



HydRIS Stabilisation Platform & Aseptic Spray Drying Technology

A solution for storing biologics at room temperature

HydRIS: How it works

- Vaccine dried onto a proprietary fibrous membrane encased within custom-designed housing
- Standard needle and syringe attached to ports of the housing
- Appropriate diluent is flushed through the housing
- Rehydration and delivery of vaccine achieved in a single action



HydRIS: Key properties

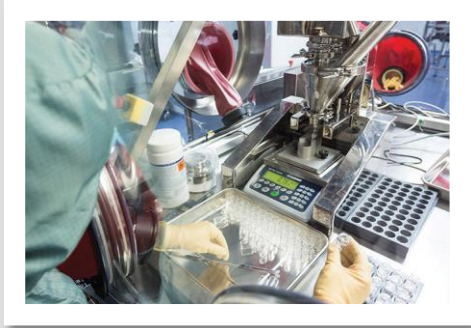
- Long term temperature stability from below 0°C to >50° C
- Proven to stabilise range of biologics including live viruses (MVA, adeno), bacterial vectors, mAbs and labile proteins
- Ready-to-inject format
- cGMP manufacturing available



cGMP Aseptic Spray Drying for Biologics

Our Capabilities

- World's first fully validated **cGMP, aseptic/apyrogenic** spray dryer.
- The technology can be utilised to manufacture sterile injectable material suitable for human use
- World's 1st aseptically spray dried Biologic manufactured at Nova for commercial use **(FDA/ EMEA approval-2015)**
- Manufacturing capability for commercial, clinical and pre-clinical supply
- Manufacturing capability for aseptic powder filling



cGMP Aseptic Spray Drying for Biologics

Bio-pharmaceuticals:

- Therapeutic Proteins/ Peptides
- Monoclonal antibodies
- Vaccines- Live/ non-live
- Blood products
- Enzymes
- Hormones
- Lyposomes

Pharmaceuticals:

- Speciality chemicals
- API
- Lipids

Aseptic Spray drying vs Lyophilisation

Characteristics	Spray Drying	Lyophilisation
Compatibility with Biologics	Yes	Yes
Mode of processing	Continuous Ability to manufacture large quantities	Batch Limited by the Freeze Dryer
Product Suitability	Sensitive Bio-pharmaceuticals	Sensitive Bio-pharmaceuticals
Particle Engineering	Control over particle & morphology Enhance bioavailability Improved mixing & dissolution	Porous lyo cake Issues with dissolution
Product Filling	Versatile Not limited by the type of container Highly flowable powder	Compatibility issues Limited by type of containers Less flowable powder
Process Scalability	Capable	Difficult
Capital, Running & Support Costs	Low	High