

# Sample Preparation Extractor (SPEx)



**Lightning Fast Extraction of API  
for Content Uniformity Testing**

# SPEX SAMPLE PREPARATION SYSTEM

## SAMPLE PREPARATION FOR CONTENT UNIFORMITY

Accurate and repeatable sample preparation is essential to determining content uniformity in pharmaceutical products. “To ensure the consistency of dosage units, each unit in a batch should have a drug substance content within a narrow range around the label claim.” USP <905> Uniformity of Dosage Units.

Traditional methods of sample extraction are often tedious and time-consuming, especially with problematic drug formulations that may take many hours to dissolve. Teledyne Hanson’s new Sample Preparation Extractor (SPEX) provides an advanced, efficient solution for rapid extraction through an innovative, proprietary combination of high frequency pulverization and forced jet mixing in a compact, programmable platform.

As samples are prepared within chemically compatible, single-use recyclable pouches, SPEX eliminates many of the problems associated with handling glassware, manual crushing, dry material measurement and transfer, cleaning validation, and the reproducibility errors inherent in manual sample-prep methods.



*Teledyne Hanson Sample Preparation Extractor*

## SPEX RAPID EXTRACTION PROCESS

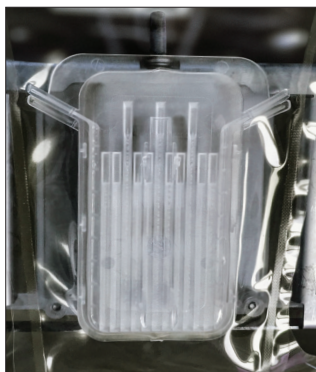
The sample extraction process using SPEX is fast and easy. The analyst clips an extraction pouch into the SPEX cassette, adds a mixture of solvents consistent with API dissolution, and places the dosage form into the top of the pouch.

Applicable dosage forms for single-sample or bulk-assay mode include tablets, lozenges, capsules, powders, beads, granules, gels, pastes, pastilles, and wax suppositories.

The analyst mounts the cassette onto the SPEX body and from the control panel selects from the methods stored in the system, or chooses “immediate mode”

to set parameters for an unstored method. High-speed pulverizing then occurs within the crushing zone for the programmed amount of time. Forced-jet mixing runs simultaneously from the start or begins later, as specified by the method.

When crushing and mixing are complete with the sample fully dissolved, the analyst uses a syringe to extract the aliquot(s) required by the analytical method and places them into appropriate vials for transfer. The pouch is removed from the cassette, emptied, and recycled or disposed of according to the lab’s standard operating procedures.



*Heavy duty polypropylene crushing plates pulsate at high frequency inside the extraction pouch.*



*Mixer bar with four rollers reciprocates at 2 Hz to generate high fluid turnover.*

## SPEX SYSTEM COMPONENTS

The rapid and reproducible extraction process of the SPEX is made possible by its powerful crushing mechanism combined with forced-jet mixing, single-use pouches, and a programmable interface.

**Powerful crushing.** High frequency pulsing in the crushing mechanism rapidly reduces whole solids to fine powders, greatly accelerating the release of API from the dosage form.

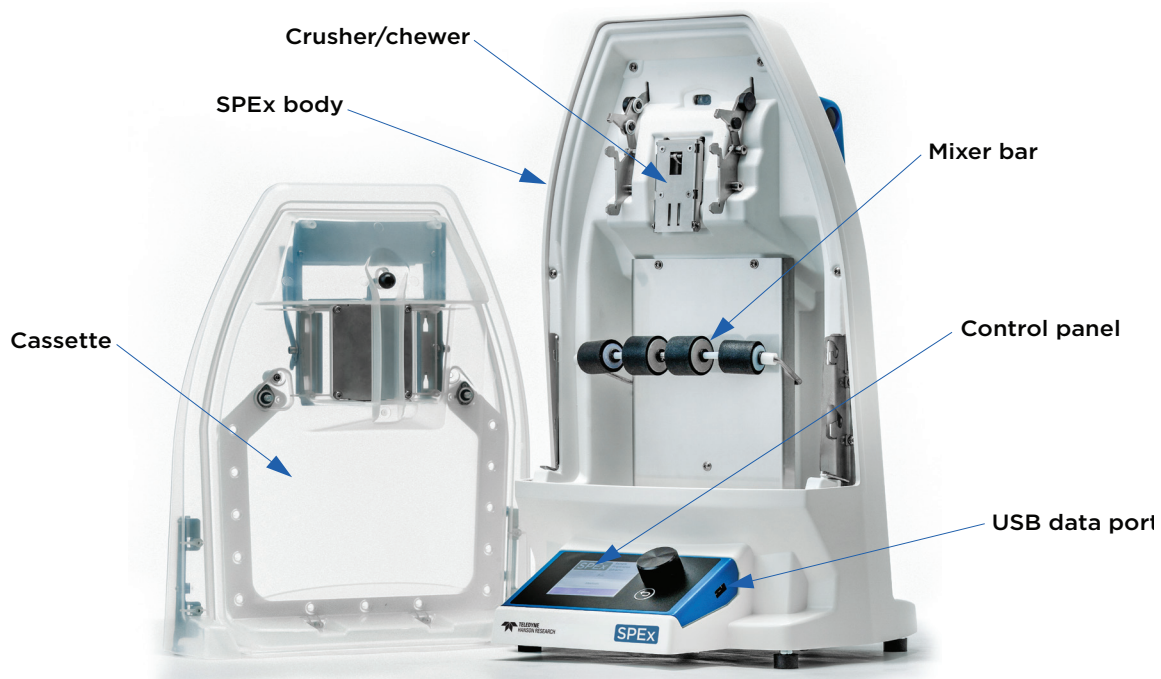
**Rapid mixing.** Reciprocating rollers on the mixing bar generate high turnover of fluids inside the pouch for faster dissolution and a homogeneous mixture.

**Single-use pouches.** Containing the process within a single-use polypropylene pouch allows extraction methods with no loss of solid mass, no carryover.

**Process automation.** Reproducibility is ensured by development and storage of extraction methods within the SPEX controller.

Designed for simplicity, ease-of-use, and prevention of common procedural errors, the SPEX system has the added benefit of reducing operator training time to a minimum.

### SPEX SYSTEM COMPONENTS



### PROGRAMMABLE CONTROL PANEL

The user-friendly SPEX interface with its single-knob control makes it fast and easy to create and run extractions. The system can be run either without a pre-programmed method (walk-up immediate mode) or with up to 30 events per stored method.

The system's self-test mode checks all sensors on start-up. Incorrect pouch installation and method programming errors are automatically detected and prevented. New method development is facilitated by unlimited use of Pause, Stop, and Resume functions.

Setting a system password protects stored methods. Easily install firmware updates via the USB data port.

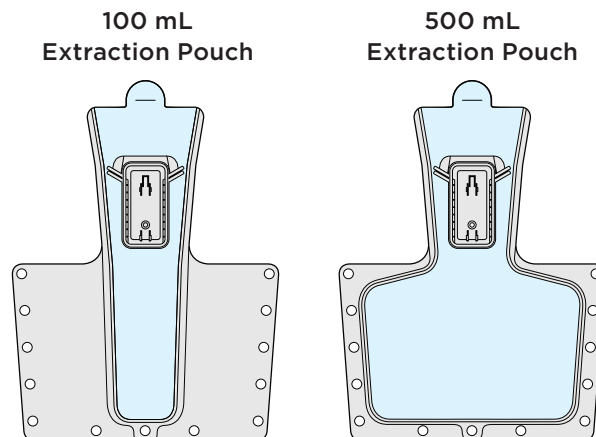


*Create, view, run, edit, copy, and delete methods through the SPEX color display.*

# SPEX SAMPLE PREPARATION SYSTEM

## SPEX EXTRACTION POUCH TECHNOLOGY

The SPEX extraction pouch is custom designed to provide the optimum conditions for rapid sample extraction. The crushing zone in the top section accepts the dosage form in its original shape with no need to break it down in advance. The lower section contains the solvent and the final sample solution. Fluid pathways between the two sections allow forced jet mixing—produced by four reciprocating rollers operating against the lower section—to accelerate dissolution. Pouches made from durable polypropylene come in two sizes: a 100 mL pouch for fluid volumes of 25 mL to 100 mL, and a 500 mL pouch for volumes of 100 mL to 500 mL.



## SPEX ACCELERATED EXTRACTION EXAMPLES

The SPEX method saves time and materials while reducing variability in a wide range of applications.

- Extraction of heterocyclic from prolonged-release hydrogel matrix reduced from 16 hours to 1 minute.
- NSAIDs from wax suppository reduced from 12 hours to 2 minutes with no need to boil and with reduced solvent consumption.
- Water-soluble vitamin from prolonged-release cellulose reduced from 18 hours to 3 minutes.
- Hard lozenge extraction reduced from 12 hours to 2 minutes and with no loss of sample.
- Heterocyclic alkaloid extracted from tobacco reduced from 4 hours to 1 minute.

## ORDERING INFORMATION

### SAMPLE PREPARATION EXTRACTOR

- 46-201-221** SPEX Sample Preparation Extractor with 1000x 100 mL Pouches
- 46-201-222** SPEX Sample Preparation Extractor with 1000x 500 mL Pouches
- 46-201-223** SPEX Sample Preparation Extractor with 500x 500 mL and 500x 100 mL Pouches

Each extractor includes a startup kit containing 1 pouch stand kit, 1 manual sampling cannula, 24 single-use syringes (20 mL), and 1 cassette. Purchase of one or more spare cassettes is recommended for higher throughput.

### CONSUMABLES

- 46-201-202** SPEX 500 mL Extraction Pouch (Pack of 100)
- 46-201-203** SPEX 100 mL Extraction Pouch (Pack of 100)
- 46-201-209** Syringe, 20 mL (Pack of 48)
- 46-201-219** Syringe, 10 mL (Pack of 48)

### ACCESSORIES

- 46-201-204** SPEX Cassette (Spare)
- 46-201-205** SPEX Pouch Compression Tool
- 46-201-210** SPEX Pouch Stand Kit (incl. 20 S-Hooks)
- 46-201-212** S-Hooks for Pouch Stand (Pack of 20)
- 74-105-360** 2-Liter Manual Sampling Cannula

### QUALIFICATION DOCUMENTS

- 46-208-205** Q-Pak Validation Guideline

For further information, please contact your local Teledyne Hanson Research representative or email us at [hansonsales@teledyne.com](mailto:hansonsales@teledyne.com)