

特点与优势 Features and Benefits

- ▶ 一次粉碎即可以获得良好的粒径分布
- ▶ 丰富的配置，可粉碎粘性 / 高硬度物料
- ▶ 高的粉碎效率和极低的产品损耗
- ▶ 可实现从研发到生产规模的精确重现
- ▶ 生产型设备完全通过 PLC 控制全自动运行
- ▶ 中试单元和生产系统可实现 WIP/CIP/SIP
- ▶ 满足高活性药物高密闭粉碎要求
- ▶ 满足无菌药物无菌粉碎生产要求
- ▶ 在危险区域符合 ATEX 指令（可完全满足 1/21 区）

- ▶ Once procession can obtaining the fine particle size distribution
- ▶ Rich configuration can handle sticky, abrasive or high hardness materials
- ▶ Highly grinding efficiency and extremely low production loss
- ▶ Accurate reproduction from R&D to mass production.
- ▶ Micronization system fully automated by PLC
- ▶ WIP, CIP and SIP systems for pilot unit and scale production
- ▶ Micronization system provide high containment of HPAPIs with operator protection
- ▶ Micronization system provide full containment of sterile APIs with product protection
- ▶ Hazardous area versions available in compliance with ATEX directive (zone 1/21)



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技术参数

TECHNICAL PARAMETERS



实验型 R&D Jet Mills



中试型 Pilot Plant Jet Mills

	Micron JETMILL Lab	Micron JETMILL Pilot
粉碎腔直径 Mill nominal diameter	1 inches (25mm)	2 inches(50mm)
预估处理量 Estimated capacity	0.5~20 g	2~500 g
批次量 Batch size	0.5~20 g	2~500 g
工作压力 Process gas pressure	0~12bar	0~12bar
工艺气体耗量 Process gas consumption	0.12 Nm ³ /Min@7bar	0.28Nm ³ /Min@7bar
工艺气体耗量 Process gas consumption	0.22Nm ³ /Min@12bar	0.45Nm ³ /Min@12bar
设备功率 Installed power	0.06Kw	0.12Kw
尺寸 Dimensions	455mm×340mm×715mm	750mm×530mm×1100mm

	Micron JETMILL 4	Micron JETMILL 6
粉碎腔直径 Mill nominal diameter	4 inches (100mm)	6 inches(150mm)
预估处理量 Estimated capacity	100g~1 kg/hr	1~7 kg/hr
批次量 Batch size	50 g~3 kg	1 kg ~ 50 kg
工作压力 Process gas pressure	0~10bar	0~10bar
工艺气体耗量 Process gas consumption	0.76 Nm ³ /Min@7bar	1.8Nm ³ /Min@7bar
工艺气体耗量 Process gas consumption	1.21 Nm ³ /Min@10bar	2.7 Nm ³ /Min@10bar
设备功率 Installed power	1.1Kw	2.5Kw
尺寸 Dimensions	1220mm×785mm×18000mm	3150mm×1150mm×2250mm

技术参数

TECHNICAL PARAMETERS



大规模生产型 Mass Production Micronization System



	Micron JETMILL 8	Micron JETMILL 12	Micron JETMILL 16	Micron JETMILL 20
粉碎腔直径 Mill nominal diameter	8 inches (200mm)	12 inches(300mm)	16 inches (400mm)	20 inches(500mm)
预估处理量 Estimated capacity	5~20 kg/hr	5~40 kg/hr	10~80 kg/hr	20~160 kg/hr
批次量 Batch size	5 kg~300 kg	10 kg~1000 kg	20 kg~3000 kg	50 kg~5000 kg
工作压力 Process gas pressure	0~10 bar	0~10 bar	0~10 bar	0~10 bar
工艺气体耗量 Process gas consumption	2.1 Nm³/Min@7bar	5.4 Nm³/Min@7bar	15 Nm³/Min@7bar	19 Nm³/Min@7bar
工艺气体耗量 Process gas consumption	3.5 Nm³/Min@10bar	8.6 Nm³/Min@10bar	26 Nm³/Min@10bar	30 Nm³/Min@10bar
设备功率 Installed power	2.5 Kw	4.0 Kw	6.0 Kw	8.0 Kw

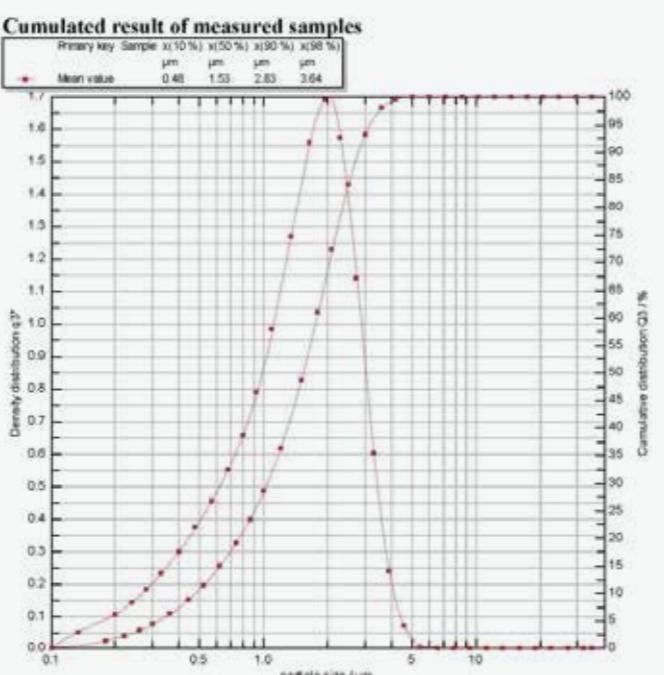
应用与原理

APPLICATION AND PRINCIPLE

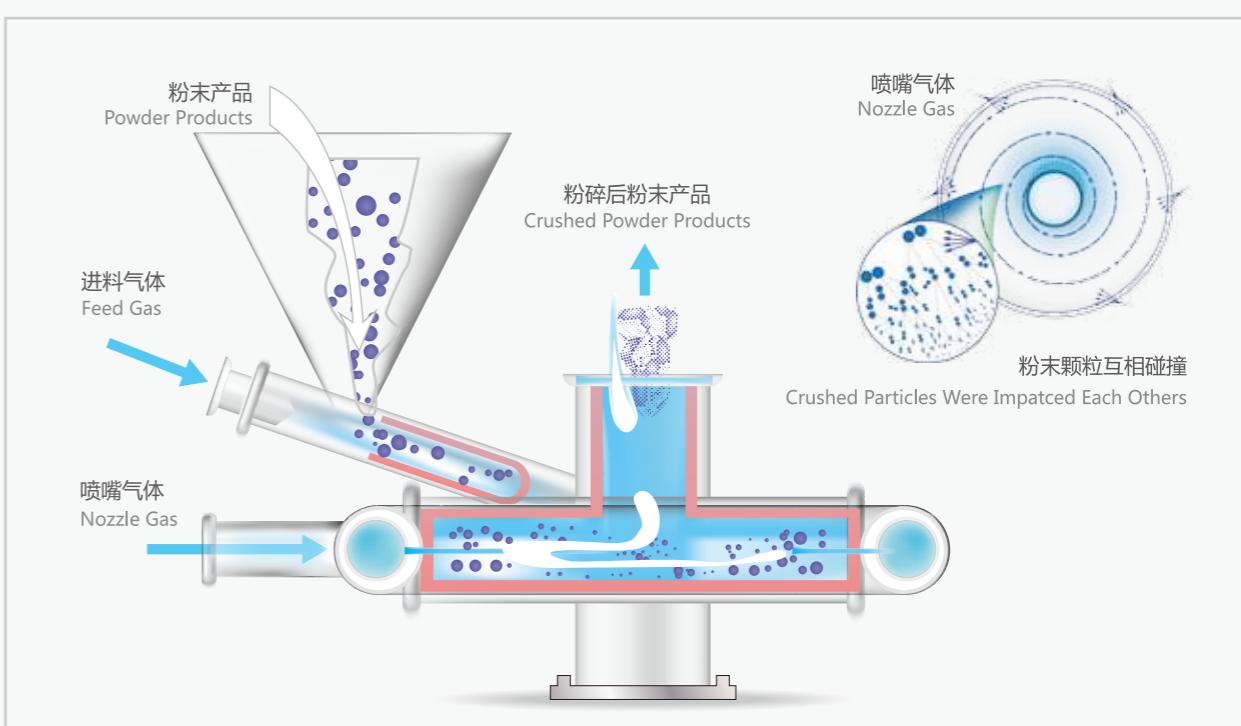
主要应用 Main Application

- ▶ 难溶性 APIs 的微粉化
- ▶ 咨体激素类 APIs 微粉化
- ▶ 抗生素类 APIs 微粉化
- ▶ 吸入制剂 APIs 与辅料的微粉化
- ▶ 抗肿瘤类 HPAPIs 微粉化
- ▶ 无菌 APIs 微粉化
- ▶ 氮气保护 APIs 微粉化
- ▶ 低熔点 APIs 超低温微粉化

- ▶ Micronization of insoluble API
- ▶ Micronization of steroid hormone APIs
- ▶ Micronization of antibiotics APIs
- ▶ Micronization of inhalation APIs and supplementary materials
- ▶ Micronization of anti-tumor APIs
- ▶ Micronization of sterile APIs
- ▶ Micronization of APIs with nitrogen
- ▶ Micronization of temperature-sensitive APIs



工作原理示意图 Working Principle Diagram



配置特点 FACILITY FEATURES



- ▶ 标准配置的容积式制药级别双螺杆式进料器，不同类型的螺杆和不同容积的料斗可选择
- ▶ 所有中试型和生产型设备均可选配失重式双螺杆进料器，精确控制进料量
- ▶ 投料方式可选：人工投料 / 真空上料机 / 料仓重力进料
- ▶ 进料器可实现 WIP/SIP 功能
- ▶ Standard volumetric pharma execution twin screw feeder, with various twin screws and various hopper dimensions
- ▶ Gravimetric twin screws feeder is suitable for all pilot unit and mass production option, it helps to control accurate feed rate
- ▶ Charging method options: manual charging, vacuum conveyor and gravity feed from stock bin
- ▶ Feeder can integrate with full WIP and SIP capability



- ▶ 进料器进料口和出口卡式软连接
- ▶ 硅胶 / 三元乙丙橡胶 / 氟橡胶 / 聚氨酯等材质可选择
- ▶ Tri-clamp flex connection used in feeder inlet and outlet
- ▶ Material options: silicone, EPDM, FKM, PU



- ▶ 可更换内衬式粉碎腔结构
- ▶ 底部气动排放阀，可实现粉碎腔的 WIP 和 SIP 功能
- ▶ 指针式粉碎腔刮浆系统，可实现高粘度粉末的连续粉碎
- ▶ 接触产品的内衬材质可选：316L 不锈钢 / PTFE / 司太立 / 陶瓷等
- ▶ Micron jet mill with interchangeable internal linings
- ▶ WIP and SIP function can be utilized through jetmill in bottom with pneumatic drain valve
- ▶ The pointer scraper system can realize the continuous mill of sticky product
- ▶ 316L stainless steel, PTFE, Stellite, Ceramic can be chosen for material of internal linings which contacts with product



- ▶ 不同形式的旋风分离粉末捕集器可分别满足多品种和大批量的生产要求
- ▶ 产品单点收集，保证生产过程产品粒径分布均匀
 - ▶ 所有的旋风分离粉末捕集器可实现 WIP 和 CIP 功能
 - ▶ 滤袋或滤筒防静电材质，均符合 FDA 要求
- ▶ various forms of cyclone can satisfy all kinds of production requirements
- ▶ Single collecting point to guarantee the same particle size of distribution
- ▶ All of the cyclones are integrated with WIP and SIP function
- ▶ Antistatic material of Filter bag and filter cartridge conform with FDA CFR (176.170, 177.1680)



- ▶ 粉末产品接触的阀门全部使用气膨胀气动蝶阀
- ▶ 可满足真空或压力环境
- ▶ 不同规格尺寸和不同材质的密封可满足不同的生产要求
- ▶ All the Valves in contact with powder products, using gas-expanding pneumatic butterfly valves
- ▶ Can be used in vacuum or high-pressure environment
- ▶ Seals of different sizes and materials can meet different production requirement



- ▶ 完全无死角的粉末取样阀
- ▶ 满足全真空和高压力的使用环境
- ▶ 最高使用温度可达 180°C
- ▶ 配合 ChargePoint 分体蝶阀使用可实现高密闭高活性产品的取样和无菌产品的取样
 - ▶ Free of dead zone design for sampling valve.
 - ▶ Match with full vacuum or high pressure in pharmaceutical industry
 - ▶ Max. temperature to 180 °C
 - ▶ High containment sampling device together with ChargePoint split butterfly valve enables the HPAPIs and sterile product sampling purpose.



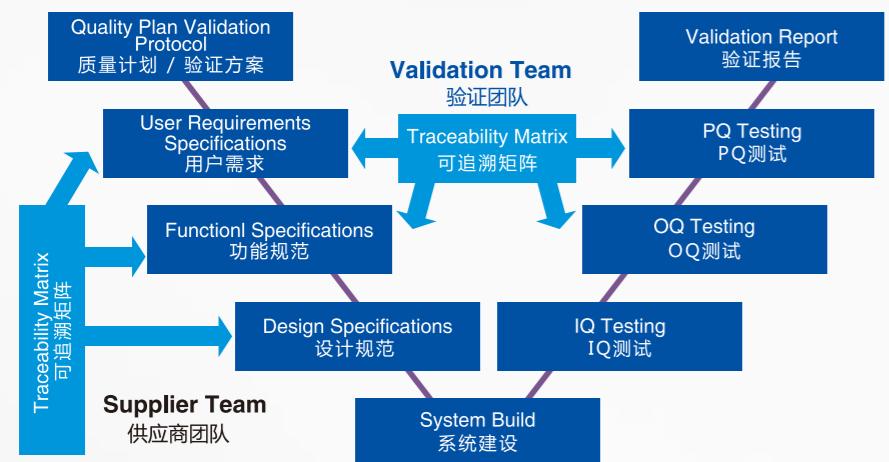
自控系统 CONTROL SYSTEM



- ▶ 微粉化系统完全通过 PLC 控制，满足 ATEX 防爆要求的 HMI 现场操作系统（可满足 1/21 区）
- ▶ 多模式组合：进料测试模式，真空进料控制模式，微粉化模式，分装模式，WIP 模式，CIP 模式，SIP 模式
- ▶ 手动控制模式和全自动控制模式选择
- ▶ 自控系统符合良好自动化生产实践指南（GAMP5）
- ▶ 自控系统遵从 FDA 21 CFR Part 11 必备功能
- ▶ 完整生产批报告，包括整个生产过程的关键参数
- ▶ 必备的电子签名和审计追踪功能

- ▶ Micronization system fully automated by PLC, on-site HMI for process control system available in compliance with ATEX directive (zone 1/21)
- ▶ Multi operating modes: Feeder feedback check mode, Vacuum conveyor mode, Micronizing mode, Charging mode ,WIP mode, CIP mode, SIP mode.
- ▶ Micronization system have provision to switch between Auto and Manual mode.
- ▶ The control system shall comply to GMAP 5
- ▶ Process control system shall comply to requisite feature of FDA 21 CFR Part 11compliance
- ▶ Full batch reporting Including key parameters of the micronizing process
- ▶ Requisite feature of electronic signature and audit tracking

验证 Verification



服务 Services

产品支持 Product Support

耗材和备品备件

上海的备件仓库有大量的备品库存，可及时满足客户需求

工程技术支持

快速解决所有机械，控制和过程工艺上的技术问题

维修

24小时/ 7天实现现场维修

销售支持 Sales Support

安装与调试

现场安装

机械和电气调试，运行测试

培训

全员培训包括操作，控制和故障处理

维护

远程维护和现场维护

售前支持 Business Support

来料测试

专业人员和不同设备用于产品特性测试

来料加工

客户可中试样品加工和批量产品加工

