RAYTOR

>NCE DP

Pre-prescription dissolution and permeability study for drug and excipient compatibility

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ABOUT US

Raytor Instruments
National High-tech Enterprise and ISO9001 Certified Enterprise

Dedicated to the R&D, production, sales and service of laboratory scientific instruments.

Providing customers with analytical equipment and applied experimental solutions in the fields of identification of new compounds, drug permeation, drug dissolution/solubility, transdermal diffusion, etc.

Covering oral, transdermal and subcutaneous drug delivery related dosage forms of pre-prescription research and quality control of products.

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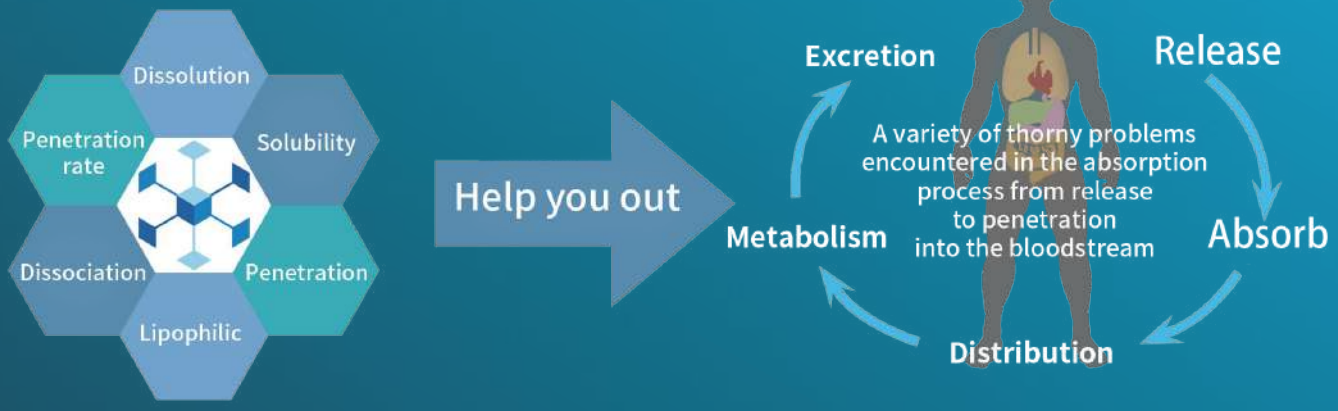

Raytor products include:
Pre-prescription research product segment series:
Physical and Chemical Parameters Analyzer, Micro Dissolution Osmosis Analysis System,Subcutaneous Injection Analyzer System, Two-phase Dissolution Analyzer System and so on;

Dissolution series products:
Flow-Through Cell Dissolution System,
Reciprocating Cartridge Dissolution System,
General Dissolution System, Transdermal Diffusion System, Mechanical Validation Kit, Solvent Degasser, etc.

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Product Series

	instrument	NCE P3 Raytor NCE Physicochemical Parameter Analyzer	NCE DP Raytor NCE Dissolution& Permeation Analyzer	NCE Subcutaneous Injection Analyzer	Raytor NCE Two-Phase Dissolution Analyzer	NCE Structural imaging system	RT7 Flow-Through Cell Dissolution System	RT8 Transdermal Diffusion System	RT3 Reciprocating Cylinder Dissolution System	RT6 General Dissolution System	RT900 Multi Batch Automatic Dissolution System
Characteristic analysis of new compounds	ionize	✓									
	logD/P	✓									
	dissolve	✓									
	Penetration absorption		✓								
Oral solid preparations	Penetration absorption		✓							✓	
	Biologic Medium		✓				✓		✓		
	GI dissolution		✓				✓		✓	✓	
	Trace dissolution		✓				✓				
	Pharmacopoeia dissolution						✓		✓	✓	✓
	Two-phase dissolution				✓					✓	
	Inherent dissolution		✓				✓			✓	
	Surface Imaging					✓					
Skin/Subcutaneous Absorption	transdermal absorption						✓	✓		✓	
	Subcutaneous absorption			✓			✓				

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PRODUCT DESIGN THEORY

Rationality

The performance indexes of the instrument meet the requirements of Chinese Pharmacopoeia, U.S.Pharmacopoeia, European Pharmacopoeia and other regulations, and the computerized system meets the requirements of 21CFRPart11.

Cleanliness

Responding to the idea of prosecutors in GMP inspections to observe details as a breakthrough, make the equipment impeccable in the details of cleaning.

Manageability

Excellent computerized management system, the unique cloud management system, allows laboratory supervisors to have full control of the experiment.

Service

We don't just manufacture instruments, we are able to provide specialized technical support related to dissolution.

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NCE DP

USED FOR THE PRE-PRESCRIPTION DISSOLUTION & PERMEATION STUDY OF DRUG/NCE WITH EXCIPIENT

NCE DP is primarily for: Pre-prescription dissolution and permeability studies of drug-excipient combinations at universities, pharmaceutical research institutes and CROs.

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SCOPE OF APPLICATION

Intrinsic dissolution rate studies of APIs:

Distinguishing between the dissolution rates of crystalline and salt forms of APIs.

PH shift model studies:

Simulating the gastro-duodenal transition process in the gastrointestinal tract and assessing the effects of drugs in this process.

Drug permeation model studies:

Coupled with PAMPA membranes to mimic small intestinal epithelial cells to analyze drug permeability.

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Intrinsic dissolution rate studies of APIs

Distinguishing between the dissolution rates of API crystalline and salt forms

The intrinsic dissolution rate (IDR) of an active pharmaceutical ingredient (API) is a key characteristic that contributes to early drug development. By understanding the IDR, formulation scientists can choose formulation strategies to improve dissolution and thus enhance drug absorption in the gastrointestinal tract.

NCE DP requires only a small amount of API tablet (tablet diameter 5.6 mm) to study the intrinsic dissolution rate of API under biological conditions, which greatly reduces the amount of FaSSIF and FeSSIF used (20-30 ml/laboratory).

The intrinsic dissolution rate experiments can further compare the effects of different crystalline forms, particle sizes and salt shapes of APIs on the dissolution rate of the drug, from which the optimal API process optimization strategy can be found.

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PH shift model studies

Simulation of the gastro-duodenal transition in the gastrointestinal tract and assessment of the effects of drugs in this process

Different organs of the body, or even the same organ, are in different stages of digestion, and their pH and other physical parameters can vary significantly, which can lead to drug precipitation under certain conditions and ultimately not be absorbed and utilized by the body. The NCE DP has a 6-channel online fiber-optic system to record the concentration changes of the drug throughout the entire process and a fully automated pH shift model for researchers to study the changes of drugs (e.g., precipitation/recovery) under conditions of pH changes with a high degree of reproducibility.

The NCE DP has a 6-channel online fiber optic system that records drug concentration changes and a fully automated pH shift model that allows researchers to reproducibly study drug changes under changing pH conditions (e.g., precipitation/dissolution), allowing researchers to identify the optimal composition of a formulation from a wide range of formulations.

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SCOPE OF APPLICATION

The NCE DP contains the Tridonic Accurate algorithm, which gives the NCE DP the ability to accurately measure compound content in turbid solutions, allowing the product to record the concentration of dissolved APIs in the presence of excipient interference or drug precipitates, especially for drug studies with UV absorption and very fast precipitation rates.

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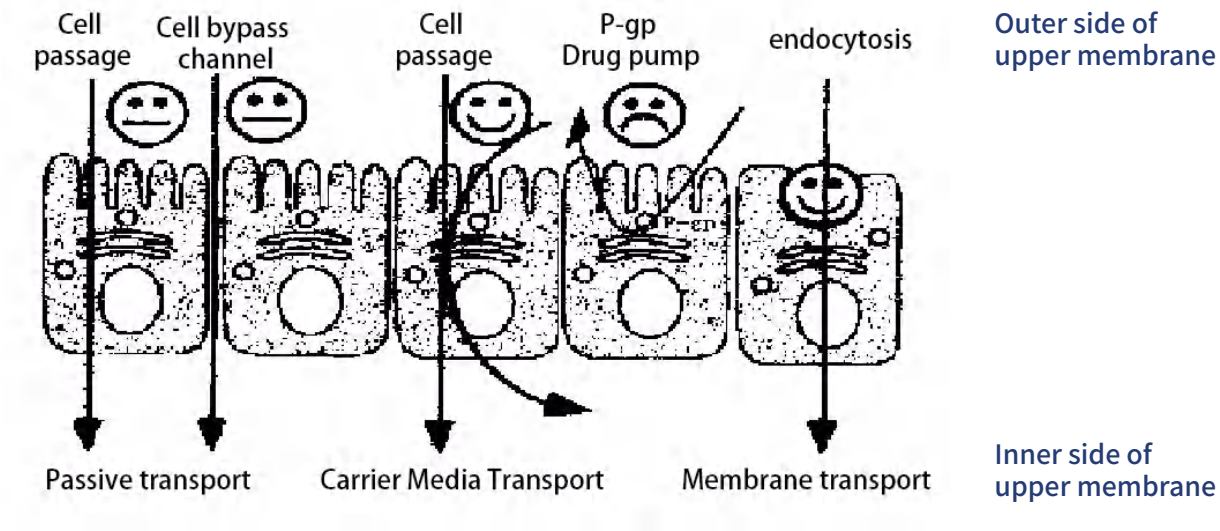
After dissolution, the drug enters the cells of the small intestine by osmosis and is further absorbed by the body; there are three modes of cellular absorption: passive, carrier, and membrane-activated transport, and more than 90% of all drugs enter the body through passive transport.

Permeation modeling in NCE DP is a solution to evaluate drug-prescription interactions by simulating the influencing factors in the passive transport of a drug and to find the optimal composition of a prescription.NCE DP, together with Bio-Flux membranes from Raytor, can be used to study the differences in the rate of permeation of APIs in different prescriptions.



Drug permeation model studies

Coupled with PAMPA membranes, which mimic small intestinal epithelial cells, the permeability of drugs was analyzed

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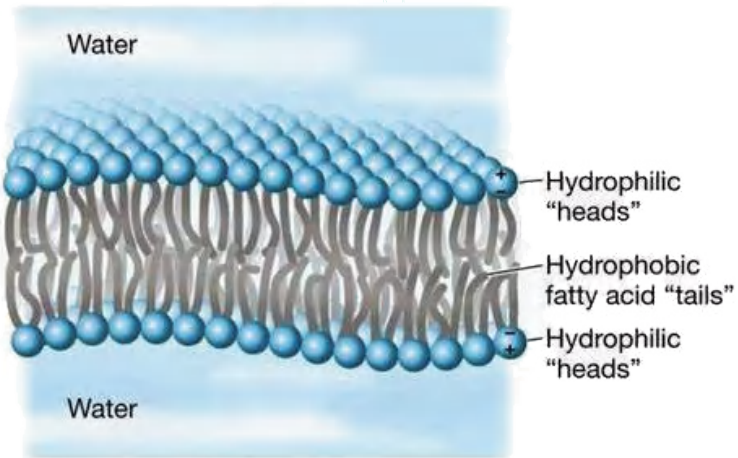

Bio-Flux membrane is a biomimetic phospholipid bilayer system that mimics the phospholipid bilayer of human small intestinal epithelial cells based on the PAMPA (Parallel artifi- cial membrane permeation assay) model by guiding the automated assembly of lecithin onto the backbone. Together with NCE DP, Bio-Flux is used to mimic the absorption of drugs by human small intestinal epithelial cells in an osmotic model.

SCOPE OF APPLICATION

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OVERALL SHOWCASE

NCE DP Mainframe

It consists of four main parts: magnetic heating and stirring device, precision solvent injection device, temperature monitoring device and UV signal testing device. The UV signal testing device consists of six UV optical fibers, which are inserted into the sample through the lifting mechanism after the start of the work, and are used to collect the UV signals of the sample during the reaction process in real time.

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User Interface Displayer

The NCE DP is equipped with intellectual property spectrum analysis software, which allows the user to set up an experimental method according to the analysis requirements, and enables the NCE DP to automatically execute the set experimental method and automatically collect the spectral signals during the analysis. The software allows the user to use the embedded mathematical model to process the dissolution & permeation profiles that have been acquired, including curve smoothing, automatic calculation of Pef, dissolution rate, permeation rate, total dissolution, total permeation, etc. The software also provides the function of spectral overlay. The software also provides a stacking function for users to quickly compare the differences between the dissolution and permeation profiles under different prescription conditions, which makes your drug and prescription matching research easier.

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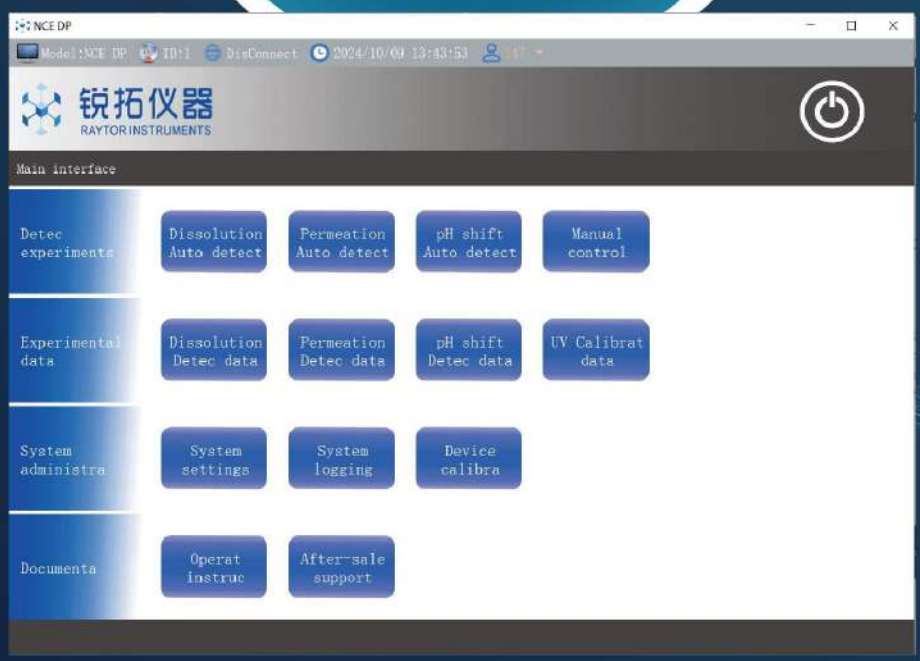
NCE DP comes standard with Raytor Dissolution Expert software.The perfect companion for your drug characterization

Raytor Dissolution Expert software helps you quickly master the use of your equipment for pH conversion, permeation, and IDR experiments, and meets the data manag ement requirements of 21CFRPART11 for audit trails, just like any other analytical equipment.



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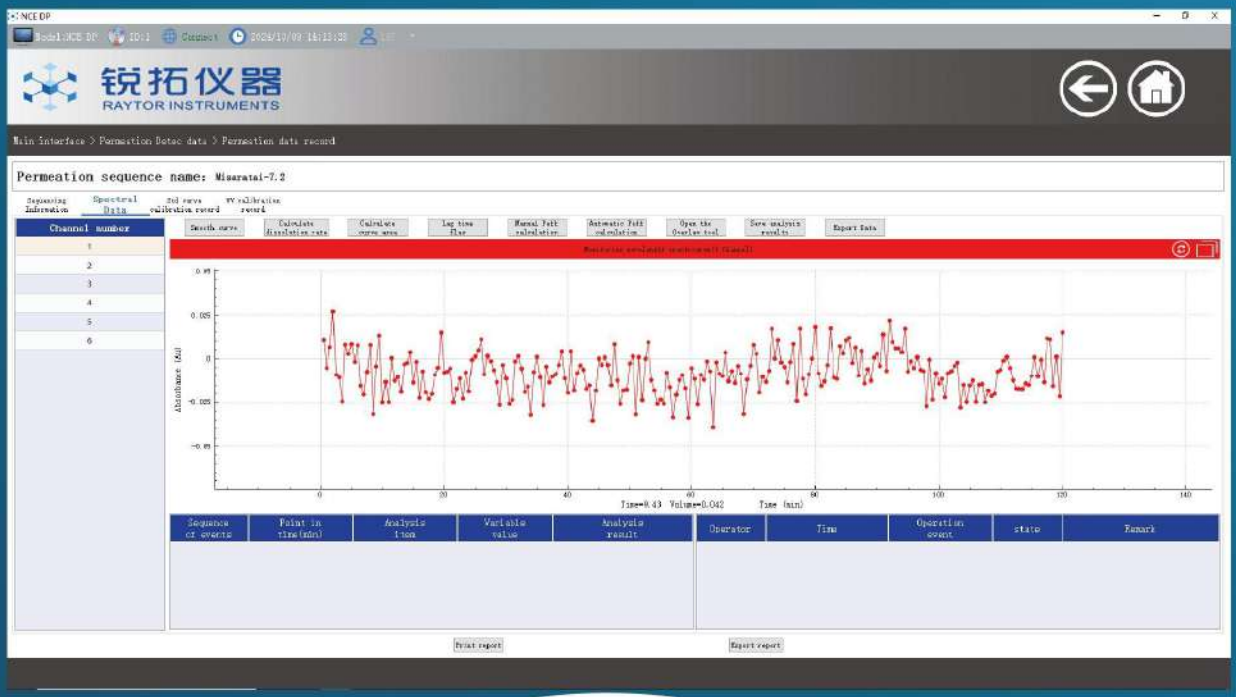

Raytor Dissolution Expert provides a variety of buttons in the toolbar that allow the experimenter to quickly optimize the raw data plots and automatically obtain the P_{eff} value at the touch of a button without the need for complex and tedious calculations; it is of course also possible to obtain the value manually, but the use of manual calculations will be recorded by the audit trail.

Users can further use the overlay tool in the Dissolution Expert software to compare graphical differences between prescriptions, and these reports are able to be printed.

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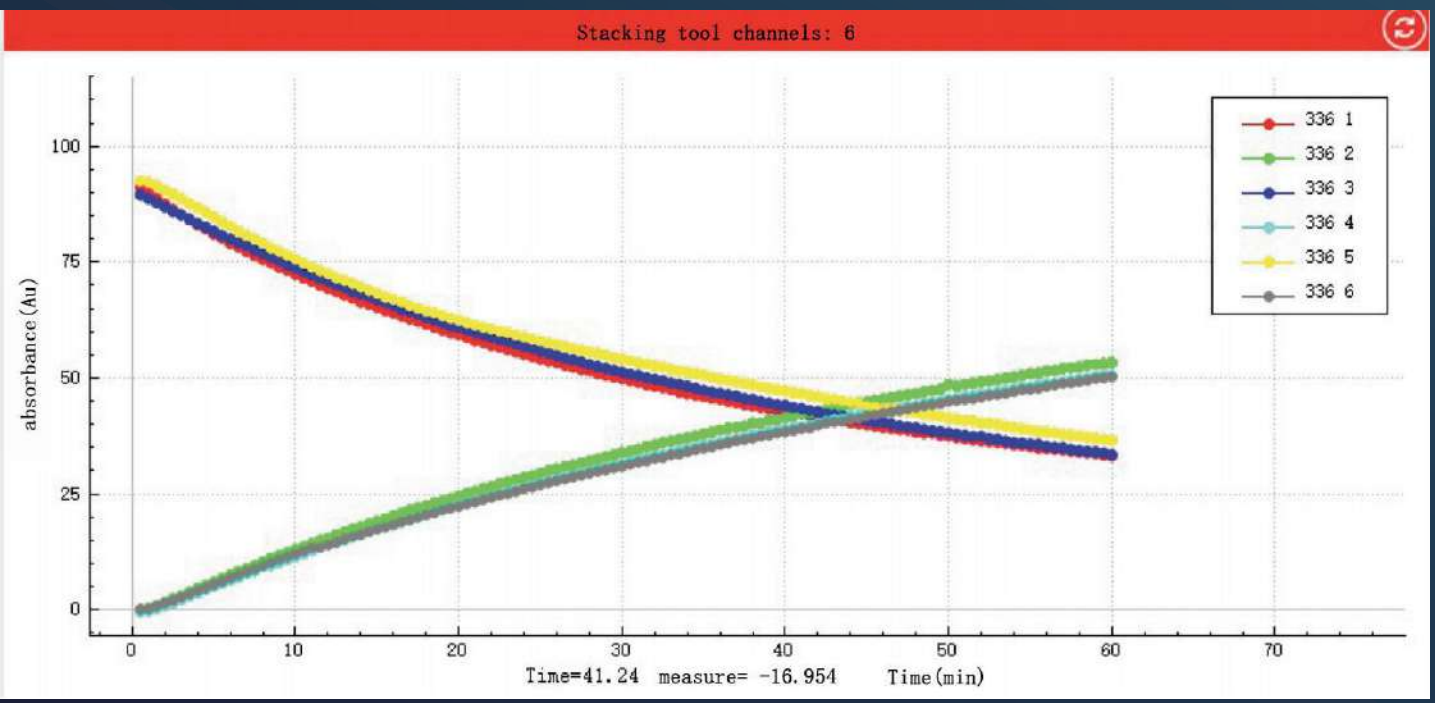
Demonstration of permeation model

In the NCE DP, an permeation model was used to study the dissolution/permeation of ibuprofen at pH=2. Channels 3 and 5 were used as donor pools to simulate the dissolution of the drug from the intestinal lumen of the human body.
Channels 3 and 5 are donor pools that simulate drug dissolution from the human intestinal lumen, while channels 4 and 6 are acceptor pools that simulate drug absorption from the cellular side of the body. As is well known to researchers, ibuprofen belongs to the BCS2 class of drugs and is absorbed at a very high rate, so as can be seen from the figure, as the drug is added to the donor pool, it is rapidly absorbed into the acceptor pool.



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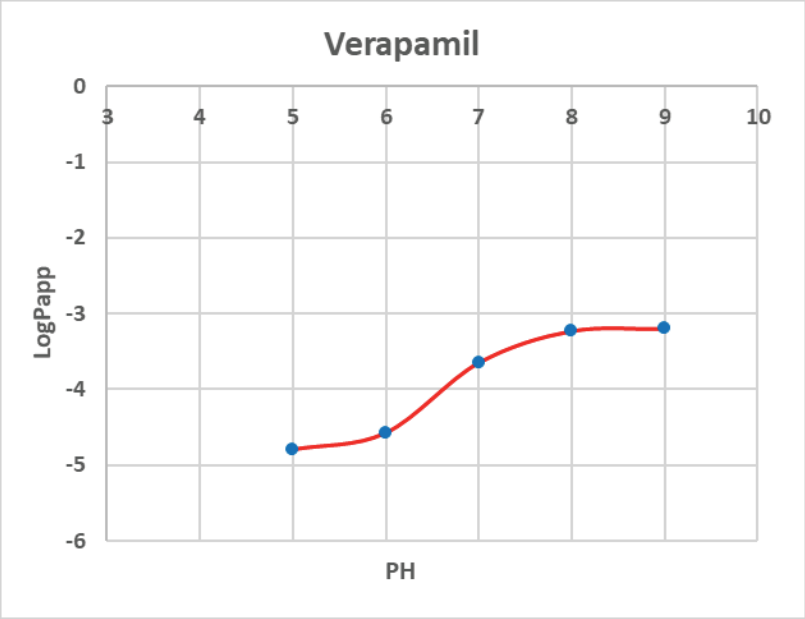
For drugs with pKa, the permeation rate of Papp is closely related to pH, and only by correctly modeling the pH value of the drug absorption chamber can we truly understand the permeation rate of the drug.
The NCE DP has three parallel channels, which can assist the user in obtaining the LogPapp-pH curves of the compounds in a fast manner. The figure below shows the Log Pap-pH curve for Verapamil.



A Log P_{app}-pH Study Based on Permeation Model

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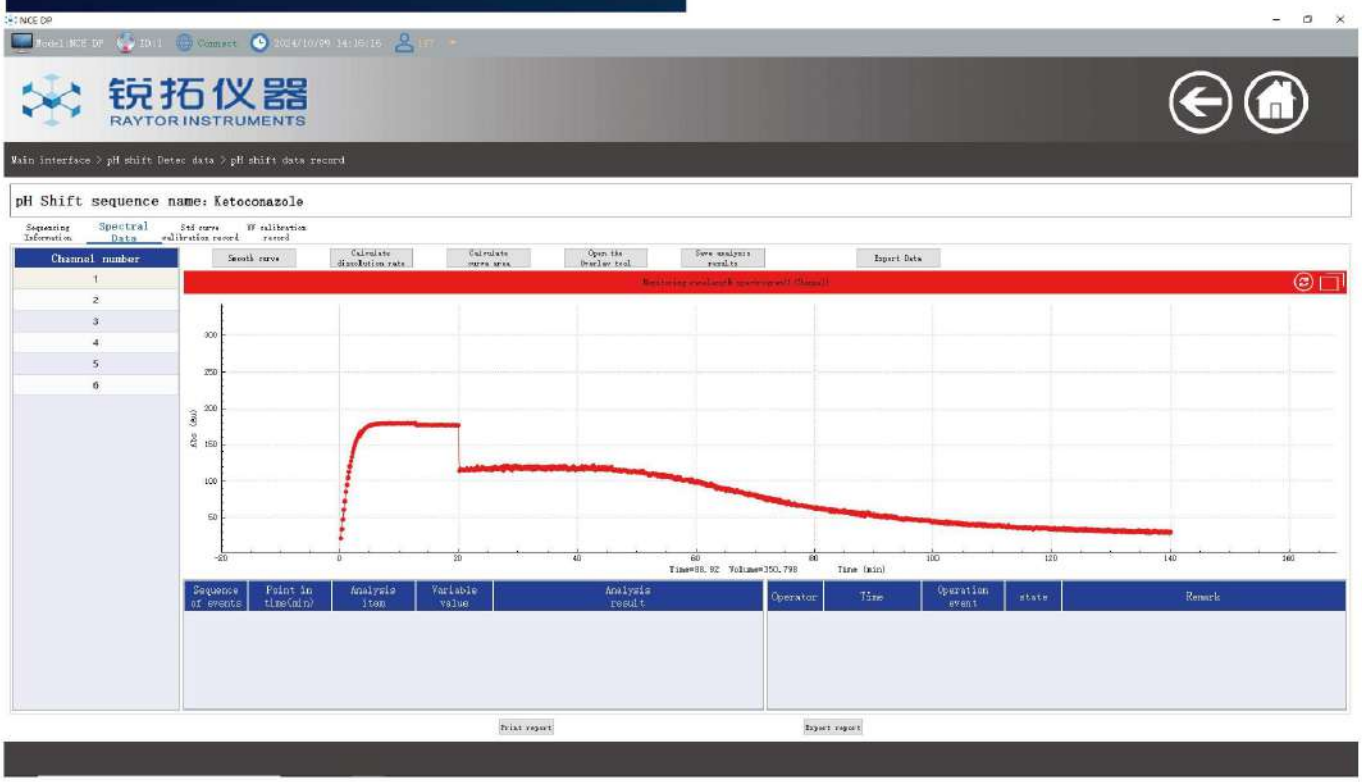
pH shift model

Pre-meal (Fa) and post-meal (Fe) have different pH values, which can lead to very different dissolution effects of certain drugs in the pH transition mode.The figure below shows the concentration profile of ketoconazole under preprandial conditions, which suggests that ketoconazole may precipitate in the small intestine leading to absorption abnormalities in the human body.



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Technical Parameter

working environment	Laboratory conditions, 20-25°C, humidity less than 60%.
Equipment size (main unit)	600mm×600mm×500mm
reaction channel	6 or 3 (for Permeation Model)
reagent channel	2
fiber optic channel	6
time accuracy	±1min
stirring rate	100-1000rpm
Rotation speed accuracy	Less than ⩽10% at 500rpm
operating temperature	Room temperature +5°C-40°C
Temperature control accuracy	±0.5°C
Liquid filling range	2-20ml
Liquid addition accuracy	＜1%
UV light range	200-600nm
UV light intensity	Fiber optic test of pure water, set the integration time to 50ms, 254nm corresponding to the original spectral value >20000
wavelength accuracy	1nm

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Technical Parameter

Deuterium lamp life	Greater than 1000h
IDR model	able fulfill (conditions or requirements)
pH conversion model	able fulfill (conditions or requirements)
Osmosis model	able fulfill (conditions or requirements)
Accurate Algorithm Components	able fulfill (conditions or requirements)
Bio-Flux Membrane Modules	Not included, additional purchase required

The information, descriptions and technical parameters in this document are subject to change without notice.

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