



Single Vial Unit (SVU)

RheaVita's Single Vial Unit (SVU) is based on Continuous Freeze-Drying Technology and is specifically designed for R&D purposes to facilitate (bio)pharmaceutical product development



About Rheavita's continuous freeze-drying technology

Perfectly suited for very fast formulation, process development and optimization with minimal material consumption.

Fast and simple process development and production scale-up, from vial level to continuous freeze-drying production lines (GMP-Flex), based on numbering up.

Rapidly evaluate the impact of various process and formulation parameters on the Critical Quality Attribute of interest with minimum API consumption. Many different parameters can be evaluated and screened in a single day, thanks to a cycle time of ~1 hour.

Custom software tool supports fast process development and production scale-up:

- Optimized process settings can be directly transferred to continuous production
- PAT and advanced process control systems ensure identical process signatures



How it works

- Spin-freeze vials with **controlled cooling and freezing**
- **Infrared-assisted and controlled** primary and secondary drying
- Thin product layer with large surface area enables **rapid freeze-drying** (~ 1 hour)
- **100% vial monitoring**, control, and inspection
- **Identical process conditions** for each vial
- **Consistent quality when scaling up** from pre-clinical to production
- Proven **process understanding** via validated mechanistic models and **digital twins (model-based design)**
- **Flexibility/production efficiency:** rapid change-over, short CIP/SIP times, flexible volume, and production capacity
- **Reduced ecological footprint** and operational costs (> 50%)

SVU enables opportunities

- Fast formulation, process development and optimization with limited material requirements, based on:
 - Fast intrinsic continuous freeze-drying concept (~ 1 hour)
 - Software predicts optimal process settings for your product and its properties
 - Implemented PAT actively controls your product processing
- Faster time to patient
- Proven efficacy and safety
- Opportunities for different types of products, including:
 - Products with low Tg' or low Tc
 - Much faster reconstitution times, e.g. for highly concentrated protein formulations
 - Formulations requiring proper and well-controlled cooling and freezing rates (e.g., cell-based formulations)
 - ATMPs
 - mRNA-LNP based formulations

Dimensions (HxWxD)	160x122x160
Controllable rate of crystallization	Through specification of constant delta-T between coolant and product
Cooling/freezing rate	0.5 - 100 °C / min
Processable critical product temperatures	Down to -60 °C
Minimum pressure	2 Pa
Accepted vial size	2R - 30R
Other accepted containers	DCC, prefilled syringes
Electrical connections	EU/US
Trending on HMI	Product temperature Pressure
Thermal camera	0.5 mm spatial resolution 0.5 K thermal resolution
Access level control (password protected)	1. Viewing 2. Operator 3. Supervisor 4. Service
Recipe/settings	XML-based
Batch record	XML-based
Safe remote access (peer-to-peer)	VPN server included



rheavita.com

info@rheavita.com