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FLOW THROUGH CELL DISSOLUTION SYSTEM (USP - IV)

Model - F7 Smart

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Flow-Through Dissolution Method

Labindia's flow-through cell method enables you to observe formulation differences that apparatus 1 and 2 may not reveal. This technique is highly recommended for poorly soluble, modified/extended release, and low -dose products. Moreover, with advancements in drug delivery platforms, USP apparatus 4 has found application in IVIVC studies and an expanding range of dosage types. Its adaptability to various solubility conditions, diverse flow -through cell types, and improved control over the hydrodynamic environment make USP apparatus 4 continuously evolve to cater to the changing requirements of in-vitro release testing.

For Various Applications:

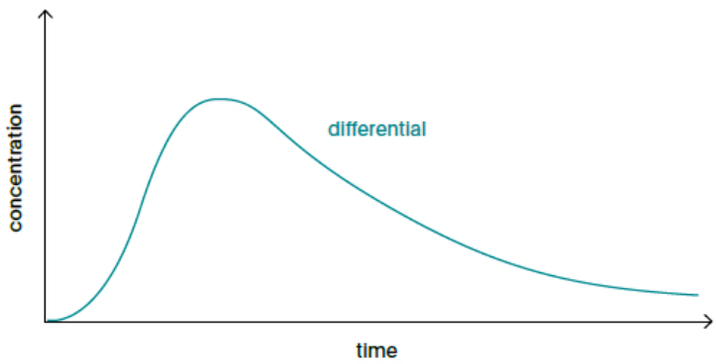
The versatility of flow-through cells enables testing of nearly all types of dosage forms. Labindia has played a crucial role in assisting pharmaceutical companies worldwide in creating robust testing methods for their applications, which even includes developing new flow-through cells to cater to novel dosage forms.

DOSAGE FORM

- MR, CR, SR & ER Tablets
- API's
- Powders
- Granules
- Capsules
- Pellets
- Medical devices
- Drug-eluting beads & stents
- Implants
- Coated ocular implants & lenses
- Suppositories
- Soft-gelatin capsules
- Parenterals
- Emulsions
- Suspensions
- Microspheres
- Semi-solids

Open Loop Setup

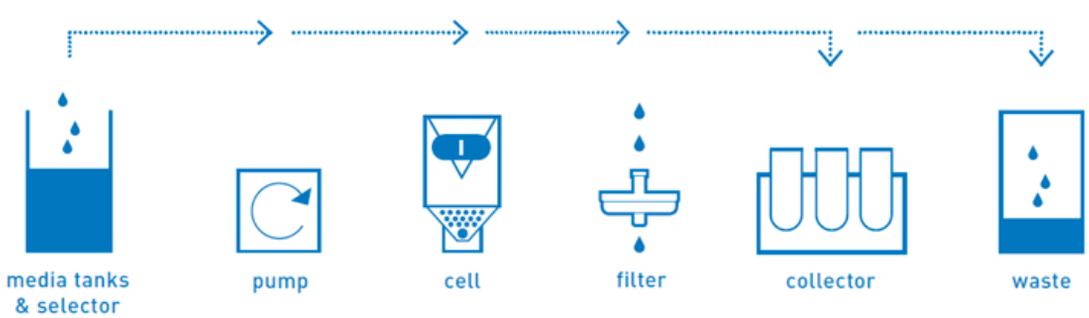
The flow-through cell system was initially intended for poorly soluble compounds, necessitating larger media volumes beyond the compendial USP 1, 2 and 3. It has consistently been associated with providing ‘optimal sink conditions’ offering flexibility in terms of the required media volume.

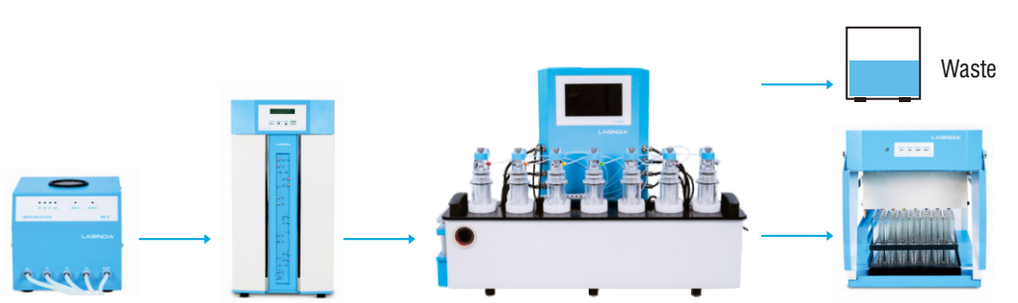


Dissolution profile of an open loop setup

The "open loop" configuration involves the continuous flow of fresh media through the dosage for m. During specific time intervals, samples are collected and can be analyzed. The total media volume used is deter mined by the flow rate. This setup allows for the use of larger media volumes without requiring solubilizing agents, effectively eliminating the impact of poor sink conditions on the test.

Automated Media Change



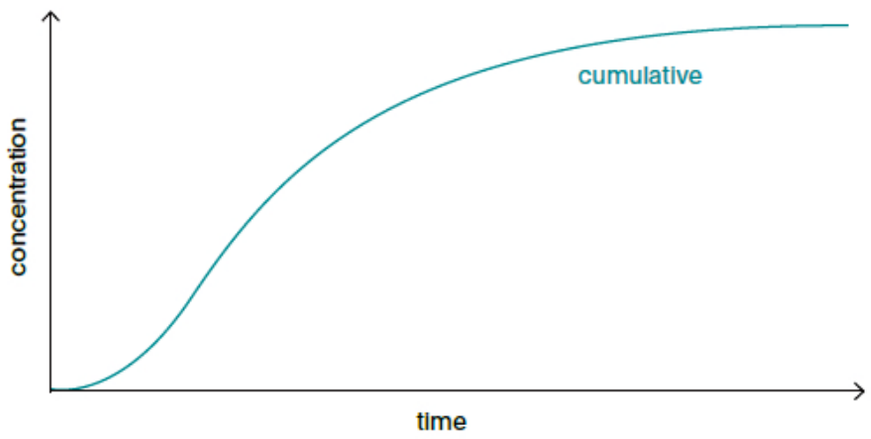


In the open loop setup, the flow cell offers the flexibility to change the type of media passing through it at predefined time intervals. This is achieved through a media selector, which automatically switches to draw from different sources, allowing for programming of up to 3 different media. Depending on the filter performance, bio-relevant dissolution media can be employed, making it par ticularly valuable for conducting IVIVC studies where the dosage form encounters the diverse pH levels of the digestive tract. Studies have demonstrated improved correlations in part due to the maintenance of sink conditions and varied hydrodynamics within the flow-through cell.

Moreover, this feature proves advantageous for evaluating enteric-coated products, modified release, and extended release formulations. Unlike the USP apparatus 1, 2, and 3 methods, which can be cumbersome to change media, the USP 4 simplifies this workflow, allowing for a straight-forward and well-documented media switch.

Closed Loop Setup

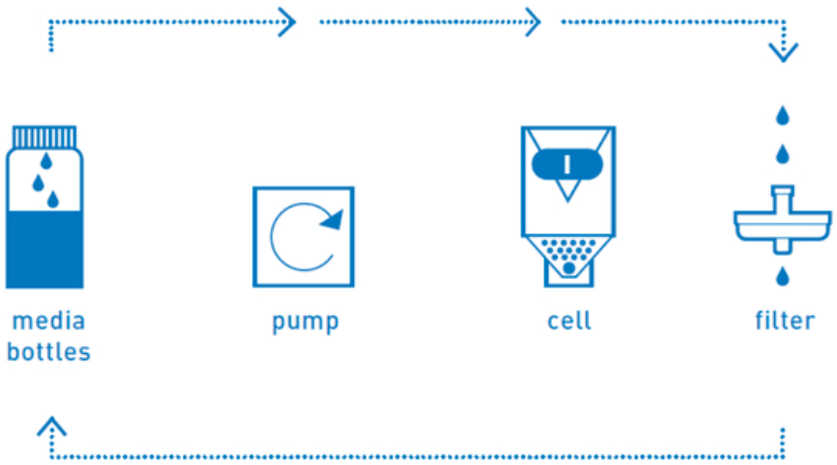
In a closed system, the flow-through method is executed in a manner similar to a USP apparatus 1 and 2 experiment. Here, a constant volume of media circulates across the dosage form. Samples can be extracted at predetermined intervals using an auto sampler.



Dissolution profile of a closed loop setup

The results obtained from closed systems are presented as cumulative dissolution curves. These systems are particularly well-suited for dosage forms that exhibit optimal solubility and sink conditions within a volume range of 25 mL to 5 L. USP 4 offers an additional avenue to compare results against traditional methods like the 250 mL, 500 mL, 900 mL, 1 L, 2 L paddle, baskets, and USP 3 methods.

Moreover, the USP 4 method brings several advantages over other USP approaches. It addresses concerns related to different hydrodynamic and mixing effects, effectively eliminating issues like coning or dead zones. Additionally, it overcomes sampling challenges and sample introduction effects that can sometimes be observed in USP apparatus 1 and 2 experiments



Small Volume Dissolution and Elution Testing

The continuous advancement of low dose formulations, such as drug eluting stents, implants, coated medical devices, injectables, and microspheres, has led to the further development of the USP 4 method to accommodate even lower media volume testing. In the realm of medical devices, the term "dissolution" has been substituted with "elution," which involves measuring the amount of drug released from a polymer coating or drug depot. These drug quantities are often extremely small, necessitating a reduction in the total media volume to address the challenges of Limit of Quantification (LOQ) during analysis. It's important to note that, in comparison to USP apparatus 1 and 2, the dosage form experiences equivalent hydrodynamic conditions regardless of the volume used in USP 4 testing.

Cells - for virtually all dosage forms

Apparatus 4 has emerged as a robust in-vitro release platform catering to diverse dosage forms. Frequently, the standard setup suffices, eliminating the need for modifications. However, for specific product types, customization of flow-through cells can prove advantageous. The availability of flow-through cells in a flexible range of geometries further enhances their adaptability to different testing requirements.

Tablets (12mm Cell)

This flow-through cell described in the EP, USP, and JP is referred to as a small cell primarily designed for testing tablets and capsules. Additionally, it offers an optional tablet holder for added convenience. Beyond its application for tablets and capsules, this versatile cell can be effectively utilized for testing suspensions, injectables, and even small medical devices and stents.

Tablets (22.6mm Cell)

This flow-through cell described in the EP, USP, and JP is characterized as a large cell specifically intended for testing tablets and capsules. Similar to the previous cell, it also offers an optional tablet holder for added convenience. However, this large cell finds broader applications and can be effectively used for testing parenterals, suspensions, and microspheres. The versatility of this cell is further enhanced by a variety of holding devices that have been developed for its use. Due to its adaptability and wide-ranging applications, it is considered the most commonly used of all flow-through cells.

Drug-eluting stents

This cell is constructed from PTFE (polytetrafluoroethylene) and finds application in medical devices, specifically drug-eluting stents. Its design is specifically geared to eliminate potential adsorption issues that may arise when using polycarbonate cells. Moreover, the inner diameter of the cell can be custom manufactured to precisely fit the dimensions of the medical device, ensuring optimal compatibility and accurate testing.

Customized flow cells

This cell is derived from a 22.6 mm cell design. It incorporates an insert cup feature, enabling testing on gels, creams, and ointments with the inclusion of a permeation membrane.

Powders and granulates

The primary purpose of this cell is to assess the apparent dissolution rate of pure solid substances, particularly for API (Active Pharmaceutical Ingredient) characterization. Additionally, it is utilized for evaluating active substances present in formulations presented as powders. This cell also serves as a valuable tool for examining granule and bead formulations during dissolution testing

Implants

This specific cell is designed for small implants and features a compact chamber to accommodate the dosage form effectively.

Suppositories and soft gelatine capsules

This cell features a unique 2-chambers design that effectively captures the lipidic excipients while enabling the dissolution media to pass through to the filter.

Holding device for dialysis insert

This cell is built upon the framework of a 22.6mm cell. It is equipped with an insert holder, enabling the testing of nanoparticles confined within a dialysis bag.

Holding device for ophthalmic lenses

This cell is a modified version of the 22.6 mm cell, featuring an insert holder specifically designed for testing drug-coated ophthalmic lenses.

Large medical devices

This cell is suitable for longer medical devices, offering the advantage of accommodating devices with a maximum length of up to 83 mm.

Flow Rate
importance of the pump

In the flow-through method, the pump plays a crucial role in maintaining a significant parameter: the flow rate of the media. The flow rate can be analogous to the RPM speed in USP apparatus 1 and 2 or the DPM (Drops Per Minute) in USP apparatus 3. It is an essential factor that influences the dissolution testing process in the flow-through cell.

The PP 07 digital piston pump is purpose-built for the USP 4 method, providing optimal performance and precision. With its 7 valveless ceramic pump heads, it ensures a remarkably high level of reproducibility and consistency during testing. The pump allows for adjusting the flow rate within a range of 1.5ml/Min to 36ml/min at 120 PPM.

One of the pump's valuable features is its capability to have different flow rates per channel. This flexibility proves to be an advantageous method development tool, particularly when creating a USP 4 dissolution method. It allows for easy experimentation and optimization during the method development process.

The PP 07 pump offers an automatic calibration/validation option, making it even more convenient for users. By linking the pump to a balance (optional) and a printer (optional), the pump undergoes an automatic check and adjustment of its flow rate for each channel, using user-defined volumes as references. The calibration protocol is generated automatically and can be conveniently printed out for record-keeping and documentation purposes. This feature streamlines the calibration process and ensures accurate and reliable flow rates for each channel of the pump.

Analytical Configurations

The F7 smart facilitates offline analysis by connecting to an auto sampler. Through its firmware, the system supports two configurations: open and closed loop, enabling the collection of sample volumes at specific time intervals. It also offers method protection and the option to connect to a printer for reporting temperature and method details. This enhances the system's versatility, ensuring precise and reproducible capillary electrophoresis analysis.

SPECIFICATIONS

F7 SMART

Method Storage:	Practically Unlimited
Software Compliance:	21 CFR Part 11
Temperature Range:	20°C to 55°C
Temperature Resolution:	0.1°C
Temperature Sensor:	DTS-Digital Temperature Sensor
Maximum Number of Intervals:	Practically Unlimited
Print Interface:	LAN/USB/Wi-Fi/Wi-Fi Direct enabled Printer
Data Backup interface:	USB/LAN Port/Wi-Fi
Display:	7" high resolution display with capacitive touch screen
Configuration:	6+1 (Blank Cell)
Back Pressure Handle Capacity:	4 Bar

PISTON PUMP (PP07)

Pump Flow:	1.5ml/Min to 36ml/min at 120 PPM
Flow Accuracy:	±5% (Open Loop System)
Flow type:	Pulsating
RPM:	20-300
Volume Accuracy for Closed Loop:	Better than 1%

SAMPLE COLLECTOR (SC07)

SC Configuration: 13*7(Open Loop) and 24*7(Closed Loop)

Sampling Volume Range:

- Open Loop - 1ml -80ml
- Closed Loop - 1. HPLC Vials Tray (0.5 ml to 2 ml)
  2. Test Tube Tray (0.5 ml to 10 ml)

Split Function: Simultaneous Collection of Sample and Waste

Status Indicator: Colour indication for Auto/Manual, Sampling and Ready Condition with single Multicolour LED

MEDIA SELECTOR (MS57)

Ports: 5 Ports (3-Media, 1-Cleaning Media, 1-Waste Collection during Clean)

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