该设备将用于制药粉体的干燥，并且必须符合 **GMP 要求、CE 符合性**以及 **21 CFR Part 11（数据完整性和电子记录）**的相关规定。

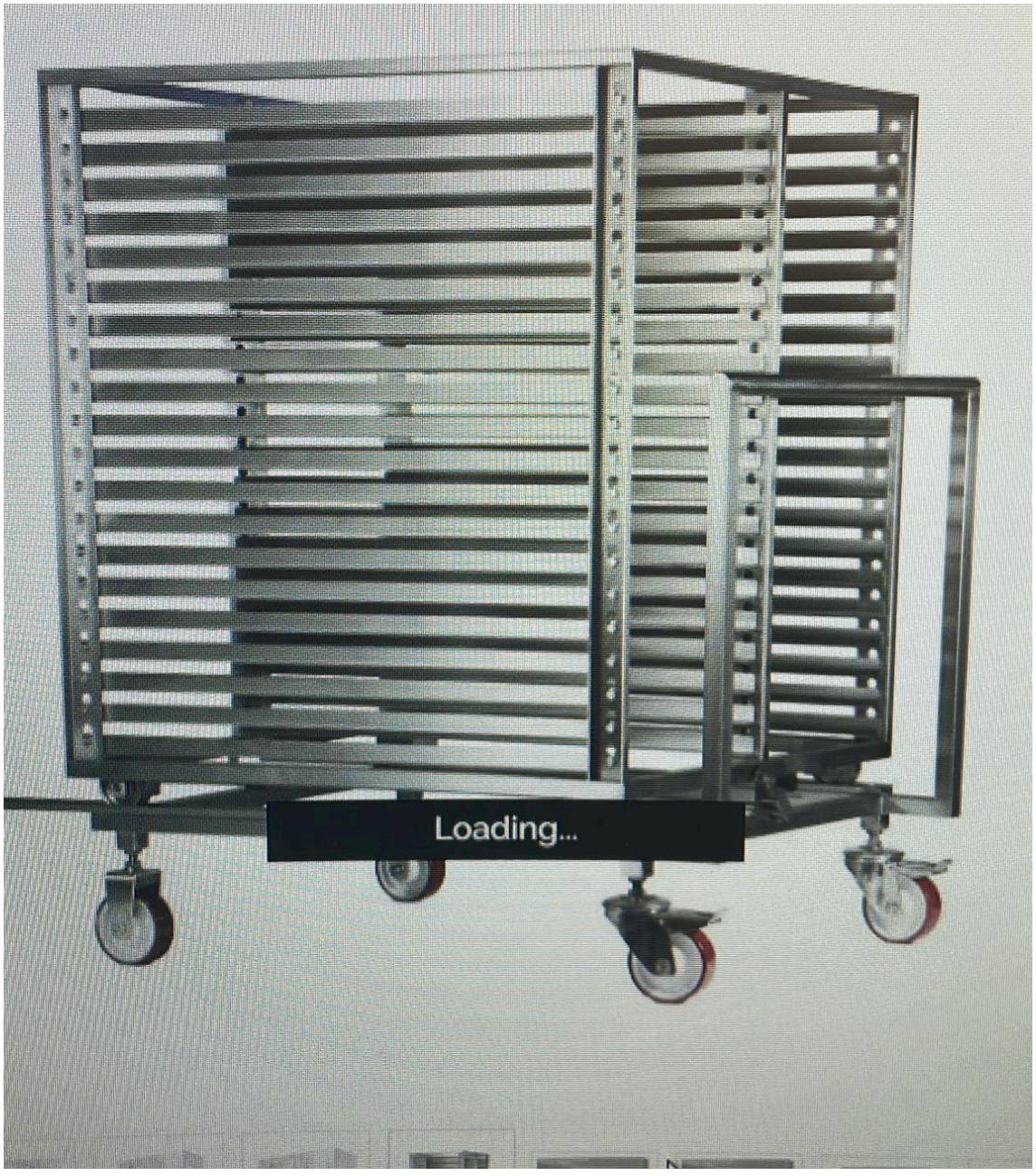
以下为初步技术要求：

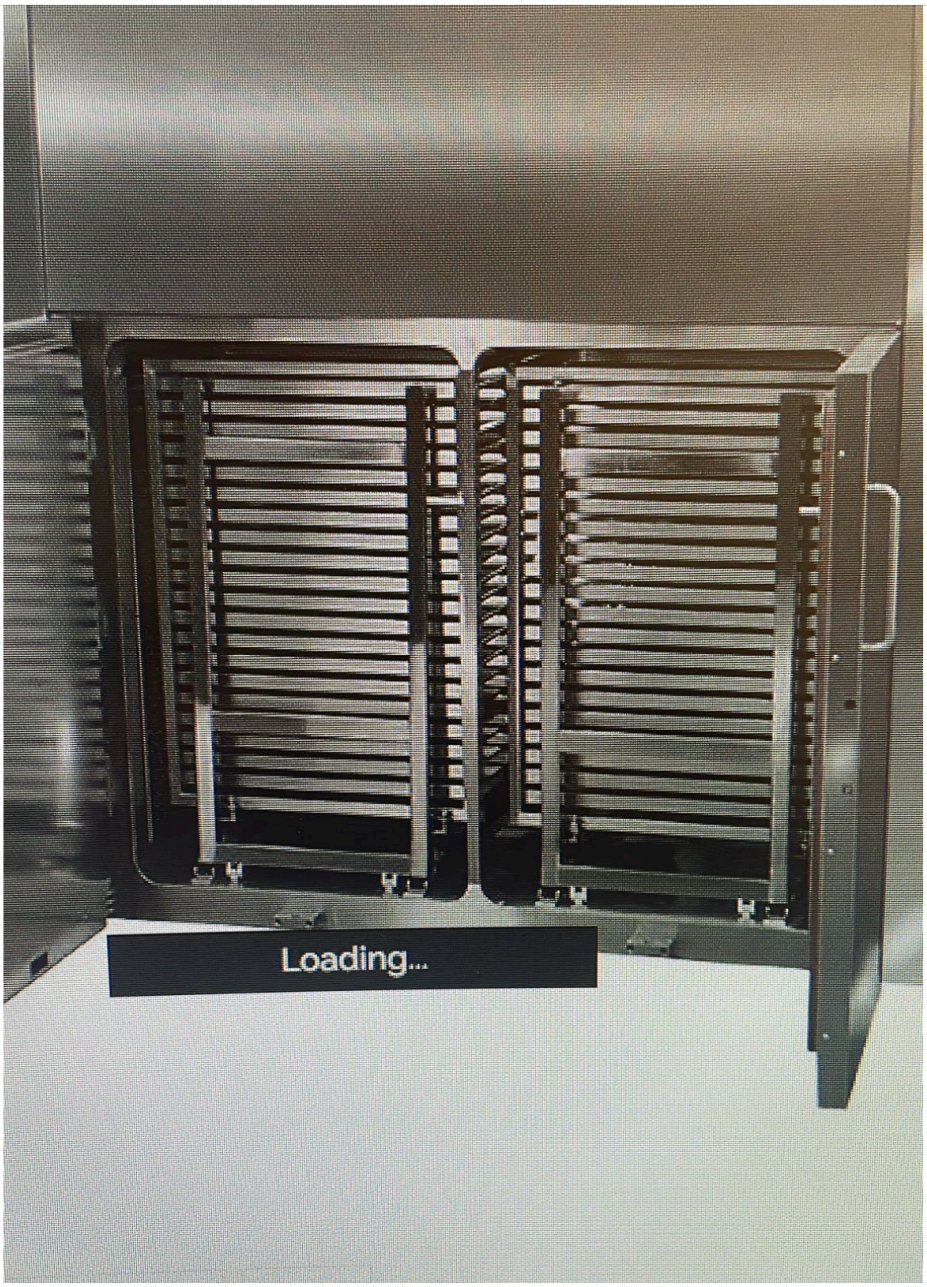
- **操作温度范围**：30 °C – 65 °C
- **加热系统**：电加热
- **产品**：制药粉体
- **批量 / 装料量**：约 130 kg
- **应用领域**：制药生产
- **合规要求**：GMP、CE、21 CFR Part 11
- **设备材质**：适用于制药用途的材料
- **均匀性与控制**：具备高温度均匀性及精确的过程控制能力，适用于经验证的制药工艺
- **控制系统**：符合数据完整性要求（审计追踪、用户权限管理、电子记录等）

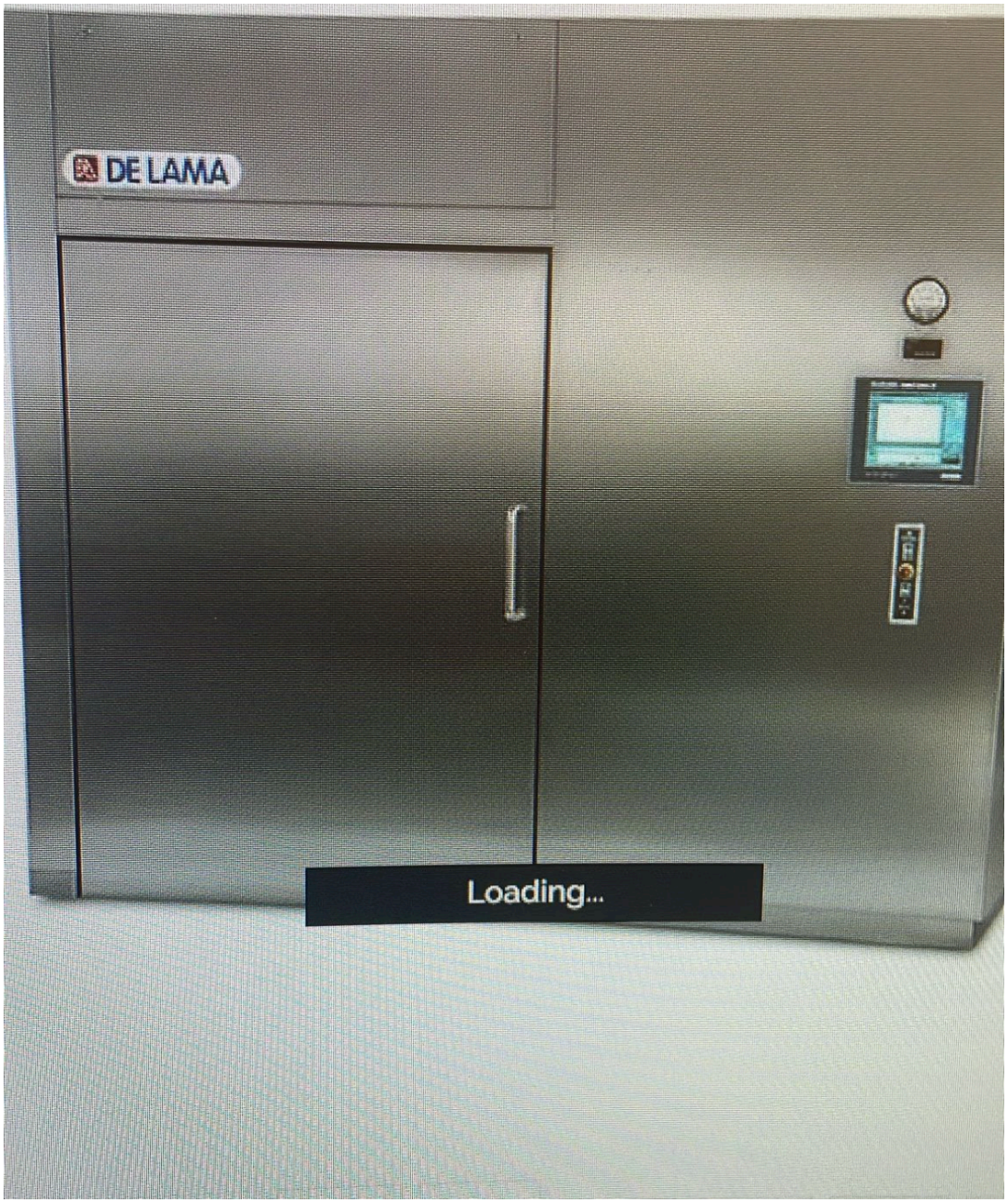
敬请在报价中包含以下内容：

- **详细的技术数据表**
- **合规性文件**（GMP、CE、21 CFR Part 11）
- **控制系统及软件规格说明**
- **预计交货周期**
- **安装与调试要求**
- **验证支持**（IQ / OQ 文件）
- **可选配置**（例如：数据记录、远程监控等）

The equipment will be used for the drying of pharmaceutical powders and must comply with GMP requirements, CE conformity, and 21 CFR Part 11 for data integrity and electronic records. Below are the preliminary technical requirements: Operating temperature range: 30 °C – 65 °C Heating system: electric heating Product: pharmaceutical powder Batch size / powder load: approx. 130 kg Application sector: pharmaceutical manufacturing Compliance: GMP, CE, 21 CFR Part 11 Material of construction: suitable for pharmaceutical use Uniformity and control: high temperature uniformity and precise process control suitable for validated pharmaceutical processes Control system: compliant with data integrity requirements (audit trail, user access levels, electronic records) Kindly include in your quotation: Detailed technical datasheet Compliance documentation (GMP, CE, 21 CFR Part 11) Control and software specifications Estimated delivery time Installation and commissioning requirements Validation support (IQ/OQ documentation) Optional features (e.g. data logging, remote monitoring)




Loading...


DE LAMA
Loading...