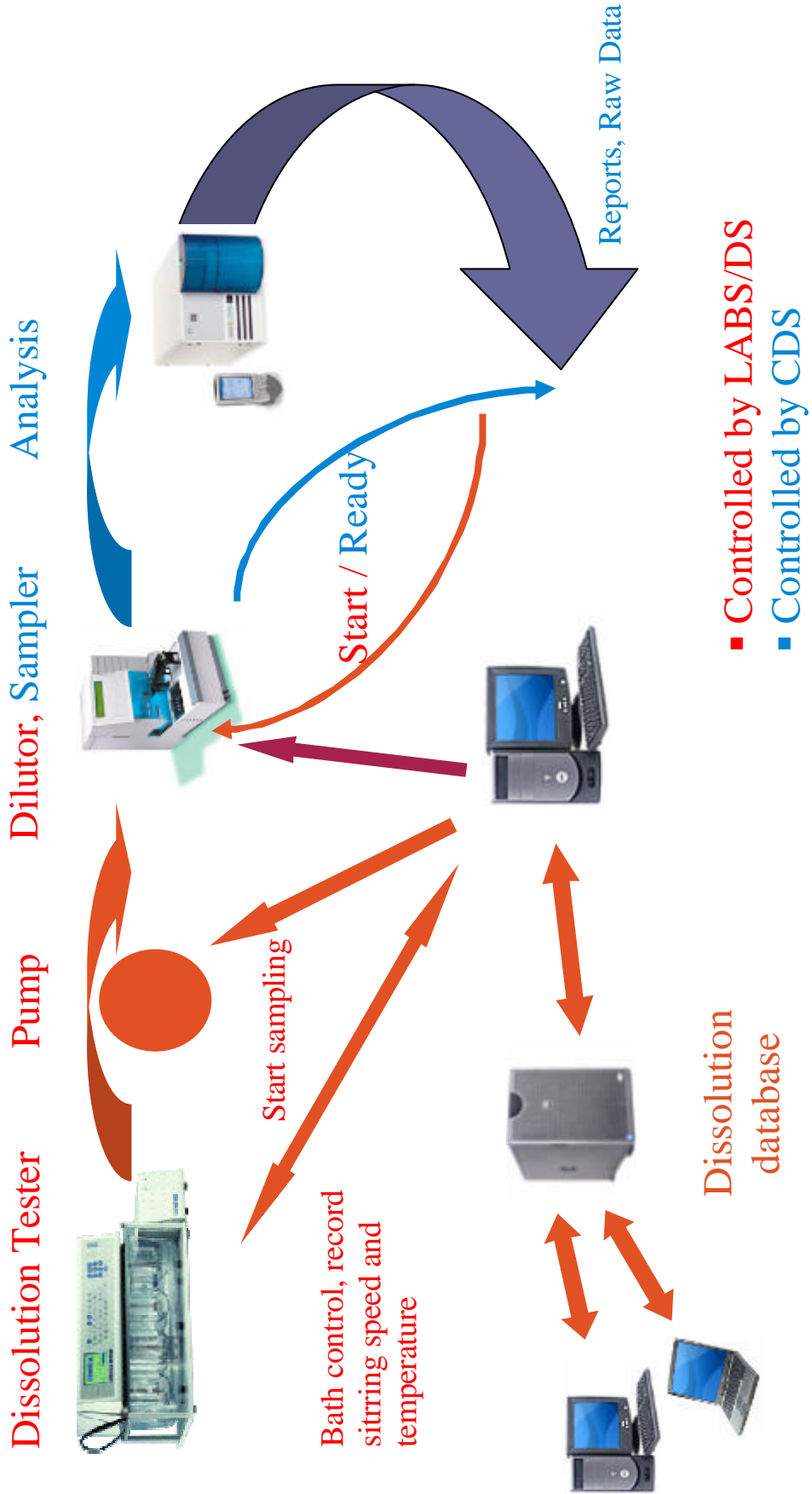
- Dissolution tester (temperature sensors, stirring speed display, sampling facility)
- Autosampler with pumping system (e.g. flexible tube pump)
- HPLC (UV spectrometer) with associated software

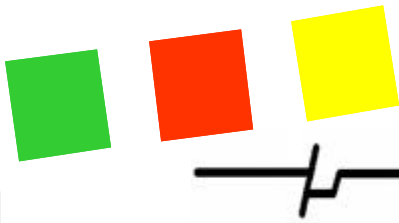
The LABS/DS dissolution system synchronizes all components and collects the relevant data. These are archived in a central data base. Dissolution runs can be evaluated and documented individually or together (level concept) in a dissolution test report.

In addition to simultaneous investigation of several active substances, manual inputs, e.g. the confirmation that the prescribed volume of the dissolution medium was used, are part of the lab/cDs test reports. This allows for a manageable documentation in the laboratory. A review by a second person can be replaced as far as possible by automatic data transfer.



Dissolution System





Functionality

The LABS/DS dissolution system is a stand alone program. A standard data system „CDS“ (e.g. *Varian's Galaxie* or *Agilent's Cerity*) is used for controlling the HPLC devices and for data acquisition.

The advantages of this concept are:

- The planned drawing times can be guaranteed in on-line and off-line mode without any delay by the data system.
- Pumps, detectors etc. are being controlled by the data system
- Existing analysis methods can be used without change.

Online-Mode

Using the “Ready” und “Start” signals of the HPLC system dissolution tests can be analyzed and evaluated „online“. Bath, Sampler, Dilutor and pump are controlled by LABS/DS. The LABS/DS system creates HPLC sequences and synchronizes the data system using the available interfaces. If necessary samples are buffered to be analyzed at a later time.

Offline-Mode

Dissolution tests are planned in LABS/DS, the system produces the necessary control sequences. The analysis of the samples takes place at a later time.

21 CFR Part 11

LABS/DS fulfills the requirements of the 21 CFR part 11 regarding the archival of electronic recordings and electronic signatures. A report generator creates dissolution reports in pdf format.

Calculations

LABS/DS logs all sample and refilling volumes. Therefore the true value of the dissolution can be computed absolutely in [mg/l] or r elatively in [% of the specified value].

The algorithm considers the following calculative corrections and computes them with varying sample volumes:

- Refilling of medium (to correct for drawing samples)
- Loss of active substance due to drawing samples
- Evaporation (long term dissolution)

