CambTEK®

Flexibility
Quality
Standardisation
Productivity
Simplicity
Environment
Economic

Sample Preparation of Solid Dosage Forms

Design Space
ICH
DoE
Content Uniformity
At-line testing
IMPURITY TESTING
OOS
BULK ASSAY
IMPS
STABILITY
LEAN SIGMA
ICH Q8
CU
Class A Accuracy

TAKE CONTROL OF YOUR PROCESSES

RES Rapid Extraction System

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RES Rapid Extraction System

1 Flexibility

The CambTEK RES is at the cutting edge of fully automated sample preparation of solid dosage forms, in development and quality assurance laboratories, and manufacturing environments. From Phase 1 Development through to Manufacturing Quality Assurance, the RES will improve quality of data, and increase productivity.

The RES has been designed to prepare a vast range of solid dosage forms, including:

- Tablets (both normal and prolonged release)
- Capsules
- Powders
- Gels
- Pastes
- Swabs
- Stents
- Beads
- Intermediate Granulations
- Pellets
- Solid & Semi-solid Matrices
- Suppositories

The RES uses turbulent fluidic flow with solvent quantities from 50mL-500mL with optional ultrasonic energy to extract samples. Pump speed is adjustable from 70mL/min to 1L/min approximately, giving full control of the extraction process, allowing the RES to perform a wide range of functions, including:

Content Uniformity Testing (CU)
Impurity Testing (imps)
Composite and Bulk Assay Testing
Stability Assay Testing (ICH)
Blend and Granulation Uniformity Testing

After extraction, the solution is filtered and the filtrate delivered to a primary 20mL vial ready for dilution or directly to an HPLC vial for analysis. All dilution and dispensing steps are performed with gravimetric feedback, delivering high repeatability and Class A accuracy. The RES then automatically performs a cleaning and drying cycle, ready to process the next sample.

Other features include:

- 5-channel solvent selection allows for complex extractions
- Off-line and adaptable for on-line with HPLC or UV/MS analysis
- Powerful extraction for unstable compounds with or without ultrasonics
- Robustness testing/design space of analytical test methods to investigate sensitivity of extraction and dilution process
- Highly variable working sequence giving random access workflow
- System achieves clean & dry state between samples allowing for full flexibility of consecutive sample types

2 Quality of Data

CambTEK has worked with analytical chemists from leading Pharmaceutical Companies in the design and testing of the RES, to ensure the common concerns within the industry were addressed.

- Designed to highest standards to ensure regulatory and quality compliance of data integrity, validity and repeatability
- Sanitary design of fluidic path, minimising leeching and carryover : studies with difficult to clean compounds show <0.1% carryover is achievable with minimal wash steps.
- Developed to exceed Class A volumetric requirements with sophisticated gravimetric feedback for closed loop confirmation of dispensing processes
- Eliminates potential variability due to analyst technique or human error
- Sample barcode tracking provides improved chain of custody to improve GMP compliance
- User control and implementable solutions for 21 CFR part 11 compliance
- Meta-data for in-process checking and conformity, answering ‘who?’, ‘when?’, and ‘what?’ queries
- Comprehensive post-extraction report allows for detailed Out Of Specification (OOS) investigations
- On-line video monitoring* assists method development and atypical OOS investigations
- Sealed vials maintain sample integrity
- Enclosed system for additional safety and sample integrity

3 Standardisation & Compliance

Platform technology for site and user independent standardisation of results, from R&D through to manufacturing.

- Supporting R&D laboratories performing DoE and new product developments supporting Quality by Design (ICH Q8)
- Pressure monitoring allows end-point confirmation utilising PAT concepts and increasing test process understanding
- Fluidics and Sonication provides good equivalency to manual methods, minimizing re-validation from manual processes to automation
- Comprehensive encrypted and secure documentation complies with 21 CFR Part 11
- User access rights control method approval and status

4 Productivity

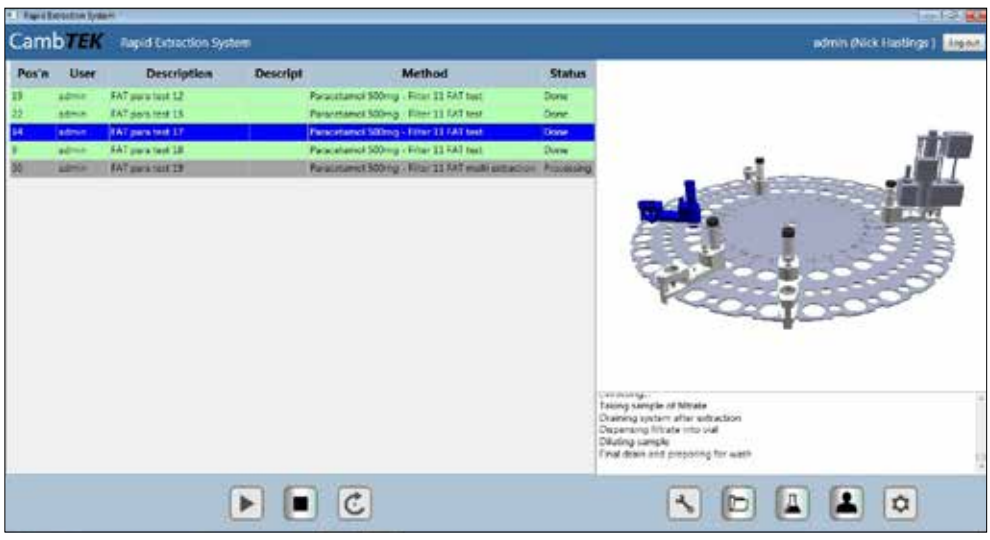
Support and improve your lean sigma initiatives and gain productivity.

- Minimal user touch-time and fast setup and operation
- Robust design and component specification for minimal downtime and maximum reliability
- Work 24/7 with 30 sample capacity, plus continuous load operation
- Smart carousel load and scan
- Easy maintenance design and software control
- Suitable for At-line testing

5 Simplicity

All aspects of the instrument are easily configured using the intuitive Graphical User Interface (GUI), from setup to method development to operation.

- Designed for intuitive operation with simple walk-up, scan, load, and run features
- Press “Play & Go” design concepts
- Barcode workflow removes need for sample placement cross-referencing by the operator
- Consumable set designed for prescriptive operation and user error reduction independent of user experience or ability



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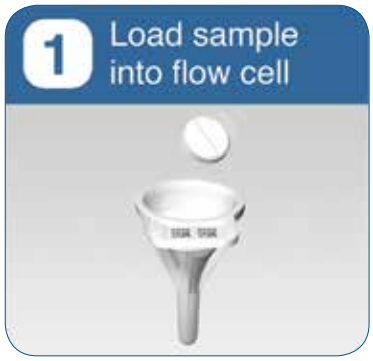
RES Rapid Extraction System

Six easy steps to sample extraction:



6 Environment & Safety

Sanitary design and turbulent fluidics enables reduced solvent consumption for wash processes and optimised extraction methods.

- Minimised extraction volumes using powerful ‘captive’ extraction principles
- Small volume dilutions to Class A specification comply with USP requirements for volumetric delivery
- Capped vials with septa for evaporation control
- Enclosed system for safe operation

7 Economic

RES delivers economic benefits by reducing manual sample preparation tasks and increasing laboratory productivity.

- Intuitive ease of use to increase productivity and reduce cost per test
- Reduction in associated solvent purchase and disposal costs
- Flexible payment options to overcome common laboratory budget constraints

*Optional Features / Additional Cost Features

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