



# RT6产品手册

RT6 PRODUCT MANUAL

## 锐拓仪器

RAYTOR INSTRUMENTS

药物溶出度仪与溶出解决方案专业提供商

Dissolution Device and Solution Professional Provider



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**锐拓仪器**  
RAYTOR INSTRUMENTS

深圳锐拓仪器 (Raytor Instruments) 位于中国智造之都深圳, 是国家高新企业、ISO9001认证企业。锐拓仪器致力于药物溶出仪器与解决方案的研发、生产、销售和服务, 拥有多项技术专利。

Raytor Instruments is located in Shenzhen, the capital of Intelligent Manufacturing in China. It is a national high-tech enterprise and a ISO9001 certified enterprise.

Raytor Instruments is committed to the research and development, production, sales and service of drug dissolution instruments and solutions, with a number of technical patents.

锐拓仪器旗下的溶出产品包括: 流池法溶出系统、往复筒法溶出系统、普通溶出自动取样系统、扩散池自动取样系统、溶出仪机械性能验证工具箱、溶媒制备仪等, 全面覆盖国内外药典中各种溶出释放度测试装置。锐拓仪器同时能够为用户提供溶出度整体解决方案。

Raytor Instruments dissolution products include: flow-through cell dissolution system, reciprocating cylinder dissolution system, ordinary dissolution automatic sampling system, diffusion cell automatic sampling system, dissolution apparatus mechanical verification toolbox, dissolution medium preparation instrument, etc., which fully cover all kinds of dissolution release test devices in Pharmacopoeia. At the same time, Raytor Instruments can provide users with the overall solution of dissolution test.

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锐拓仪器  
RAYTOR INSTRUMENTS

# 完善的产品线

Perfect Product Line

## RT7

### 流池法溶出系统

Flow-Through Cell Dissolution System

药典流池法



## RT3

### 往复筒法溶出系统

Reciprocating Cylinder Dissolution System

药典往复筒法、往复支架法

## RT6

### 普通溶出系统

General Dissolution Series

药典篮法、浆法、小杯法、浆碟法、  
转筒法、浸没池法.....





## RT8

### 药物透皮扩散系统

Transdermal Diffusion System

药典扩散池法

## RT5

### 溶出介质制备脱气系统

Medium Preparation Degassing System

溶出介质的制备、脱气



## RT2

### 溶出仪物理校准工具

Dissolution Mechanical Calibration Series

校准工作站、校准工具包

# 产品设计理念

Product Design Concept



## 合规性

### Compliance

仪器性能指标符合中国药典、美国药典、欧洲药典等法规要求，计算机化系统符合21CFR Part 11 的要求。

The performance of the instrument meets the requirements of Chinese Pharmacopoeia, United States Pharmacopeia, European Pharmacopoeia and other regulations, and the computerized system meets the requirements of 21CFR Part 11.



## 清洁性

### Cleanliness

应对GMP检查中检察官以观察细节作为突破口的思路，让设备在清洗的细节上无懈可击。

In response to GMP inspection, prosecutors should observe the details as a breakthrough, so that the cleaning details of the equipment are impeccable.



## 管理性 Management

卓越的计算机管理系统，国内独家的云管理系统，让实验室主管全面掌控设备。

Excellent computer management system, domestic exclusive cloud management system, let the laboratory director control the equipment.



## 方法开发 Method Development

我们不只是生产仪器，我们还能够提供溶出相关的专业技术支持。

We are not only producing instruments, we can provide professional technical support related to dissolution.

# 锐拓溶出软件系统

## Raytor Dissolution Software System

锐拓溶出仪软件系统操作简单，容易上手，可以预存至少200条溶出实验方法，并具有至少三级权限管理和审计追踪功能、具有数据备份和PDF等不可更改的格式导出功能，完全符合美国 21CFR PART11，中国GMP，欧盟GMP等法规对数据完整性的要求。

The software system of Raytor dissolution apparatus is simple to operate and easy to use. It can store at least 200 dissolution test methods, and has at least three levels of permission level and audit track functions, data backup and PDF format export functions. It fully meets the requirements of data integrity of 21CFR PART 11.China GMP.EU GMP and other regulations.





## 用户权限管理 User Permissions Control

- 可分配至少3种权限等级：系统管理员、实验室主管、操作员。

At least 3 kinds of permission level can be allocated, including: system administrator, lab supervisor, general operator.

- 可由客户根据自身风险评估，定义权限等级的细则。

The detailed rules of each permission level can be customized by customers according to their own risk assessment.

- 可预设至少100个登陆账户、密码，用户操作权限分级管控。

At least 100 login accounts and passwords can be set up, and the user operation permission can be controlled by different levels.

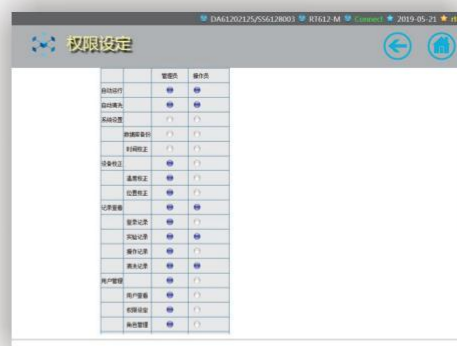
## 审计追踪 Audit trail

- 各个层面追踪到具体账号的审计追踪，包括登陆记录、实验记录、操作记录、清洗记录等。

All levels of audit tracking, including: landing records, experimental records, operating records, cleaning records, etc.

- 审计追踪记录可被检索、导出和打印。

Audit track records can be retrieved, exported and printed.



# 锐拓溶出软件系统

## Raytor Dissolution Software System

### 方法建立和调用

#### Method Preset and Invokes

- 可以建立和保存至少200条溶出实验方法。  
It can preset and store at least 200 dissolution test method.
- 溶出方法和UV/Vis检测方法同步设定。  
Dissolution method and UV/Vis detection method are set synchronously.
- 用户可以调用已经保存的溶出实验方法进行自动溶出实验。  
Users can call the saved dissolution experiment method for automatic dissolution experiment.
- 所有溶出方法的创建者和创建日期均可以被追溯。  
Users can call the saved dissolution experiment method for automatic dissolution experiment.



**SYSPLF**

水浴温度: 37.00 °C      实验员: rt01  
 搅拌转速: 100 r/min      设备编号: DA61202125/SS6128003  
 溶出方法: 篮法      实验品名: SYSP  
 溶出体积: 900 mL      溶媒类型: H2O  
 取样量: 10 mL      调温搅拌: 否  
 终液转速: 200 r/min      创建人: admin  
 持续时间: 0 分钟      创建时间: 2019-04-18 17:25:37

| 取样点(分) | 1  | 2  | 3  | 4  | 5  | 6  | 7  | 8  | 9  | 10 |
|--------|----|----|----|----|----|----|----|----|----|----|
| 取样点(分) | 30 | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  |
| 取样点(分) | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 |
| 取样点(分) | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  | 0  |

开始实验

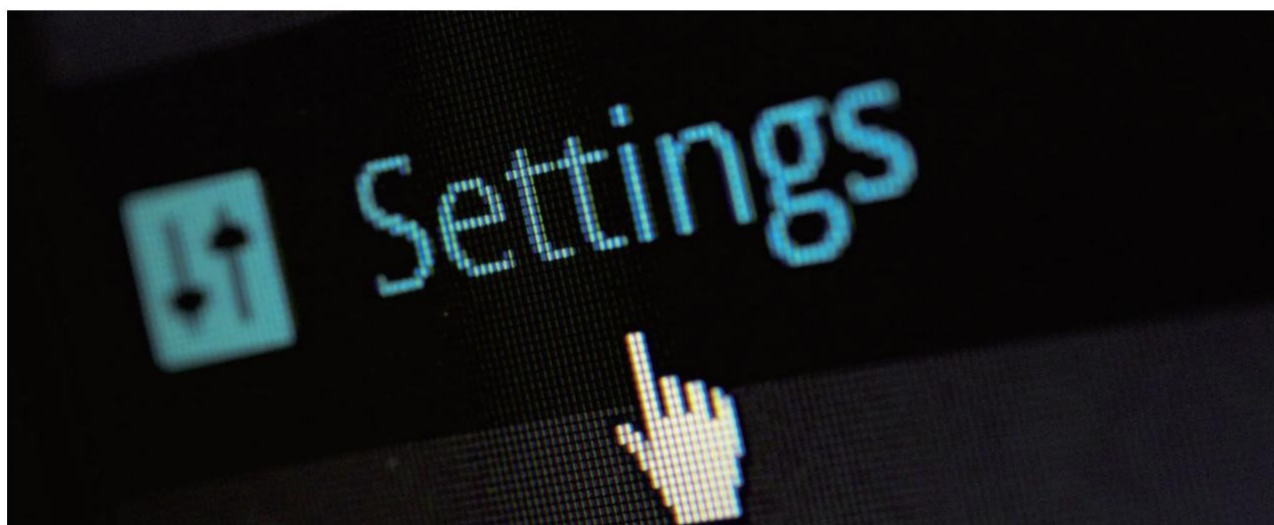


**实验记录**

实验时间从: 到: 点

| ID | 实验名称   | 操作员  | 开始时间             | 结束时间             | 药品批次 |
|----|--------|------|------------------|------------------|------|
| 1  | SYSPLF | rt01 | 2019-05-21 15:04 | 2019-05-21 15:05 | 1    |

1/1 Total 1





## 电子数据完整性 Electronic Data Integrity

- 单机版配备数据库系统，系统存储容量可满足至少10年的记录存储。

The stand-alone version is equipped with a database system, the system storage capacity can meet at least 10 years of record storage.

- 实验期间能够实时显示实验参数，并能够同步生成准确、一致的电子数据。

During the experiment, the test parameters can be real-time display, accurate and consistent electronic data can be generated synchronously.

- 实时显示UV/Vis检测结果(选配在线UV/Vis检测时)。

Real-time display of the UV/Vis detection results (for online UV / Vis detection).

- 实验完成后，系统将自动生成实验报告。

After the experiment, the system will automatically generate the experiment report.

- 电子数据可以被检索、导出、备份和打印。

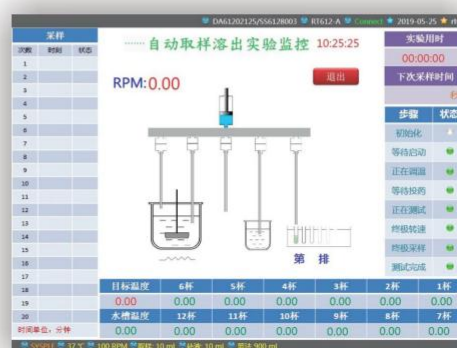
Electronic data can be retrieved, exported, backed up and printed.

- 系统数据库可以备份和还原。

The system database can be backed up and restored.

- 所有电子数据均受到保护，避免被随意篡改或删除。

Electronic data are protected from being tampered with or deleted.



| ID | 实验名称   | 操作员 | 开始时间             | 结束时间             | 药品批次 |
|----|--------|-----|------------------|------------------|------|
| 1  | SYSPLF | rd1 | 2019-05-21 15:04 | 2019-05-21 15:05 | 1    |

| 方法名称: SYSPLF |                     |       |                     |
|--------------|---------------------|-------|---------------------|
| 实验员:         | rd1                 | 开始时间: | 2019-05-21 15:04:12 |
| 设备编号:        | DA61202125556128003 | 结束时间: | 2019-05-21 15:05:48 |
| 药品批次:        | 1                   | 溶剂名称: | H2O                 |
| 实验品名:        | SYSP                | 溶出方法: | 篮法                  |
| 溶出体积:        | 900 ml              | 取样量:  | 10 ml               |
| 溶出转速:        | 200 RPM             | 溶出时间: | 0 min               |
| 设定温度:        | 37°C                | 设定转速: | 100 RPM             |
| 采样时间:        | -                   | 采样2:  | -                   |
|              |                     | 采样3:  | -                   |

# 锐拓溶出软件系统

## Raytor Dissolution Software System

### 计算机化系统技术支持服务

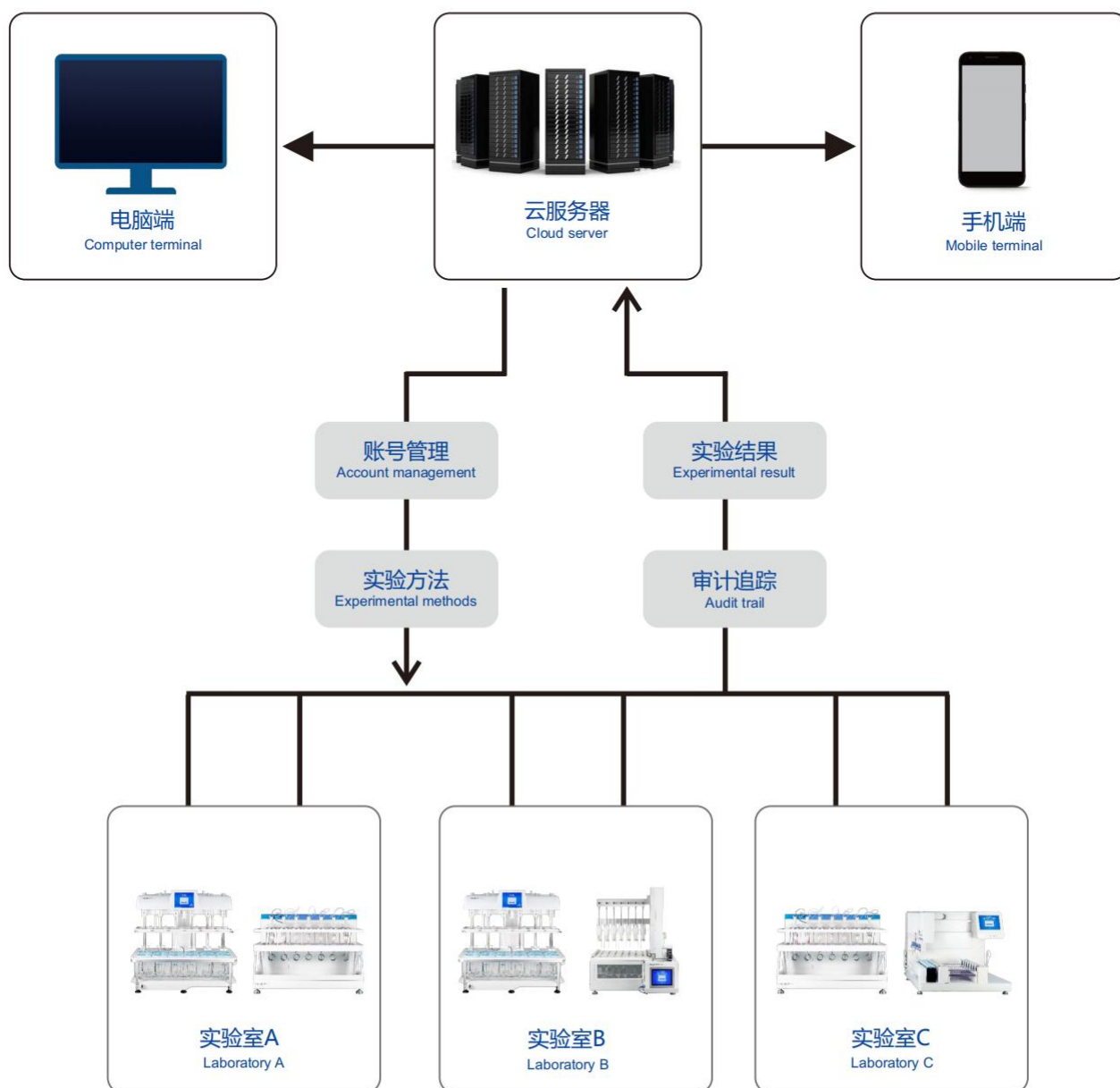
#### Computerized System Technical Support Services

- 溶出仪计算机化系统验证服务。  
Validation service of dissolution apparatus computerized system.
- 电子数据云系统服务器架设服务。  
Electronic data cloud system server setup service.
- 操作系统可以进行升级和根据用户需求进行定制。  
The operating system can be upgraded and customized according to user requirements.



## 锐拓电子数据云系统

### Raytor Electronic Data Cloud System





锐拓仪器  
RAYTOR INSTRUMENTS

# RT6 普通溶出度系列

General Dissolution Series

## 型号配置 Model Configuration



**RT600 8杯手动取样溶出仪**

RT600 8 position Manual Sampling Dissolution Apparatus



**RT612 12杯手动取样溶出仪**

RT612 12 Position Manual Sampling Dissolution Apparatus



**RT600-ST 8杯自动取样溶出系统**

RT600-ST 8 position Automatic Sampling Dissolution System



**RT612-ST 12杯自动取样溶出系统**

RT612 12 Position Automatic Sampling Dissolution System



**RT600-UV 在线紫外自动检测溶出系统**

RT600-UV UV Online Automatic Detection Dissolution System

# RT6 溶出仪

## Dissolution Apparatus



锐拓RT6系列溶出仪的机械性能完全满足中国药典、药物溶出度仪机械验证指导原则、美国药典、FDA DPA-LOP.002、ASTM E2503-07、USP Toolkit、ICH指导原则等国内外法规和标准。

The mechanical performance parameters of the Raytor RT6 series dissolution apparatus fully meet the requirements of domestic and foreign regulations and standards such as: Chinese Pharmacopoeia, Guidelines for Mechanical Qualification of Drug Dissolution Apparatus, US Pharmacopoeia, FDA DPA-LOP.002, ASTM E2503-07, USP Toolkit, ICH Guidelines and so on.

锐拓RT6系列溶出仪可通过更换不同装置组件，满足以下实验测试需求：

Raytor RT6 series dissolution apparatus can meet the following experimental test requirements by replacing different device components:

- 篮法  
Basket Method
- 桨法  
Paddle Method
- 小杯法  
Mini Vessel Method
- 桨碟法  
Paddle over Disk Method
- 转筒法  
Dissolution Cylinder Method
- 浸没池法  
Immersion Cell Method
- 固定式药片篮法  
Stationary Tablet Basket Method
- 支持定制特殊方法的溶出部件  
Customized Parts for Special Methods

## 创新设计 Innovative Design

- 溶媒自动预热功能，可设定仪器在指定时间自动开始恒温水浴加热。  
With the automatic preheating function of medium, the instrument can be set to automatically start constant temperature water bath heating at the specified time.
- 可选配粉末/颗粒自动投药模块，实现粉末/颗粒制剂的自动同步投药。  
Powder / particle automatic dosing module is optional, to realize automatic synchronous dosing of powder / particle preparation.

## 取样 Sampling

- 依照溶出实验方法和溶媒体积，自动定位取样针的取样位置。  
Automatically and accurately locate sampling needle according to dissolution method and medium volume.
- 非驻留式取样针，减少扰流的产生。  
Non-resident sampling needle reduces disturbance.
- **自动取样：**可以设置自动溶出取样方法，到达取样时间点时取样针会自动下降和取样。  
Automatic sampling: Automatic dissolution sampling method can be set up. When the sampling time is reached, the sampling needle will automatically low down and sample.
- **手动取样：**可以通过取样口进行手动取样，或使用自动定位取样针进行手动取样。  
Manual Sampling: Sampling through a reserved sampling port. Or sampling through an automatic positioning sampling needle.



## 溶出杯包覆式创新专利设计 Innovative Design of Dissolution Vessel

- 锐拓溶出杯口采取包覆式设计，更加耐用。  
Raytor design innovative collar incorporated onto the vessel which can be more durable.
- 将溶出杯的三个凸扣对准底座孔位三个凹位，放入溶出杯，顺时针方向旋转30°，即可完成安装，快捷准确。  
Align the three convex buckles of the vessel with the concave position of the base hole and put in it, rotate the vessel clockwise by 30 degrees. The installation can be completed quickly and accurately.



## 桨篮共轴专利设计 Patent Design of Propeller Basket Coaxial

- 共轴分体式溶出部件，可以适配篮法、桨法、小杯法、桨碟法、转筒法、浸没池法。  
Coaxial split dissolution parts can be adapted to basket method, paddle method, mini vessel method, paddle over disk method, cylinder method and immersion cell method.
- 分段式转轴设计，溶出方法切换无需人工重新调整定位搅拌件高度。  
It is not necessary to readjust the height of dissolution unit after switching dissolution method.
- 连接处位于溶媒液面上方，便于清洁，无残留风险。  
The connection is located above the media surface, easy to clean and no risk of residue.



## 水浴槽设计

### Water Bath Design

- 一体成型圆角设计，水循环无死角，水浴恒温能力更优秀。

Integrated forming design with round corner, no dead angle in water circulation. Excellent ability of constant temperature in water bath.

- 无清洁死角，水浴可被彻底排干。

No cleaning dead corner, water bath can be thoroughly drained.

- 水循环加热系统在水浴槽后方，与其他部件隔离，消除振动影响。

The water circulating heating system is located behind the water bath isolated from other parts and eliminates the vibration impact.



## 自动同步投药

### Automatic Synchronous Dosing

- 消除投药时间差，投药时间点可被审计追踪。

Eliminate the time difference of dosing, and the time point of dosing can be tracked.

- 取样时间自动计时，到达取样时间前，会有提示鸣响。

Sampling time is automatically timed. Before reaching the sampling time, there will be a reminder ringing.



# RT6-ST 智能型·自动取样溶出系统

Smart Type • Automatic Sampling Dissolution System



“更加创新、更加智能”一直是锐拓仪器不懈追求的目标，而RT6-ST智能型自动取样溶出系统则能充分体现这种智能创新核心理念。基于现有的技术积累，RT6-ST系列进一步优化了用户使用体验。而面向未来，RT6-ST系列亦被赋予了更多的智能化创新设计。

"More innovation and intelligence" has always been the goal of Raytor Instruments, and RT6-ST smart type automatic sampling dissolution system can fully reflect the core concept of this intelligent innovation. Based on the existing technology accumulation, the RT6-ST series further optimized the user experience. For the future, RT6-ST series has also been endowed with more intelligent innovative designs.

RT6-ST系列包括：**RT600-ST** 8杯自动取样溶出系统、**RT612-ST** 12杯自动取样溶出系统。并可增配锐拓电子数据云系统、溶出视频监控系統。

The RT6-ST series includes: **RT600-ST** 8 position Automatic Sampling Dissolution System, **RT612-ST** 12 position Automatic Sampling Dissolution System. It can also be equipped with Raytor Electronic Data Cloud System and Dissolution Monitoring Video System.

## 精准取样

### Accurate Sampling

高精度取样泵，能有效地提供准确而精密的取样。

High-precision sampling pump, which can effectively provide accurate and precise sampling.

取样前预润洗取样管路和回路，样品浓度更加精准。

Sampling pipelines and circuits are embellish washed before sampling to ensure more accurate sample concentration.

取样后，将管路的残留液体吹扫排空，取样体积更加准确管路无样品残留。

After sampling, the residual liquid in the pipeline will be purged and emptied, so that the sampling volume is more accurate and there is no sample residue.



## 管路系统

### Pipeline System

采用高化学稳定性、高抗吸附的Teflon管路系统，避免取样管路腐蚀或吸附样品。

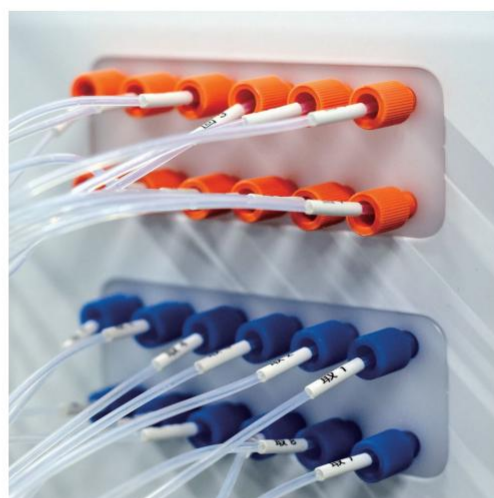
Teflon pipeline system with high chemical stability and high anti-adsorption was used to avoid corrosion of sampling pipeline or sample adsorption.

各个通道完全独立取样管路，避免样品溶液交叉污染。

The completely independent sampling pipeline of each channel can effectively avoid cross contamination of sample solution.

拥有自动回补溶媒和自动清洗管路的功能。

The functions of automatically repairing the medium and cleaning the pipeline.



## 自动在线过滤

### Automatic Online Filtering

可以加装二级在线过滤器，仪器可自动实现预先润洗饱和和滤膜的功能。

Dual on-line filters can be installed, and the instrument can automatically realize the function of embellish washing saturated filter.

支持多种的在线过滤方案，例如：注样针前端过滤、泵前过滤或客户定制的过滤方案。

More online filtering schemes are supported, such as sample injection probe front-end filtering, pump front filtering or customized filtering schemes.



## 自动样品收集

### Automatic Sample Collection

180位1.5mL液相小瓶样品托盘和优化取样系统，可以将样品溶液直接收集到液相小瓶中。

The 180 position sample rack for 1.5mL liquid vial and the optimized sampling system can directly collect the sample solution into the liquid vial.

优化型注样针，更低残留、更耐腐蚀。并可直接将样品溶液注入预切盖的液相小瓶中。

Optimized sample injection probe, lower residue and more corrosion resistance. And it can directly inject the sample solution into the LC vial with the pre cut cap.

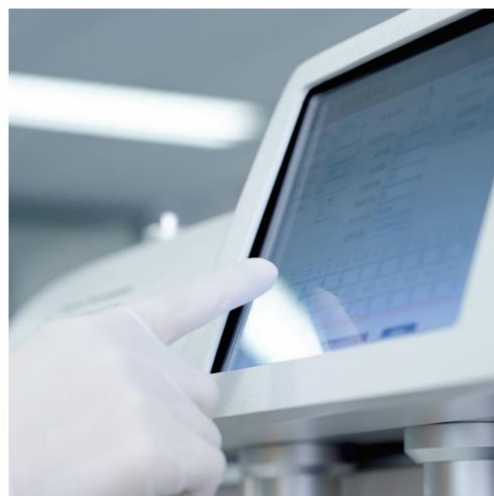


## 创新设计

### Innovative Design

支持在溶出过程中更换溶媒的自动运行实验。更换溶媒的时间点、体积和更换后的搅拌转速等参数均可被设定。取样针将根据更换溶媒后的溶媒体积变化，自动定位到正确的取样位置。

Support the automatic experiment of changing medium during dissolution. The time point, volume and stirring speed after medium replacement can be set. The sampling probe will automatically locate to the correct sampling position according to the change of medium volume after medium replacement.



## 智能定制

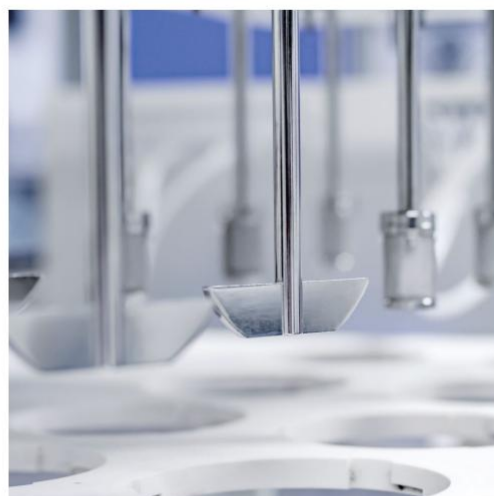
### Intelligent Customization

可选配智能双转速模式，12杯溶出仪的左右各6个转轴可以设定两种不同的转速。

Smart dual speed mode is optional, the rotational speed of the 6 shafts on the right and left of the 12 vessel dissolution apparatus can be set respectively.

可选配粉末/颗粒自动投药模块，实现粉末/颗粒的自动同步投药。

Powder / particle automatic dosing module is optional, to realize the automatic and synchronous dosing of powder / particle .



# RT6-ST 智能型 · 锐拓电子数据云系统

Smart Type · Raytor Electronic Data Cloud System

- 锐拓云系统可同时连接至少250台不同类型的实验仪器。例如，可以将RT6-ST溶出系统与流池法溶出系统、往复筒法溶出系统、药物透皮扩散系统等进行互联，实现真正的智能化管理。

Raytor cloud system can connect at least 250 different types of experimental instruments at the same time. For example, RT6-ST dissolution system can be interconnected with flow-through cell dissolution system, reciprocating cylinder dissolution system, drug transdermal diffusion system, etc, to realize real intelligent management.

- 服务器将自动备份各实验设备中的实验记录和审计追踪，并可通过服务器导出或打印。

The server will automatically back up the experimental records and audit trails in each experimental instruments, and can export or print them through the server.

- 可通过服务器远程监控目前联网的所有实验设备的运行状态。

The running status of all currently networked experimental instruments can be monitored through the server.

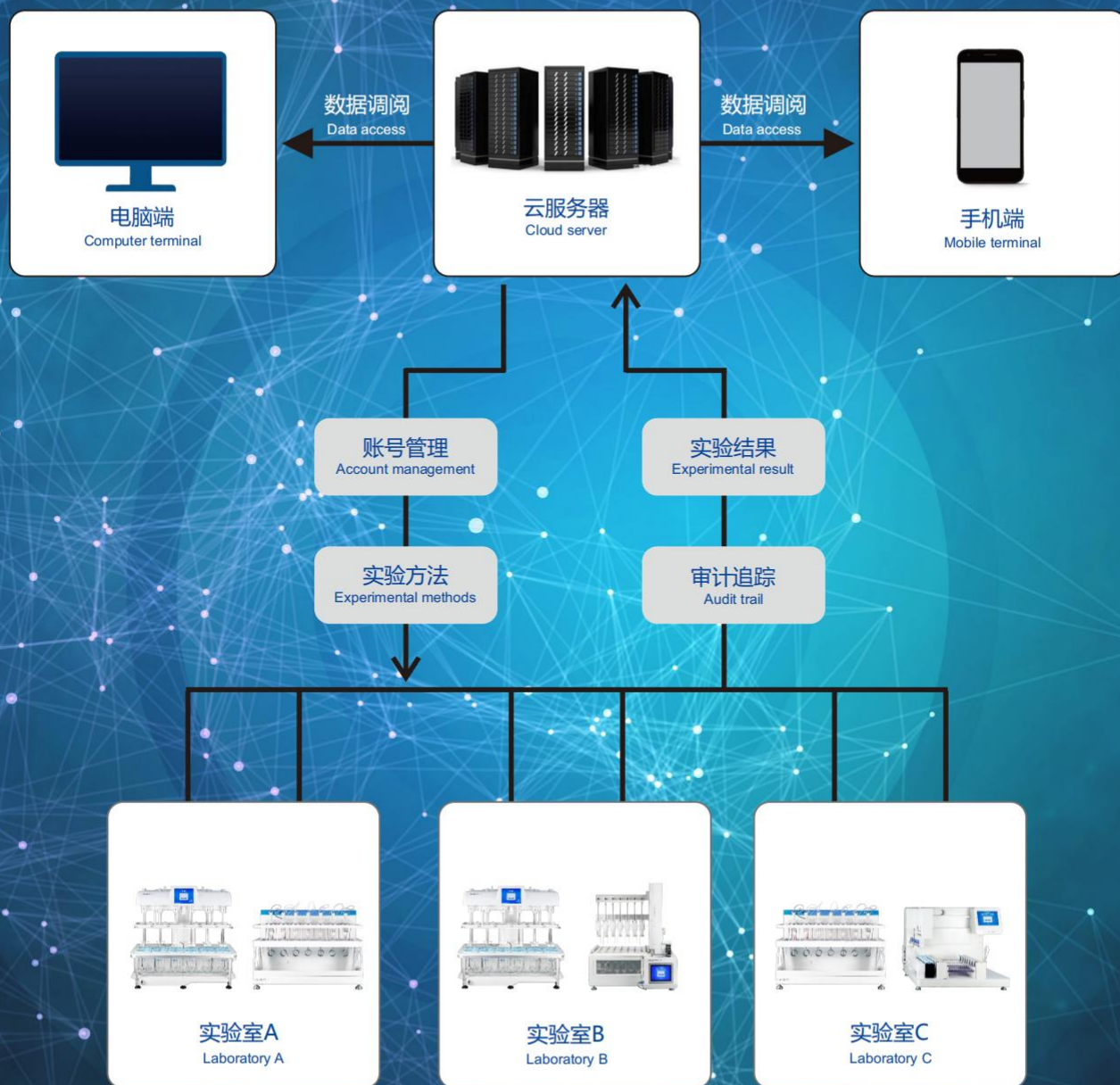
- 可通过服务器进行用户管理和权限设定。支持多用户同时登录服务器系统。

User management and permission setting can be performed through the server. Support multiple users to log in to the server system at the same time.

- 锐拓云系统可根据客户的需求进行升级或定制。

Raytor cloud system can be upgraded or customized according to customer needs.





# RT6-ST 智能型 • 溶出视频监控系统

Smart Type • Dissolution Monitoring Video System



- 适配型号：RT600-ST, RT612-ST。  
Applicable models: RT600-ST, RT612-ST.
- 高清微距摄像头。  
HD macro camera.
- 监控摄像头路数：8 / 16 / 32。  
Number of surveillance cameras: 8 / 16 / 32.
- 内存容量（可选）：1TB / 2TB / 4TB / 6TB / 8TB。  
Memory capacity (optional): 1TB / 2TB / 4TB / 6TB / 8TB.
- 支持视频文件以MP4的格式导出。  
Support the export of video files in MP4 format.

高清微距摄像头可安装在溶出杯底部，溶出杯侧面。进一步地，锐拓仪器提供转篮顶部的摄像头安装方案，实现药物溶出现象全方位无死角监控。

The high-definition macro camera can be installed at the bottom and side of the dissolution vessel. Further, Raytor Instruments provides a camera installation scheme at the top of the basket to realize the omnidirectional monitoring of drug dissolution.



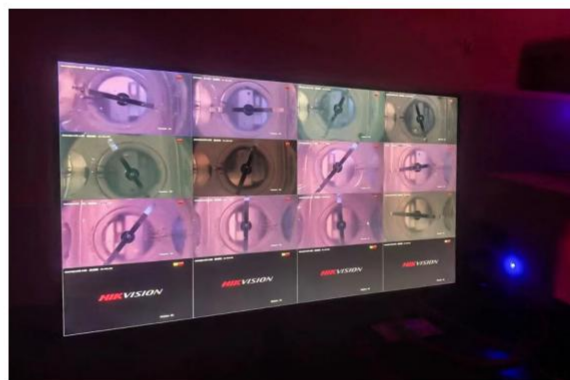
支持一台监控主机连接多台锐拓RT6-ST溶出系统，实现多机并联监控。监控系统以连续录像的方式收集样品溶出视频，保证涵盖这个溶出实验过程。

Support a monitoring host to connect multiple RT6-ST systems to realize parallel monitoring of multiple machines. The monitoring system collects sample dissolution videos in the form of continuous video to ensure that the experiment process is covered.



为了应对光敏样品的溶出现象监控，锐拓提供在避光环境下的溶出视频监控解决方案。并支持更多的溶出视频系统定制服务。

In order to monitor the dissolution of photosensitive samples, Raytor provides a solution for dissolution video monitoring in a dark environment. It also supports more customized services for dissolution video system.



# RT600-UV

## 在线UV自动检测溶出系统

Dissolution UV-online Automatic Detection System



锐拓在线UV自动检测溶出系统 (RT600-UV) 是锐拓仪器在第三代溶出操作系统基础上推出的最新产品，RT600-UV系统包括自动溶出仪，自动取样工作站和紫外-可见分光光度计。RT600-UV支持自动溶出取样、自动在线UV检测，更方便用户药物研发、例行检测工作，极大地提升工作效率。

Raytor Dissolution UV-online Automatic Detection System (RT600-UV) is the latest product of Raytor Instruments based on the third generation dissolution operating system. RT600-UV system includes Automatic Dissolution Apparatus, Automatic Sampling Workstation and Ultraviolet-Visible Spectrophotometer. RT600-UV supports automatic dissolution sampling and on-line ultraviolet detection. It is more convenient for users to develop drugs and routine detection, and greatly improves work efficiency.

通过自动溶出仪的溶出操作系统控制自动溶出仪，自动取样工作站和紫外-可见分光光度计，支持预设并调用溶出在线紫外自动检测方法，溶出系统将按照预设的方法自动完成自动溶出取样和自动在线紫外检测。测试结果实时反馈到溶出操作系统的界面中，自动实时生成受保护的电子数据文档。

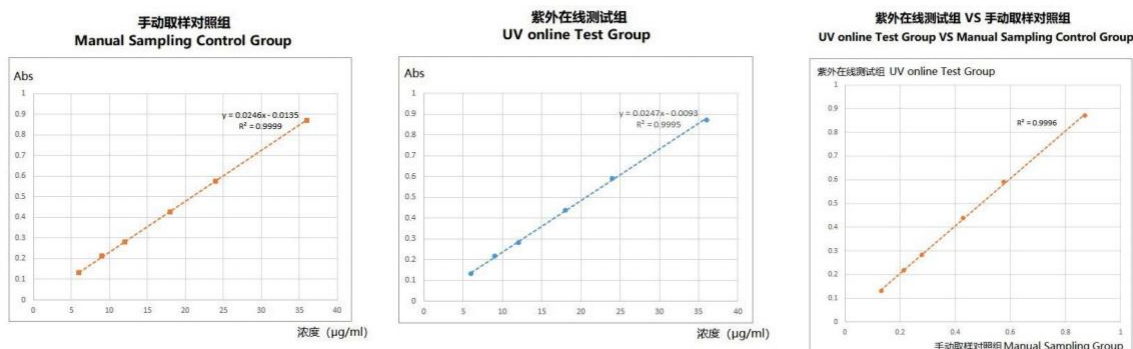
Automatic dissolution apparatus, automatic sampling workstation and the ultraviolet-visible spectrophotometer are controlled by the same dissolution operating system in the automatic dissolution apparatus. It supports the preset and invokes the on-line ultraviolet automatic detection method for dissolution. The dissolution system will automatically complete the automatic dissolution sampling and the automatic on-line ultraviolet detection according to the preset method. The test results are fed back to the interface of the dissolution operating system in real time, and the protected electronic data documents are automatically generated in real time.

## 准确度 Accuracy

分别使用手动取样测试和紫外在线测试，连续检测不同浓度水杨酸溶液。以水杨酸浓度为X轴，样品吸光度为Y轴，建立线性回归曲线，并计算各曲线的R平方值。

Continuous detect the absorbance of salicylic acid solution with different concentration by manual sampling and UV on-line respectively. Linear regression curves were established with salicylic acid concentration as X-axis and absorbance as Y-axis, and calculate the R-square values of each curve.

- 紫外在线测试结果呈现优秀的线性相关性，R平方值为0.9995，与手动取样对照组无差异。  
The results of UV on-line test showed excellent linear correlation, R-square value was 0.9995, and there was no significant difference with the manual sampling control group.
- 使用手动取样对照组的吸光度为X轴，紫外在线测试组的吸光度为Y轴，建立线性回归曲线，其R平方值为0.9996。此结果表明锐拓在线紫外自动检测溶出系统具有极其优秀的精准度。  
Linear regression curves were established with the absorbance of the manual sampling control group as X-axis and the absorbance of UV-online test group as Y-axis. The R-square value was 0.9996. The results show that Raytor Dissolution UV-online Automatic Detection System has excellent accuracy.

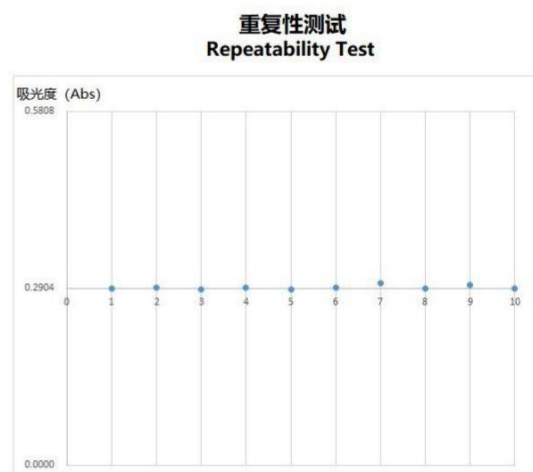


## 重复性 Repeatability

对相同浓度的样品溶液连续执行10次在线取样，每次取样后随即执行在线紫外自动检测。

Perform 10 consecutive on-line sampling for the same concentration of sample solution and detect the absorbance by Raytor Dissolution UV-online Automatic Detection System after each sampling.

- 10次测试结果的相对标准偏差 (RSD) < 2.0%。  
The relative standard deviation (RSD) of 10 UV-online test results was < 2.0%.
- 紫外在线测试的吸光度平均值与手动取样测试的吸光度平均值的差异 < 2%。  
The difference between the average absorbance of UV-online test group and manual sampling control group was < 2%.



## RT6系列溶出配件 RT6 Series Dissolution Accessories

### 溶出杯

#### Dissolution Vessel

尺寸规格符合药典要求的1L溶出杯。

The size and specifications of 1L dissolution vessel meet the requirements of pharmacopoeia.



### 溶出转篮

#### Dissolution Basket

尺寸规格符合药典要求，适用于所有标准溶出度仪。材质：316L不锈钢；网孔：40目、100目。

The size and specifications meet the requirements of the Pharmacopoeia and are suitable for all standard dissolution apparatus. Material: 316L stainless steel; mesh: 40 meshes, 100 meshes. 40 Meshes, 100 Meshes.



### 搅拌桨

#### Dissolution Paddle

尺寸规格符合药典要求，适用于所有标准溶出度仪。材质：316L不锈钢；可定制特氟龙（PTFE）防腐蚀涂层。

The size and specifications meet the requirements of the Pharmacopoeia and are suitable for all standard dissolution apparatus. Material: 316L stainless steel; Teflon (PTFE) anti-corrosion coating can be customized.



### 沉降篮

#### Dissolution Sinkers

尺寸规格符合药典要求，适用于所有标准溶出度仪。材质：316L不锈钢。

The size and specifications meet the requirements of the Pharmacopoeia and are suitable for all standard dissolution apparatus. Material: 316L stainless steel.





## 桨碟法装置（方法1）

### Paddle over Disk Apparatus (Method 1)

尺寸符合中国药典第四法（桨碟法）方法1的要求。材质：316L不锈钢; 外径：92mm。

Meets the requirements of method 1 of the dissolution 4th method (paddle over disk) of Chinese Pharmacopoeia. Material: 316L stainless steel; Outer diameter: 92mm.



## 桨碟法装置（方法2）

### Paddle over Disk Apparatus (Method 2)

符合中国药典第四法（桨碟法）方法2、美国药典、欧洲药典的技术要求。材质：316L不锈钢; 外径：41.2mm。

Meets the technical requirements in Chinese Pharmacopoeia < 0931 >, US Pharmacopoeia and European Pharmacopoeia. Material: 316L stainless steel; Outer diameter: 41.2mm.



## 转筒法配件

### Dissolution Cylinder

尺寸规格符合药典要求，适用于所有标准溶出度仪。材质：316L不锈钢。

The size and specifications meet the requirements of the Pharmacopoeia and are suitable for all standard dissolution apparatus. Material: 316L stainless steel.



## 固定式药片篮

### Stationary Tablet Basket

尺寸符合美国药典（USP）对固定式药片篮（Stationary Tablet Basket）的要求。材质：316L不锈钢。

The size and specifications meets the requirements of the US Pharmacopoeia (USP) for stationary tablet basket. Material: 316L stainless steel.



## RT6系列溶出配件 RT6 Series Dissolution Accessories

### 柱状取样滤芯

#### Sampling Filter Element

柱状取样滤芯安装于溶出仪取样针口位置。取样滤芯滤孔尺寸规格：10 $\mu$ m、30 $\mu$ m、50 $\mu$ m。

The cylindrical sampling filter element is installed at the sampling needle of the dissolution apparatus. Specification of sampling filter element: 10  $\mu$ m, 30  $\mu$ m, 50  $\mu$ m.



### 溶出配件晾干展示架

#### Dissolution Accessories Drying Display Rack

适用于溶出搅拌桨、溶出转篮、篮轴和手动取样针的晾干、存放和展示。

Suitable for drying, storage and display of dissolution stirring paddle, dissolution basket, basket shaft and manual sampling needle.



### 小杯法溶出配件

#### Dissolution Paddle

适用于锐拓溶出仪的小杯法溶出杯及溶出配件，符合中国药典0931溶出度与释放度测定法——第三法（小杯法）的要求。配件包含：（1）精密小杯法溶出杯，材质：玻璃。（2）溶出杯固定部件。（3）精密小杯法搅拌桨，材质：316L不锈钢。

The mini vessel and related accessories applicable to Raytor dissolution apparatus, and meet the requirements of the third method (mini vessel method) in Chinese Pharmacopoeia 0931<Dissolution and Release Determination>. Accessories include: (1) Precision mini vessel, material: glass. (2) Dissolution Vessel Fixing Parts. (3) Precision paddle for mini vessel method, material: 316L stainless steel.





## 浸没池装置

### Immersion Cell Apparatus

锐拓仪器浸没池装置符合美国药典<1724> 半固体药物性能试验 (Semisolid Drug Products Performance Tests) 的要求。适用于半固体制剂的体外释放度测试。

Raytor immersion cell apparatus meets the requirements of USP < 1724 > Semisolid Drug Products Performance Tests. It is suitable for in vitro release test of semi-solid preparations.

浸没池装置主要包括以下配件：浸没池、平底溶出杯、溶出杯适配环、小搅拌桨、装药辅助工具。

The immersion cell apparatus mainly includes the following accessories: Immersion Cell, Flat Bottom Dissolution Vessel, Dissolution Vessel Adapter Ring, Mini Paddle, Auxiliary Tools.

锐拓浸没池装置通过溶出杯适配环，可完全适配锐拓RT600/RT612系列溶出仪。搅拌小桨叶采用共轴分体式设计，将其旋入溶出仪母轴即可完成安装，无需重新定位桨叶高度。

Raytor immersion tank device can fully adapt RT600 / RT612 series dissolution apparatus through dissolution vessel adapter ring. The mini paddle adopts coaxial split design, which can be installed by screwing it into the master shaft of the dissolution apparatus without repositioning the paddle height.



# 售后服务与技术支持

After Sales Service & Technical Support

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## 验证与确认

### Validation and Qualification

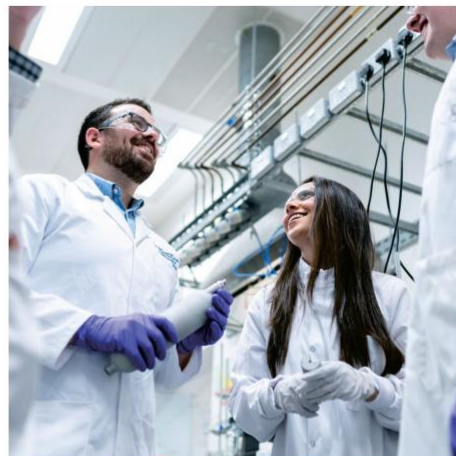
锐拓仪器能够为您的全系列溶出系统提供全面且专业的验证与确认服务。所有验证与确认服务都会附有符合法规要求的完整专业的文件报告。

Raytor Instruments can provide comprehensive and professional validation and qualification services for your dissolution systems. All verification and validation services will be accompanied by complete and professional documents meeting regulatory requirements.

我们能够提供的验证&确认服务包括且不限于：

The validation & qualification services we can provide include but are not limited to:

- 篮法、桨法 IQ/OQ/PQ  
Basket Method, Paddle Method IQ/OQ/PQ
- 中国药典小杯法 IQ/OQ/PQ  
ChP Mini Vessel Method IQ/OQ/PQ
- 桨碟法 IQ/OQ  
Paddle over Disk Method IQ/OQ
- 转筒法 IQ/OQ  
Dissolution Cylinder Method IQ/OQ
- 浸没池法 IQ/OQ  
Immersion Cell Method IQ/OQ
- 流池法 IQ/OQ  
Flow-Through Cell Method IQ/OQ
- 往复桶法、往复支架法 IQ/OQ  
Reciprocating Cylinder and Holder IQ/OQ
- 扩散池法 IQ/OQ  
Diffusion Cell Method IQ/OQ
- 计算机化系统验证  
Computerized System Validation
- 溶出系统清洁验证  
Dissolution System Cleaning Validation

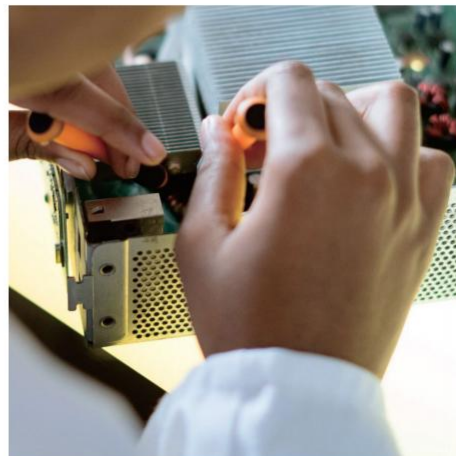


## 维修和预防性维护

### Repair & Preventive Maintenance

锐拓仪器售后服务团队能够快速应对您的仪器维修需求。锐拓仪器提供涵盖维修，预防性维护和维修后再确认的服务，让您的仪器始终处于最佳状态。

Raytor Instruments after-sales service team can quickly respond to your instrument maintenance needs. Raytor Instruments provides services covering repair, preventive maintenance and requalification after repair, to keep your instrument at its best.



## 培训与交流

### Training & Communication

锐拓仪器能够为您提供全系列溶出系统的使用操作培训。另外，锐拓仪器的专业技术团队能够根据您的实验需求，针对特定的技术细节进行更深层次的交流。

Raytor Instruments can provide you with a full series of training on the operation of dissolution system. In addition, the professional technical team of Raytor Instruments can conduct deeper communication for specific technical details according to your experimental needs.



## 应用技术支持

### Application Technical Support

锐拓仪器拥有强大的应用技术实验室团队，能够承接客户的新颖溶出方法开发，例如流池法、往复筒法。并协助客户进行溶出结果异常调查。

Raytor Instrument has a strong application technology laboratory team, which can undertake the development of new dissolution methods from customers, such as flow-through cell method and reciprocating cylinder method. And assist the customer to investigate the abnormal dissolution results.

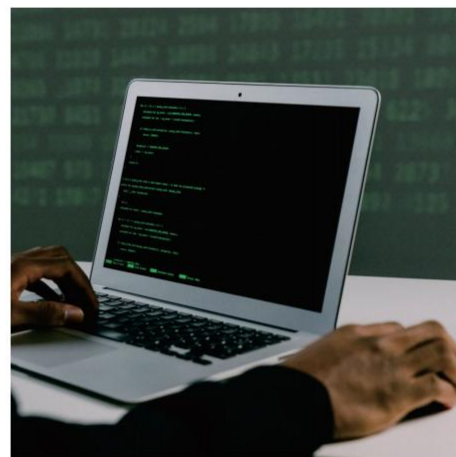


## 架设电子数据云系统服务器

### Electronic Data Cloud System Server

通过架设电子数据云系统服务器，连接多个实验室中的全部溶出系统，实现所有溶出系统的记录、用户、方法等电子数据的统一管理和自动备份。

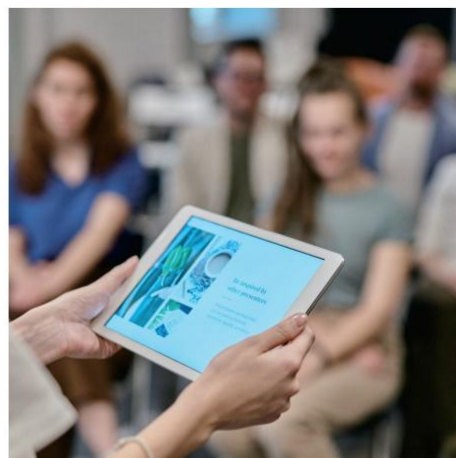
The electronic data cloud system server is to connect all dissolution systems in multiple laboratories to realize the unified management and automatic backup of electronic data such as records, users and methods of all dissolution systems.



## 技术研讨会 Technical Seminar

锐拓仪器会在全国各种制药技术研讨会中分享最新溶出研究成果。您可以关注锐拓仪器的参会安排，在研讨会现场跟我们的技术专家进行交流。

Raytor Instruments will share the latest dissolution research results in various national pharmaceutical technology seminars. You can pay attention to the participation arrangement of Raytor and communicate with our technical experts at the seminar site.



## 锐拓线上大讲堂 Raytor Online Lecture Hall

锐拓仪器会定期在线上举办大讲堂，介绍最新的溶出前沿技术。您可以进入大讲堂的直播平台收看技术宣讲，并在线上与技术专家进行交流互动。

Raytor Instruments will regularly hold a lecture hall online to introduce the latest dissolution cutting-edge technology. You can enter the live broadcast platform of the auditorium to watch the technical lectures and interact with technical experts online.



## 微信公众号 WeChat Official Account

锐拓仪器的微信公众号会定期分享应用实验案例、公布锐拓线上大讲堂和技术研讨会的安排。您可以关注我们的公众号，以获得最新的资讯。

The official account of WeChat public of Raytor Instruments will regularly share the application experiment cases, announce the arrangement of the lecture hall and technical seminar. You can pay attention to our official account for the latest information.



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



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文件版本号：DS-S001-2303003