

# RT3

## 往复筒法溶出系统

Reciprocating Cylinder Dissolution System

中国药典 第七法

USP Apparatus 3

EP Apparatus 3



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



# 锐拓仪器

## Raytor Instruments

深圳市锐拓仪器设备有限公司位于中国创新之都深圳，国家高新技术企业。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，为用户提供性能稳定品质卓越的溶出仪、溶出自动取样系统、溶出度在线紫外检测解决方案、溶出仪机械性能验证工具箱、溶媒制备仪等产品。同时为用户提供药物溶出度整体解决方案。

Raytor Instruments Co., Ltd. (Raytor Instruments) is located in the innovative capital of China, Shenzhen, national high tech enterprise. It devotes itself to the research and development, production, sales and service of dissolution apparatus and solutions, providing users with stable performance and excellent quality dissolution apparatus, dissolution automatic sampling system, and so on. Solutions for on-line UV detection of dissolution sample, dissolution apparatus mechanical verification toolbox, medium preparation instrument and other products. At the same time, it provides users with the overall solution of drug dissolution for users.

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# RT3 往复筒法溶出系统

## Reciprocating Cylinder Dissolution System

精准、稳定的仪器性能，完全满足中国药典、美国药典、欧洲药典对往复筒法溶出测试的要求。

Accurate and stable instrument performance, and fully meet the requirements of ChP, USP and EP for the dissolution test of reciprocating cylinder method.

配备多排溶出杯，可同时使用多种不同pH的溶出介质，模拟人体胃肠道条件。

Equipped with multi row dissolution vessel, it can use a variety of dissolution media with different pH at the same time to simulate the gastrointestinal conditions of human body.

先进的自动化设计，包括自动更换溶出介质和自动取样，使溶出实验更加高效和准确。

Advanced automatic design, including automatic changing of dissolution medium and automatic sampling, making the dissolution experiment more efficient and accurate.

锐拓自主开发的仪器操作系统能够完全符合数据完整性和审计追踪的要求。

The instrument operating system independently developed by Raytor fully meets the requirement of data integrity and audit track.

适用于多种制剂的体外释放度测试，例如：缓释制剂、控释制剂、速释制剂、咀嚼制剂、颗粒制剂等。

It is suitable for in vitro dissolution test of various preparation, such as sustained release preparations, controlled release preparations, immediate release preparations, chewing preparations, granule preparations, etc.

### 型号配置

#### Model Configuration

#### RT3

手动取样 往复筒法溶出仪

Manual Sampling Reciprocating Cylinder  
Dissolution Apparatus

#### RT3-AT

自动取样 往复筒法溶出系统

Automatic Sampling Reciprocating Cylinder  
Dissolution System



# RT3 — 精准 · 稳定 · 高效

Precise Stable Efficient

 Raytor Instruments

## 往复升降电机

### Reciprocating Lifting Motor

可设定往复速率（4~60 DPM）、往复行程（2~10 cm）、浸入时间和沥干时间。

The reciprocating rate (4 ~ 60 DPM), reciprocating stroke (2 ~ 10 cm), immersion time and drain time can be set.

## 自动换排电机

### Automatic Displacement Motor

根据方法设定的时间间隔，自动将往复筒转移到下一排溶出杯中。

According to the time interval set by the method, it will automatically transfer the reciprocating cylinder to the next row of dissolution vessel.

## 自动溶出杯盖

### Automatic Dissolution Vessel Cover

溶出杯盖自动开启和关闭，有效减少溶出介质的蒸发损失。

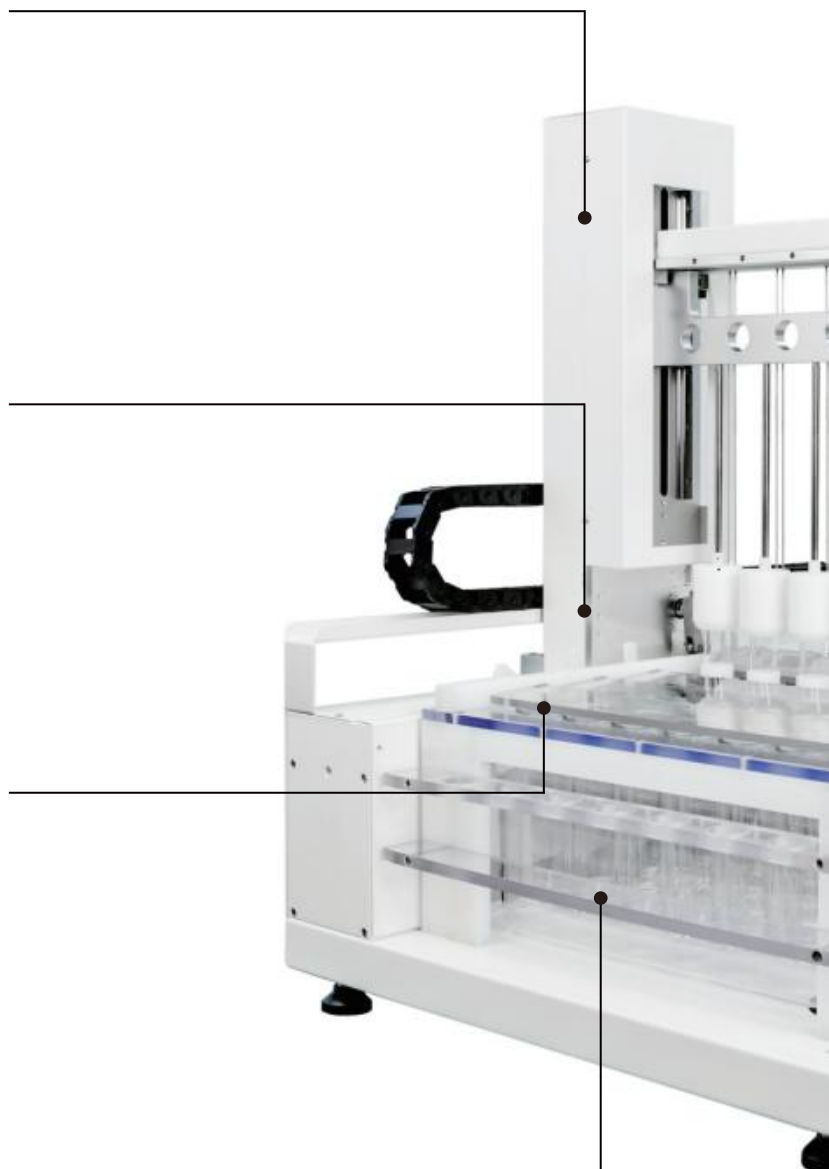
The cover of dissolution vessel can automatically open and close, effectively reduce the evaporation loss of the dissolution medium.

## 往复筒晾放架

### Reciprocating Cylinder Rack

将使用完的往复筒清洗干净并放置在晾放架上晾干、方便下次实验取用。

Clean the used reciprocating cylinders and place them on the rack for drying, which is convenient for the next experiment.





## 自动定位取样针

### Automatic Positioning Sampling Needles

根据方法设定的溶出介质体积，取样针自动定位至杯底与液面的中点。

According to the volume of dissolution medium set by the method, the sampling needles will automatically position to the midpoint from the bottom of the vessel to the liquid level.

## 往复筒安装支架

### Reciprocating Cylinder Mounting Bracket

共轴分体式设计，可快速将往复筒部件更换为其他往复支架部件。

The coaxial split design makes it quickly to replace the reciprocating cylinder with other reciprocating holder.

## 人机交互界面

### User Computer Interface

8.4 寸触控屏，预装锐拓溶出操作系统，符合数据完整性要求。

8.4-inch touch screen, pre installed with the Raytor dissolution operating system, meeting the data integrity requirements.

## 一体式水浴槽

### Integral Moulding Water Bath

一体成型圆角设计，无清洁死角，水浴可被彻底排干。

Integrated moulding and rounded angle design, no cleaning dead angle, water bath can be completely drained.



## RT3-AT 自动取样系统 RT3-AT Automatic Sampling System

锐拓仪器在溶出实验自动取样领域有深厚的积累，专门为往复筒法溶出实验设计自动取样解决方案。RT3-AT 自动取样往复筒法溶出系统，能有效地在每个设定的时间点提供准确而精密的取样，体现高效、准确、稳定、软件易用等优势。

Raytor has a deep study in the field of dissolution automatic sampling and specially designed the automatic sampling solution for the dissolution experiment of reciprocating cylinder method. The RT3-AT automatic sampling reciprocating cylinder dissolution system, which can effectively provide accurate and precise sampling at each time point, reflecting the advantages of high efficiency, accuracy, stability, easy-to-use software.



- 取样前预先润洗取样管路和回路，让样品浓度更加精准。  
Sampling pipe and return pipe are embellish washed before sampling to ensure more accurate sample concentration.
- 取样后，将取样管路、回路、注样针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 sampling, return and injection needle pipe will be purged and emptied, so that the sampling volume is more accurate and there is no sample residue in the pipe.
- 拥有自动回补溶媒和自动清洗管路的功能。  
The functions of automatically repairing the solvent and cleaning the pipeline .

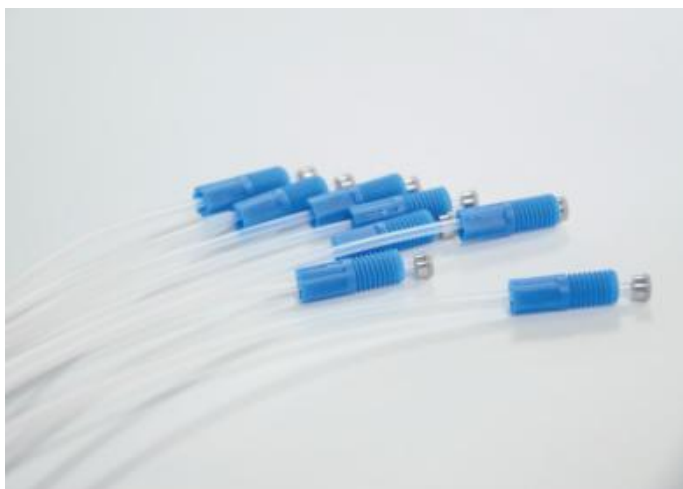


可以在自动取样工作站的注样针前端安装盘状滤头，实现在线过滤的功能。

The disk filters can be installed at the front end of the sample injection needle of the automatic sampling workstation to realize the online filtering function.

在方法设定界面中，设定需要舍去初滤液的体积，达到预先润洗饱和滤膜的目的。

In the method setting interface, set the volume of the initial filtrate to be discarded to achieve the purpose of pre wetting and saturating the filters.



采用高化学稳定性、高抗吸附的Teflon管路。有效避免取样管路发生腐蚀或吸附样品。

The Teflon sampling pipe with high chemical stability and high anti-adsorption was used to avoid corrosion and sample adsorption.

RT3提供灵活的取样方案。即使没有配备自动取样工作站，用户也可以通过溶出仪主机上的取样孔进行手动取样。

RT3 provides flexible sampling scheme. Even if there is no automatic sampling workstation, the user can perform the manually sampling through the sampling hole on the dissolution apparatus.



## 溶出仪软件系统 Dissolution Apparatus Software System

锐拓自主开发的溶出仪软件系统功能强大、界面简练、操作方便、容易上手。软件系统完全符合美国21 CFR PART 11, 中国GMP, 欧盟GMP等法规的要求。

The dissolution software system developed by Raytor is powerful, interface succinct, convenient and easy to operate. The software system fully complies with the requirements of 21 CFR Part 11 of the United States, GMP of China, GMP of the European Union and other regulations.

### 用户权限管理

#### User Permissions Control

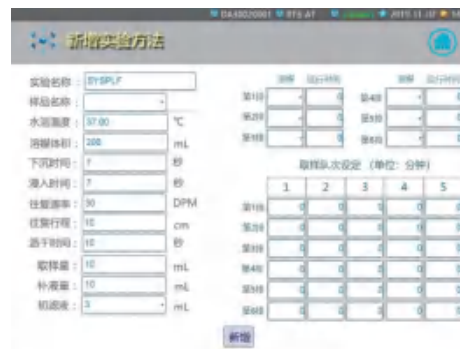
- 可分配至少3种权限等级：系统管理员、主管、操作员。  
At least 3 kinds of permission level can be allocated, including: system administrator, supervisor, general operator.
- 可由客户根据自身风险评估，自定义每种权限等级的细则。  
Customers can customize the permission rules of each permission level according to their own risk assessment.
- 可预设至少100个登录账号、密码，操作权限分级管控。  
At least 100 login accounts and passwords can be set up, and the operation permission can be controlled by different levels.



### 方法建立和调用

#### Method Preset and Invokes

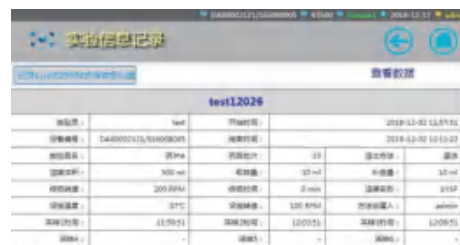
- 可以建立和保存至少200条溶出实验方法。  
It can preset and store at least 200 dissolution test method.
- 溶出方法和UV/Vis检测方法同步设定。  
Dissolution method and UV/Vis detection method are set synchronously.



### 审计追踪

#### Audit trail

- 各个层面追溯到具体账号的审计追踪，包括登录记录、实验记录、操作记录、清洗记录等。  
All levels of audit tracking, including: login records, experimental records, operating records, cleaning records, etc.
- 审计追踪记录可以被检索、导出和打印。  
Audit track records can be retrieved, exported and printed.





## 电子数据完整性

### Electronic Data Integrity

- 实验期间能够实时显示转速、温度等参数，并能够同步生成准确、一致的电子数据。  
During the experiment, the parameters such as rotational speed and temperature can be real-time display, accurate and consistent electronic data can be generated synchronously.
- 实时显示UV/Vis检测 results 和溶出曲线（选配在线UV/Vis检测时）。  
Real-time display of the UV/Vis detection results and dissolution curve.
- 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.
- 系统存储容量可满足至少10年的记录存储。  
The system storage capacity can meet at least 10 years of record storage.
- 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.



## 技术支持服务

### 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.



## RT3系列溶出仪配件 Accessory for RT3 Series Dissolution Apparatus

### 溶出杯

#### Dissolution Vessel

尺寸符合药典要求的300mL精品玻璃溶出杯。适用于标准往复筒法溶出仪。

300ml high quality glass vessel with dimensions meet pharmacopoeia requirement. It is applicable to the standard reciprocating cylinder dissolution apparatus.



### 往复筒

#### Reciprocating Cylinder

尺寸符合药典要求的玻璃往复筒（内管长100mm）。适用于标准往复筒法溶出仪。

Glass reciprocating cylinder (the length of inner tube: 100mm) with dimensions meet pharmacopoeia requirement. It is applicable to the standard reciprocating cylinder dissolution apparatus.



### 往复筒上下盖配件

#### Upper and Lower Cover Accessory of Reciprocating Cylinder

尺寸符合药典要求。

The dimensions meet pharmacopoeia requirement.

上盖、下盖材质：特氟龙。

Material of upper cover and lower cover: Teflon.

杆轴材质：316L不锈钢。

Shaft material: 316L stainless steel.



### 筛网

#### Mesh Screen

可选各种孔径规格的筛网，适用于标准往复筒法溶出装置。

All kinds of mesh specification can be selected, which is suitable for the standard reciprocating cylinder dissolution device.



### 防蒸发杯盖

#### Evaporation Cap

尺寸符合药典要求防蒸发杯盖，适用于标准往复筒法溶出仪。

Evaporation cap with dimensions meet pharmacopoeia requirement. It is applicable to the standard reciprocating cylinder dissolution apparatus.



RT3系列往复筒法溶出仪技术参数 Technical Parameters of RT3 Series Reciprocating Cylinder Dissolution Apparatus		
指标 Metrics		技术参数 Technical Parameter
溶出仪水平度 Dissolution Apparatus Level		$\leq 0.3^{\circ}$
杆轴垂直度 Shaft Verticality		$\leq 90.0^{\circ} \pm 0.5^{\circ}$
最长运行时间 Maximum Running Time		600 小时 (Hour)
溶出杯排数 Dissolution Vessel Row Number		300ml 标准溶出杯: 7管 × 6排 300ml Standard Vessel: 7 tubes × 6 Rows 1000ml 溶出杯: 3管 × 3排 1000ml Vessel: 3 tubes × 3 Rows
温度参数 Temperature Parameters	控温范围 Temperature Control Range	室温~50°C Room Temperature ~50°C
	测温分辨率 Thermometric Resolution	0.01°C
	温度测量误差 Thermometric Error	$\leq \pm 0.2^{\circ}\text{C}$
	溶出杯间温度差异 Temperature Difference between Vessels	$< \pm 0.5^{\circ}\text{C}$
往复行程 Reciprocating Stroke	可调范围 Adjustable Range	20 ~ 100 mm
	误差 Error	$< \pm 1 \text{ mm}$
往复速率 Reciprocating Rate	可调范围 Adjustable Range	4 ~ 60 DPM (次/分钟)
	误差 Error	$< \pm 5\%$
自动取样工作站技术参数 Technical Parameters of Automatic Sampling Workstation		
指标 Metrics		技术参数 Technical Parameter
取样动力泵 Sampling Pump		高精度紧密注射泵 High Precision Compact Injection Pump
最大可设定取样次数 Maximum Settable Sampling Number		30次 (Times)
取样体积 Maximum Sampling Volume		1 ~ 10 mL
取样精度 Sampling Precision		$\leq \pm 1\%$
样品收集器 Sample Collector		样品收集数量: 7个样品 × 15排 Sample Collection Quantity: 7 Samples × 15 Rows 可适配10ml试管或HPLC小瓶 Suitable for 10ml Test Tube or HPLC Vial



[www.raytor.cn](http://www.raytor.cn)

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