

## 冷冻干燥设备和自动进出系统方案 为生物和制药工业提供专业解决方案

## Freeze dryer and Auto loading system Reliable, innovative solution for Pharma and Bio industry



## LY®MAC®

# 上海凛马机械科技有限公司

地址: 浙江省嘉兴市秀洲区康和路500号B19厂房

座机:0573-82335102 传真:0573-82335103 邮件: sales@lyomac.com 网站: www.lyomac.com

## LYOMAC TECHNOLOGY LTD

Office Add: No.588, Caonong Road, Shanghai-201612,

Factory Add: B19 Plant, No.500 Kanghe Road, Jiaxing,

Zhejiang 314000 CHINA Ph:0086-573-82335102 Fax:0086-573-82335103 Mail: sales@lyomac.com

Web: www.lyomac.com



凛马真空冷冻干燥机 SALES@LYOMAC.COM

## 公司简介

浙江凛马制药设备有限公司是专业致力于为生物制药,营养品等行业提供高品质冷冻干燥设备和技术服务的厂家。

公司从 2009 年成立以来,已经为超过十五个国家的生物制药,营养品公司提供了满足FDA和GMP的项目,共计超过200多个项目。同时公司建立了完善的海内外售后服务团队。公司拥有专业的设计,生产和制造队伍,配备了先进的加工,验证和检测设备,并且能提供满足不同国家的法律和规范,包括UL,CE, CSA, ASME等安全法规。

凛马拥有国内最具经验和专业度的团队,秉承"为生物和医药工业提供最专业冻干解决方案的理念。公司持续将研发和满足法规相结合开发最新产品,专利数量逐年增加,同时开发了西林瓶和托盘原料的自动进出料系统。为制药工业的无人化,无菌控制提供了满足不同的客户的技术方案,被评委浙江省科技型企业。



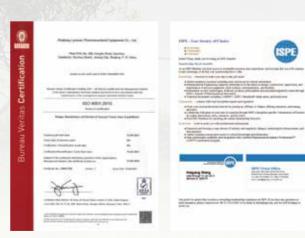
## Company profile

LYOMAC was founded in 2009, as a leading supplier to provide state of art, innovative and reliable freeze-drying equipment for biological, pharmaceutical and nutraceutical industry.

During the past decade, Lyomac has built freeze drying system in more than 15countries with projects more than 200 sets. Most of them compliance with cGMPGAMP5 and FDA. And Lyomac manage all service and technical support for all end users.

Lyomac has advanced quality control instrument and facilities to fabric freeze dryer and automation systems. Which is a base to provide high reliable and precision freeze drying solution. Lyomac able to provide various quality and certificate for different nation's regulatory, Including UL, CE, ASME, CSA etc.

The most value for Lvomac is we have most experence and professional team. with commitment of Best freeze drying solution for bio and pharma industry, We are constantly develop innovative technology for customized demand freeze dryer solution.







### 产品范围 Production Scope

Freeze dryer 冷冻干燥设备

凛马公司为制药,生物,诊断试剂以及营养品行业提供完整的 冻干解决方案,特别是在西林瓶制剂的产品冻干。

凛马的特点在于工程项目均能满足 GMP 和 GAMP5 法规的文件,安装服务和配件供应。

我们的产品包含了标准和定制的冻干设备,自动装料系统。

Lyomac supplies freeze drying equipment to the pharmaceutical, biotechnology, diagnostic and nutrient markets. A particular product strength is supplying large custom lyophilization systems for the production of parenteral and veterinary pharmaceuticals. Lyomac provides complete project support from design specifications through engineering, fabrication, GMP and GAMP 5 documentation packages, installation, service, and parts. Lyomac product line of lyophilization process equipment includes a broad range of standard and custom freeze dryers, autoloading systems



Vacuum Chamber 真空干燥箱



Ice Condenser 冷凝器 / 冷阱



▶ Refrigeration system 制冷系统



Vacuum system 真空系统



Pneumatic and Hydraulic 气动和液压系统



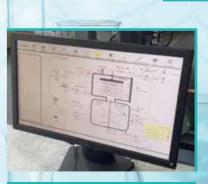
Auto loading system 自动进出料系统



Steam SIP system 蒸汽灭菌系统



▶ Electrical control cabinet 电控柜



SCADA control system SCADA 控制系统

### ▶ Laboratory freeze dryer 实验型冷冻干燥机



实验冻干机主要是为了生物,药品原料,营养品等冻干产品的工艺研发,小试生产,最大产量达到12:L的干燥量,可以根据客户需求设计不同的制冷温度需求,其特点是:

- ◆无配套要求,只需要配电即可
- ◆外配电脑控制scada系统,数据采集可靠
- ◆使用低噪音设计,便于办公室使用
- ◆面板不锈钢设计, 无菌室可用
- ◆可配置压塞,共晶点测试,清洗和灭菌系统

Laboratory freeze dryer is developed for biotech, pharmaceutical and other industry R&D. Drying capacity up to 12 Liters, more customized design according to user's requirement, with features of:

- ◆Less utility, just need electrical plug in to use
- ◆Build with computer SCADA system, precise data report will be record
- ◆Low noise running, easy use at office
- ◆Optional to build with stainless steel panle, sterile room allowed to install.
- ◆Optional to be with stoppering, eutectic detector, CIP and SIP system

Model 型무	LYOPRO-0.2	LYOPRO-0.4	LYOPRO-0.6
Drying capacity( Liter) 干燥量	4	8	12
Shelf area( ㎡) 板层面积	0.24	0.40	0.60
Shelf size(L*W*H)(mm) 板层尺寸	400*300*13	450*300*13	500*300 *13
Usable shelf No 板层数量	2	3	4
Vial loading quantity 西林瓶装量 φ 16 φ 22	980 500	1660 875	2460 1300
Inter-Shelf distance (mm)板层间距	75	75	75
Shelf ultimate cooling temperature(℃) 板层极限温度	-40/-55	-40/-55	-40/-55
Condenser ultimate cooling temperature(℃) 冷凝器极限温度	-50/-75	-50/-75	-70/-75
Ultimate vacuum(Pa) 极限真空	€2	<b>≤</b> 2	<b>≤</b> 2
Installation dimension(L*W*H)(mm) 安装尺寸	1200*800*1900	1400*900*1900	1500*1200*1900
Weight(Kg) 重量	300	500	800
Power(KW) 电功率	4.0	5.0	8.0





本系列冻干机主要是为了满足中试生产的需求,最大干燥量可以达到150L,可以满足大多数注射西林瓶,原料类产品的冻干。符合cGMP和FDA法规,并且配备不同可选装置,主要特点导。

- ◆整体设计,安装和使用都方便
- ◆全自动负压压塞
- ◆全自动冻干,灭菌和清洗
- ◆无人化电脑操作,存储工艺可达千条以上,符合GAMP法规
- ◆隔板平整度小于1mm,温差小于1℃
- ◆布局可按照客户要求实现整体或者分体设计,采用环保制冷剂,整机满足环保要求,节 省按装空间

The pilot model freeze dryer with drying capacity up to 150 Liters, cover most demand for vial or other material commercial production, compliance with cGMP and FDA. More optional systems available, main features are:

- ◆Integrated design, compact and easy install
- ◆ Automatic shelf stoppering under vacuum
- ◆ Automatic control for freeze drying, SIP and CIP
- ◆Scada control system compliance with GAMP regulation and save up to thousand recipes
- ◆Shelf flatness less than 1.0mm, temperature uniformity less than 1 °C
- ◆Environment friendly refrigerant
- ◆Flexible arrangement design, suit user's plant layout, thus space saved

Model 型 <del>号</del>	LYOPRO-1.0	LYOPRO-2.0	LYOPRO-3.0	LYOPRO-5.0	LYOPRO-7.5
Drying capacity(Liter) 干燥量	20	40	60	100	150
Shelf area( ㎡) 板层面积	1.08	2.16	3.24	5.40	7.56
Shelf size(L*W*H)(mm) 板层尺寸	600*450*20	900*600*20	900*600*20	1200*900*20	1200*900*20
Usable shelf No 板层数量	4	4	6	5	7
Vial loading quantity 西林瓶装量	4400 2200	9000 4500	14000 7500	20000 10000	32000 16000
Inter-Shelf distance (mm)板层间距	90	90	90	90	90
Shelf ultimate cooling temperature(℃) 板层极限温度	<b>-</b> 55	<b>–</b> 55	<b>–</b> 55	<b>-</b> 55	<b>–</b> 55
Condenser ultimate cooling temperature(℃) 冷凝器极限温度	<b>-</b> 75	<b>–</b> 75	<b>–</b> 75	<b>-</b> 75	<b>–</b> 75
Ultimate vacuum(Pa) 极限真空	≤1.0	≤1.0	≤1.0	≤1.0	≤1.0
Installation dimension(L*W*H)(mm) 安装尺寸	3000*1400*2200	3200*1500*2200	4000*1500*2200	4500*1750* 2200	5000*1750* 2400
Weight(Kg) 重量	2000	3500	4500	7500	8500
Power(KW) 电功率	18	22.0	28.0	40.0	52

### Industrial freeze dryer 生产冻干机





本系列冻干机主要是为了满足批量生产的需求,最大干燥量可以达到1,000L,可以满足大多数注射西林瓶,原料类产品的冻干。符合cGMP和FDA法规,并且配备不同可选装置,主要特点是:

- ◆全自动负压压塞
- ◆全自动冻干,灭菌和清洗
- ◆无人化电脑操作,存储工艺可达千条以上,符合GAMP法规
- ◆隔板平整度小于1mm,温差小于1度
- ◆配备节能控制功能
- ◆设备制冷工质符合环保要求
- ◆布局可按照客户要求实现整体或者分体设计,节省安装空间

The industrial model freeze dryer with drying capacity up to 1,000 Liters, cover most demand for vial or other material commercial production, compliance with cGMP and FDA. More optional systems available, main features are:

- ◆ Automatic shelf stoppering under vacuum
- ◆ Automactic control for freeze drying, SIP and CIP
- ◆Scada control system compliance with GAMP regulation and save up to thousand recipes
- ◆Shelf flatness less than 1.0mm, temperature uniformity less than 1.90
- ◆Energy saving control system by control compressor and vacuum pump
- ◆Environment friendly refrigerant
- ◆Flexible arrangement design, suit user's plant layout,thus space saved

Model 型묵	LYOPRO-10.0	LYOPRO-13.0	LYOPRO-16.0	LYOPRO-20.0	LYOPRO-25.0	LYOPRO-30.0	LYOPRO-40.0	LYOPRO-50.0
Ice capacity(Kg)捕冰量	200	260	320	400	500	600	800	1000
Shelf area( ㎡) 板层面积	9.72	12.96	15.84	19.80	24.75	30.00	42.00	49.50
Shelf size(L*W)(mm) 板层尺寸	1200*900	1200*1200	1200*1200	1500*1200	1500*1500	2000*1500	2000*1500	2200*1500
Useable Shelf No 板层数量	9	9	11	11	11	10	14	15
Vial loading quantity 西林瓶数量 φ 16 φ 22	40000 20000	56000 28000	68000 34000	80000 40000	100000 50000	120000 60000	175000 85000	200000 100000
Inter. Shelf distance 板层间距(mm)	100	100	100	100	100	100	90	90
Shelf ultimate cooling temperature(℃)板层极限温度	<b>-</b> 55	<b>-</b> 55	<b>–</b> 55	<b>-</b> 55				
Condenser ultimate cooling temperature(℃) 冷凝器极限温度	<b>–</b> 75	<b>–</b> 75	<b>-</b> 75	<b>–</b> 75	<b>–</b> 75	<b>–</b> 75	<b>–</b> 75	<b>–</b> 75
Ultimate vacuum(Pa) 极限真空	≤1.0	≤1.0	≤1.0	≤1.0	≤1.0	≤1.0	≤1.0	≤1.0
Installation dimension(L*W*H)(mm) 安装尺寸	6000*1750*3800	6800*2000*3800	6800*2000*4200	7500*2000*4200	7200*3000*4200	7600*3000*4200	7600*3200*4500	9600*2300*4700
Weight(Kg) 重量	10000	12500	15000	17500	20000	25000	30000	35000
Power(KW) 电功率	63.0	77.5	91.5	120.0	135.0	147.0	179.0	215.0

▶ Freee dryer Auto loader 冻干机自动进出料系统

凛马公司为大型冻干生产工艺提供不同的产品自动进出冻干机的解决方案(ALAUS),全部按照制药工业的规范GMP, FDA进行设计.主要针对西林瓶和原料药的冻干同时运行稳定,自动化程度高。全自动伺服高精度控制,主要的方案有:

#### 全自动固定式西林瓶进出系统:

#### 固定式托盘进出系统:

- 该方式自动对接灌装线或者灌装泵到冻干机小门,出料后自动传送到轧盖机或者包装机(针对原料药)。托盘按排进出冻干机 无需更换件,西林瓶规格较多的用途更合适
- 适合无菌原料药的方案
- 可以配备无菌隔离器或者层流系统,无菌和防护等级高全自动控制无需人工干预

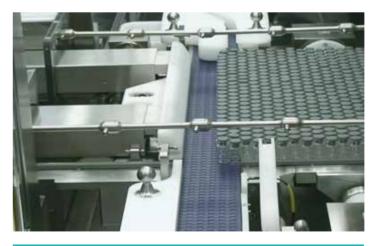
- No change parts required, suitable for different vial size application







输送带和冻干机对接桥



Push&Pull mechanism 西林瓶进出机构



Rabs/isolator 屏障 / 隔离系统



凛马制药设备

▶ Optional systems on freeze dryer 冻干机可选系统方案



▶ External CIP water tank 外置清洗水罐

凛马公司为不同用户提供不同需求的可选配置,应用于西林瓶或者托盘原料的生产工艺,满足GMP法规和实现高效稳定的自动化生产需求。

Lyomac provide more optional system to meet different application, by vial or API process

Not just by meet GMP regulation, we als considering reliability and fully automation i long term running



SIP system 在位灭菌系统



Hydraulic stoppering system 隔板液压压塞升降装置



Oil Free vacuum pump system 无油干式真空泵



Screw compressor 螺杆机组



▶ Sub door (Pizza door) system 小门机构



▶ Trolly and tray 小车和托盘



# 为什么选择凛马? Why with Lyomac?

- ◆理解GMP理念并融合进整个生产全流程
- ◆Understand GMP conception and forged into whole production process
- ◆我们拥有设计,生产,服务和验证的专业团队
- ◆ Professional team with design, production, validation and service
- ◆拥有完善的现代化的生产条件及验证设备
- ◆ Advanced, state of art production and validation facility
- ◆满足个性化URS需求,并且快速响应交货
- ◆ Dedicated to providings solution for various requirement, and with short delivery time
- ◆周到的服务,直到产品验证和培训结束,并且终身服务
- ◆Complete service package, from installation, validation and training. Life time support
- ◆在全球15个以上国家安装设备,项目管理团队经验丰富
- ◆ Experience accumulated at more than 15 countries, well organized project management











Working flow chart 工作流程图 Confirm specification 客户信息 交流和确认所有技术参数 技术需求 Before start 项目交流 onceptiona Layout design, Functional specification design 设备布局,工厂技术描述 概念设计 roiect start Mechanical, electrical, Software's production design, procurement and 机械,电器和软件设计,采购和安装 开始生产组装 16~24 week 16-24周 Internal test Based on IQ,OQ,PQ,DQ,SQ 内部测试 建立IQ,OQ,PQ,DQ,SQ等文件体系 Client on factory for test and inspection FAT 1~6 Weeks Packing for delivery 工厂验收 1-6周 客户现场检查验收后安排包装 By air, land or sea, with different packing standard 1 week Delivery 针对海运, 陆运或者空运, 采取不同的包装 包装发货 client site installation, training, validation, trial production SAT 1 week 客户现场安装,培训,验证和试生产 现场验收 Preventive/Emergency maintenance, spare parts 1 year Varranty servi supply, remote service 质保期服务 预维护,紧急服务,配件供应,远程协助等