



RT3产品手册

RT3 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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目录

公司介绍 02

Company Introduction

完善的产品线 04

Perfect Product Line

产品设计理念 06

Product Design Concept

锐拓溶出软件系统 08

Raytor Dissolution Software System

RT3 往复筒法溶出系统 14

RT3 Reciprocating Cylinder Dissolution System

RT3 往复筒法溶出仪 16

RT3 Reciprocating Cylinder Dissolution Apparatus

RT3-AT 自动取样往复筒法溶出系统 18

RT3-AT Automatic Sampling Reciprocating Cylinder Dissolution System

售后服务与技术支持 22

After Sales Service & Technical Support



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.

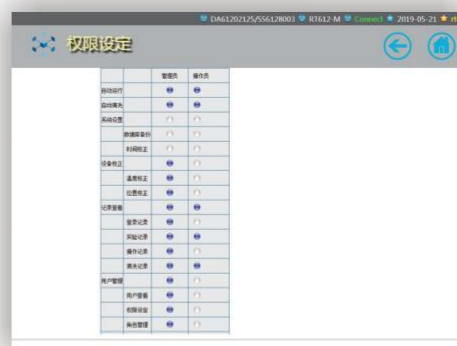
审计追踪 Audit trail

- 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

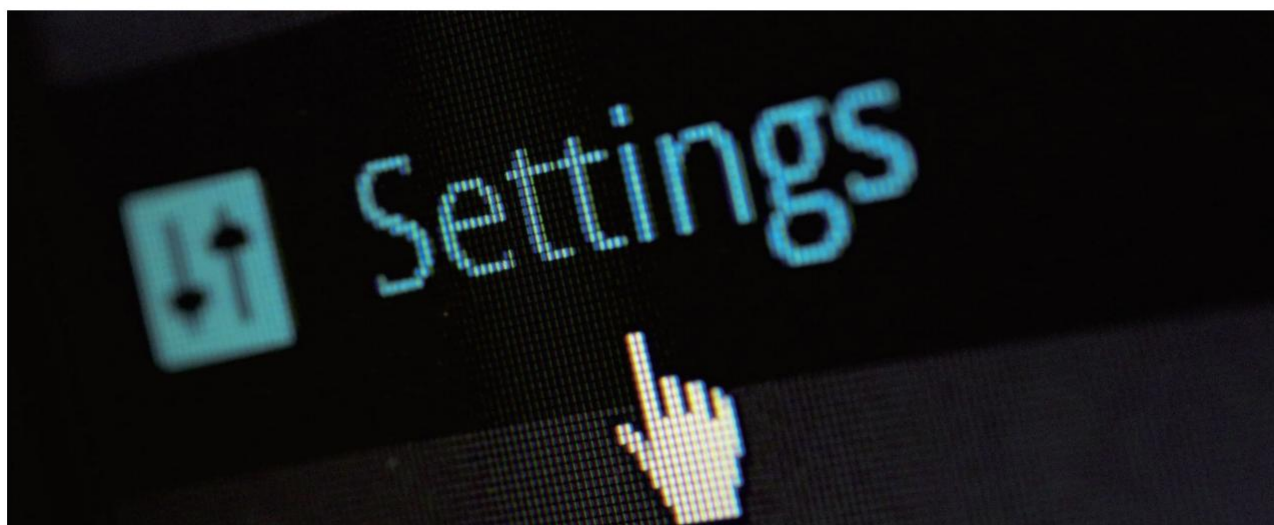


实验记录

实验时间从: 到: 点选

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



- 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。

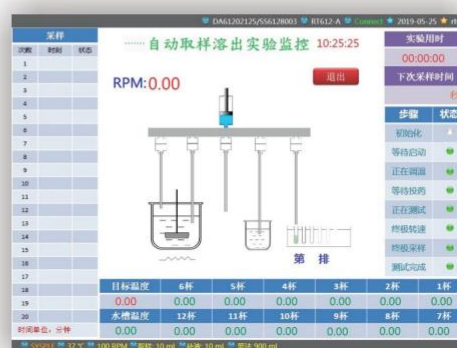
Electronic data can be retrieved, exported, backed up and printed.

- 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.



锐拓溶出软件系统

Raytor Dissolution Software System

计算机化系统技术支持服务

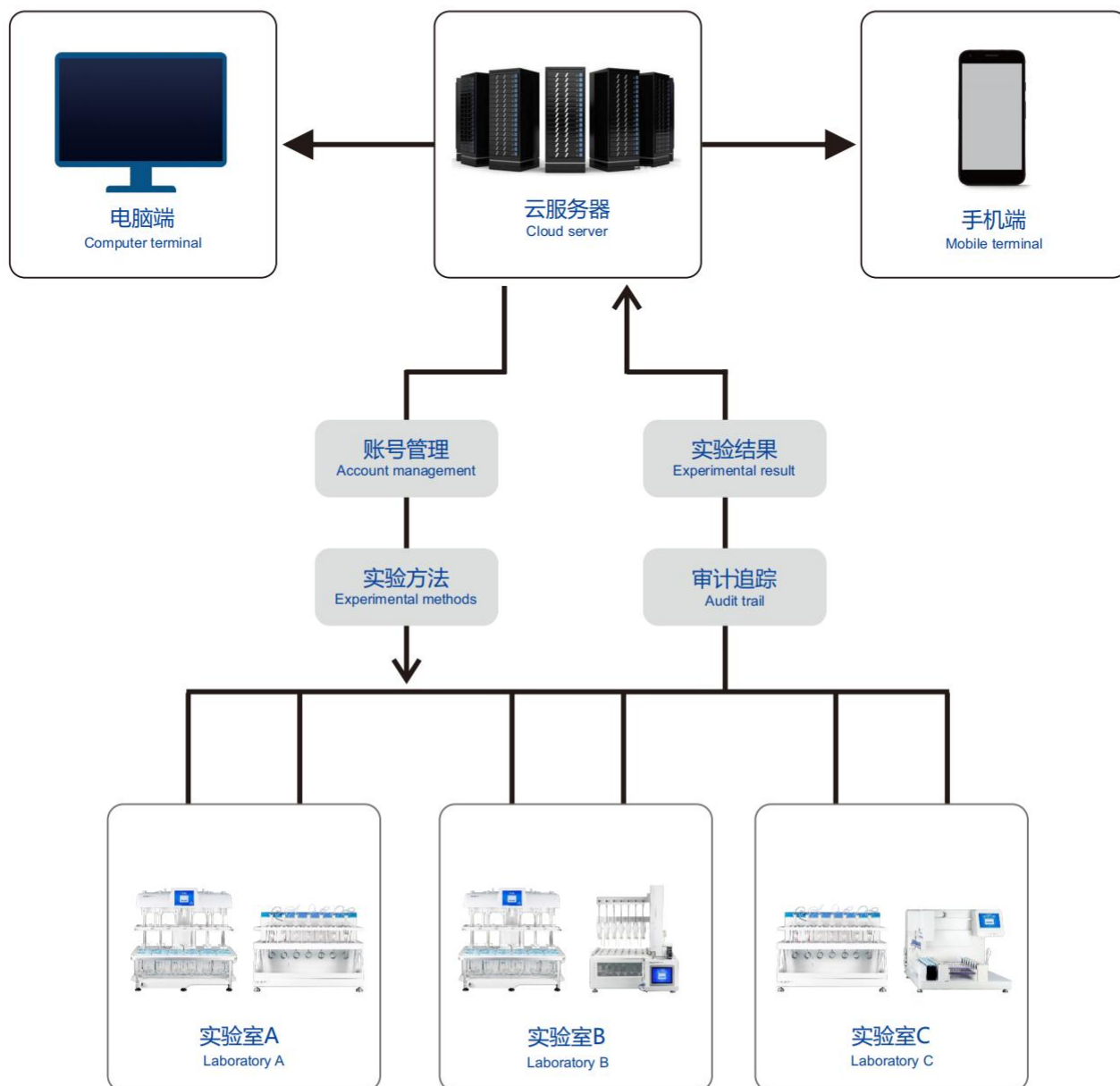
Computerized System Technical Support Services

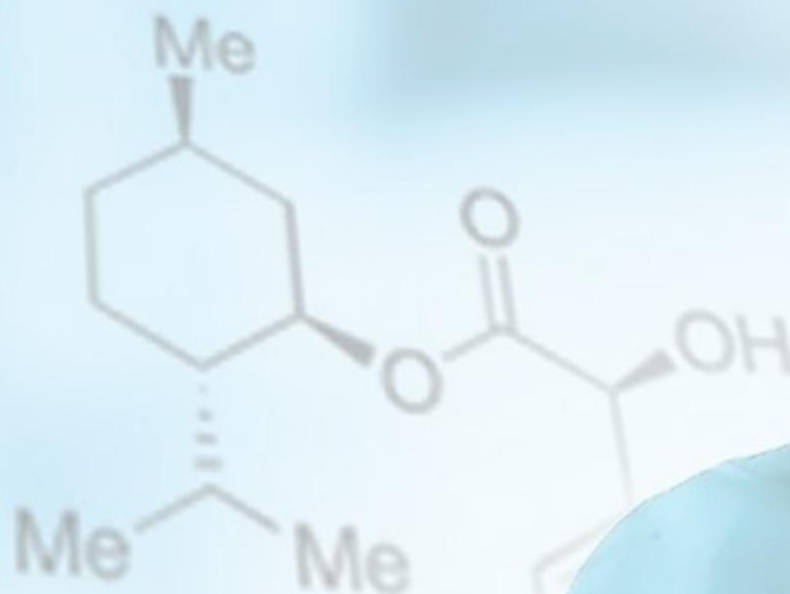
- 溶出仪计算机化系统验证服务。
Validation service of dissolution apparatus computerized system.
- 电子数据云系统服务器架设服务。
Electronic data cloud system server setup service.
- 操作系统可以进行升级和根据用户需求进行定制。
The operating system can be upgraded and customized according to user requirements.



锐拓电子数据云系统

Raytor Electronic Data Cloud System





RT3 往复筒法溶出系统

Reciprocating Cylinder Dissolution System

型号配置 Model Configuration



RT3 手动取样往复筒法溶出仪
RT3 Manual Sampling Reciprocating Cylinder
Dissolution Apparatus



RT3-AT 自动取样往复筒法溶出系统
RT3-AT Automatic Sampling 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.

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.

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.

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。

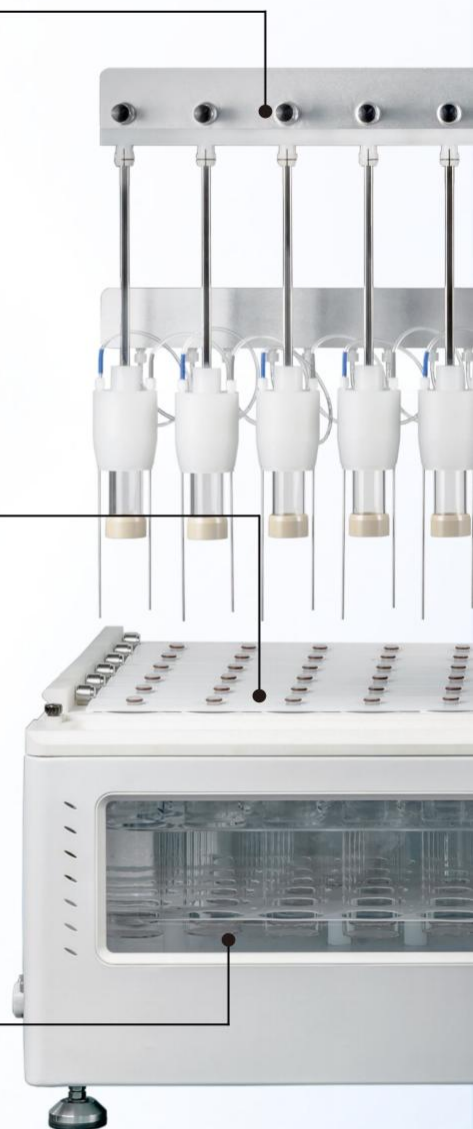
The cover of dissolution vessel can automatically open and close, effectively reduce the evaporation loss of the dissolution medium.

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.





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.

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.

RT3-AT 自动取样往复筒法溶出系统

RT3-AT Automatic Sampling Reciprocating Cylinder Dissolution 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。

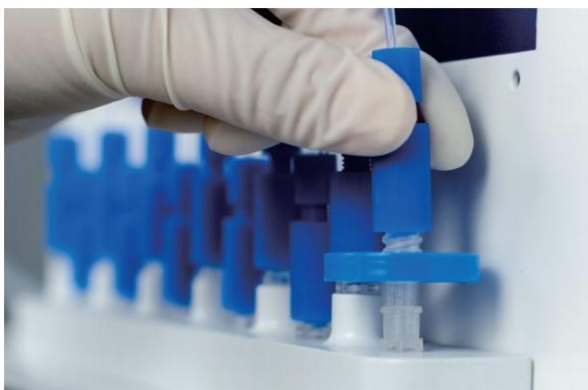
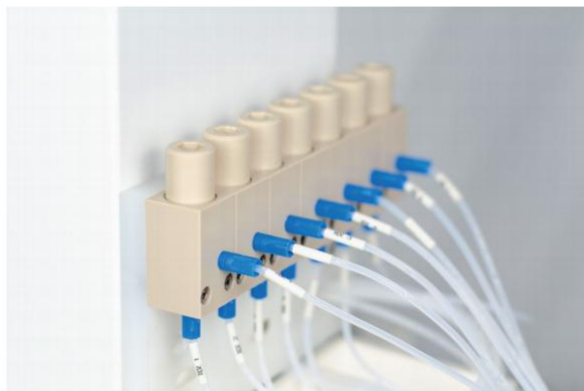
Raytor has a deep study in the field of dissolution automatic sampling and specially designed the automatic sampling solution for the dissolution experiment of reciprocating cylinder method. The RT3-AT automatic sampling reciprocating cylinder dissolution system, which can effectively provide accurate 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.

配备泵前过滤装置，可以安装各种规格的柱状滤芯，在自动取样过程中，滤去没有完全溶解的药物大颗粒，预防取样管路和阀门堵塞。

Equipped with a filter device in front of the pump, various specifications of cylindrical filter elements can be installed. In the process of automatic sampling, large particles of drugs that are not completely dissolved can be filtered out to prevent blockage of sampling pipe and valve.



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 .

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系列溶出仪配件 RT3 Series Dissolution Accessories

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

尺寸符合药典要求的防蒸发杯盖，可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.



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 μ m、30 μ m、50 μ m。

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



售后服务与技术支持

After Sales Service & Technical Support

验证与确认

Validation and Qualification

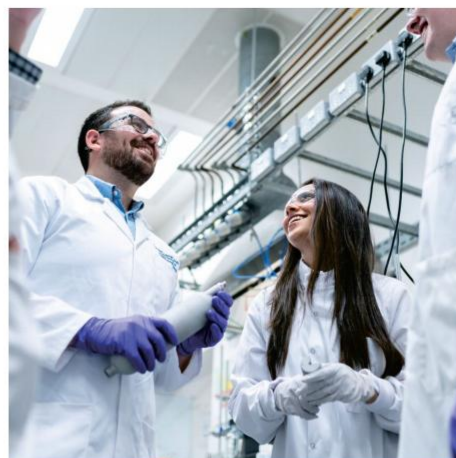
锐拓仪器能够为您的全系列溶出系统提供全面且专业的验证与确认服务。所有验证与确认服务都会附有符合法规要求的完整专业的文件报告。

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

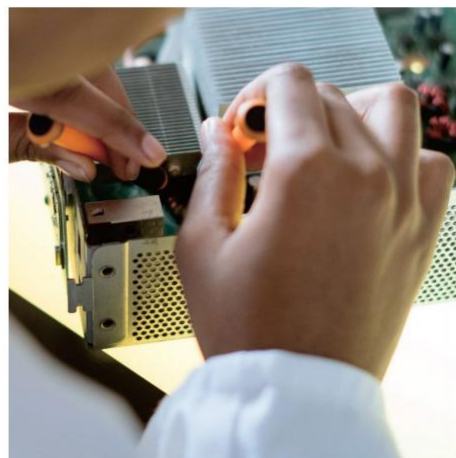


维修和预防性维护

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.

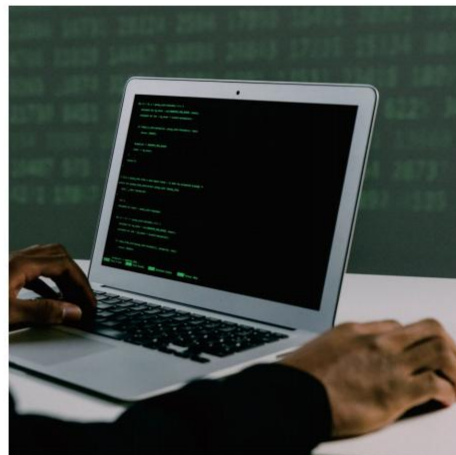


架设电子数据云系统服务器

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。

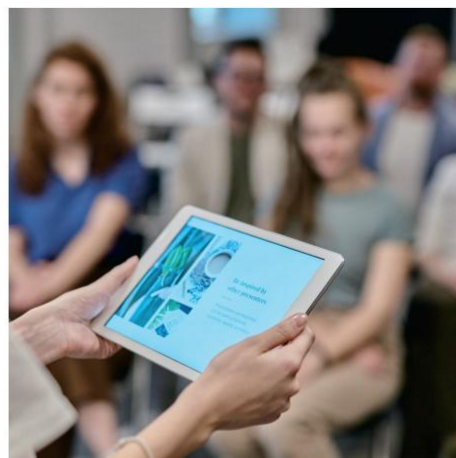
The electronic data cloud system server is to connect all dissolution systems in multiple laboratories to realize the unified management and automatic backup of electronic data such as records, users and methods of all dissolution systems.



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.



本文中的信息、说明和技术参数如有变更，恕不另行通知。

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

