IMA LIFE

Aseptic Processing & Freeze Drying Solutions

NEBULA

NEBULA is a high-speed decontamination tunnel that sterilises tubs and trays containing RTU material as they enter and transit isolated production lines in continuous mode. This new technology is capable of efficiently achieving **6-log surface decontamination** by using aerodynamic containment of highly concentrated vapour phase hydrogen peroxide.


TUB/TRAY OPENING
NEBULA

Hyperspeed decontamination technology

NEBULA establishes an unprecedented approach to ensuring 100% sterility of tubs and trays containing RTU material transiting aseptic fill-finish lines. In order to avoid the known risks involved in introducing material into aseptic isolators, NEBULA has been designed to accomplish a failsafe decontamination process at high speeds, handling up to 6 tubs/trays per minute.

NEBULA is made up of 3 chambers in which pressure is managed to ensure safety and processing efficiency. CFD (Computational Fluid Dynamics) studies have been conducted to guarantee maximum containment of H_2O_2 avoiding its circulation within the isolator and making it safe for operators and the cleanroom environment.

NEBULA is the ultimate method in the category of surface decontamination technologies, with marked differences compared to the alternative NTT (No-Touch-Transfer) technology. A continuous system, not a batch process, NEBULA provides the following benefits:

1. HIGH-SPEED, CONTINUOUS DECONTAMINATION
2. ABSENCE OF ROBOTIC MANIPULATION
3. MINIMAL IMPACT ON LINE LAYOUT
4. FULL FLEXIBILITY, INDEPENDENT OF PACKAGING SIZE AND RTU MATERIAL

How NEBULA successfully addresses issues raised in GMP Annex 1

The technology behind **NEBULA** represents an effective response to GMP Annex 1 guidelines. Sterility assurance risks should be minimised during material transfer, therefore need to be adequately *supported by high capability transfer technology*.

Seamlessly integrated into an aseptic fill-finish line, NEBULA **enhances processing performance**, offers **extensive flexibility** and provides a valid means of guaranteeing **excellent sterility assurance**.

NEBULA accomplishes what no other solution has done before, especially in terms of speed and simplicity.

NEBULA

Infeed system at a glance

Introducing RTU material into an aseptic environment is a critical aspect of all isolated production lines for injectable pharmaceutical specialties. Two material transfer technology categories exist for both continuous and batch processing, NTT systems implementing mechanised de-bagging and systems using decontamination agents, light-based, chemical or radiation-based.

CONTINUOUS vs BATCH PROCESSING

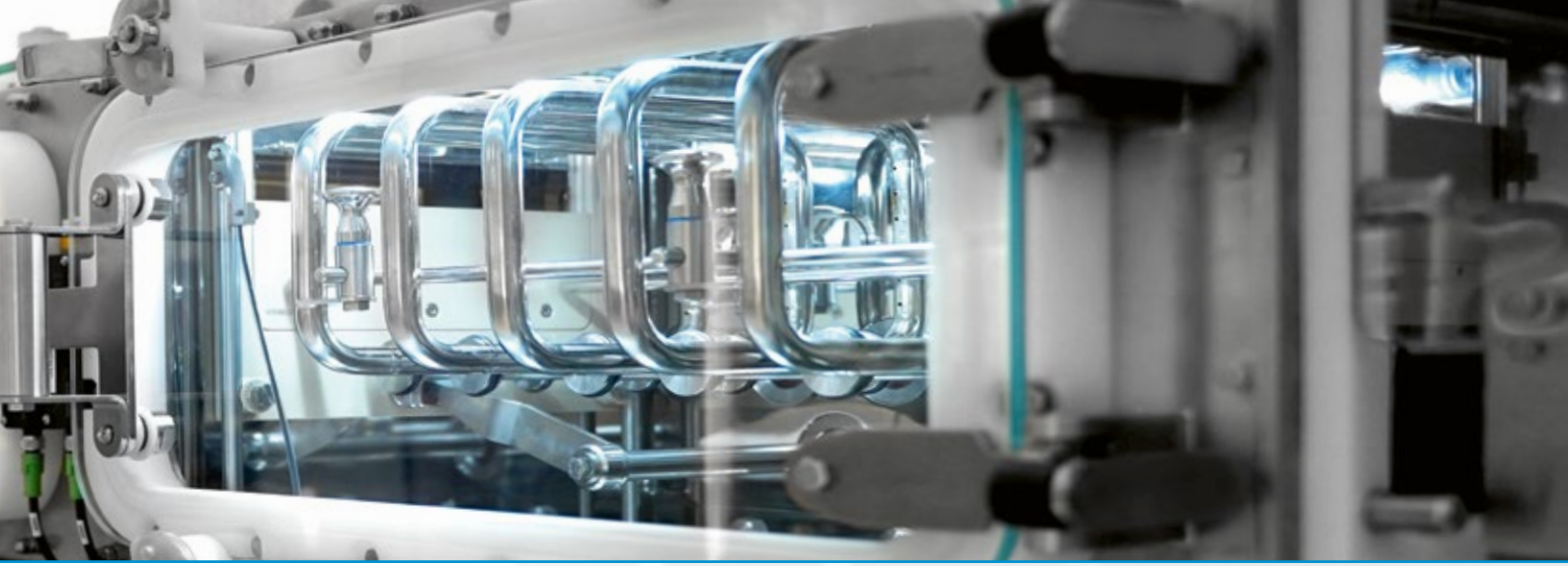
NEBULA is an efficient, simple concept which avoids the complexity of NTT systems. It is based on chemical decontamination by HC-VPHP and provides an easily-managed tub or tray infeed process. Whereas NTT systems have a non-negligible impact on line layout, NEBULA is a 3-stage tunnel which simplifies the entire decontamination process, starting from a standard infeed.

HIGHLY CONCENTRATED VAPOUR PHASE HYDROGEN PEROXIDE DECONTAMINATION

Innovation, simplicity and unprecedented performance

NEBULA is essentially a 3-stage decontamination tunnel preceded by the infeed area and followed by tub or tray peeling in a Grade A zone. The tunnel is comprised of 3 interconnected modules: heating chamber, decontamination chamber and purging chamber. The process is performed automatically in a controlled environment in which temperature, hydrogen peroxide concentration and atmospheric pressure are regulated precisely to maximise efficiency and material sterility.

FULLY AUTOMATIC PROCESS IN A CONTROLLED ENVIRONMENT



Risk mitigation

NEBULA minimises risks of hydrogen peroxide residue by virtue of the extremely short processing time. Moreover, H_2O_2 containment is ensured by CFD studies and a patented design concept. Lastly, specific performance qualification has been implemented for each packaging type for RTU material.

CONTAINMENT ASSURED THROUGH COMPUTATIONAL FLUID DYNAMICS

Phase 1.
Tub heating

Inside the heating chamber, the outer surfaces of the RTU container are heated, thereby preparing the container to withstand the decontamination phase without the risk of condensation. The heating chamber is designed to minimise the time required to reach optimum temperature and thus reduce the penetration of thermal energy into the primary containers inside the packaging. Uniform temperature distribution and achievement of the required thermal values is one of the aspects verified during the system qualification phase.

MINIMAL HEAT PENETRATION INTO PRIMARY CONTAINERS

Phase 2.
Tub decontamination

The decontamination chamber is the heart of the system in which highly concentrated VPHP is injected through rings with appropriate radial perforations. The rings are designed to achieve uniform diffusion of HC-VPHP, so that the entire outer surface of the RTU container is decontaminated. The container advances at a constant rate, allowing a defined and validated exposure time. This ensures the 6-log abatement of the microbiological load. The very short transit time (20-30 seconds) minimises penetration of VPHP inside the container. The chamber is kept at a specific pressure and is designed so that the suction points in the inlet and outlet areas prevent the spread of hydrogen peroxide to adjacent chambers. Compared to traditional physical barriers that seal off the area during the decontamination phase, thereby unable to accommodate a continuous process, the design of the decontamination chamber allows a continuous flow thanks to this innovative aerodynamic containment solution.

6-LOG ABATEMENT OF MICROBIOLOGICAL LOAD IN LESS THAN 30 SECONDS

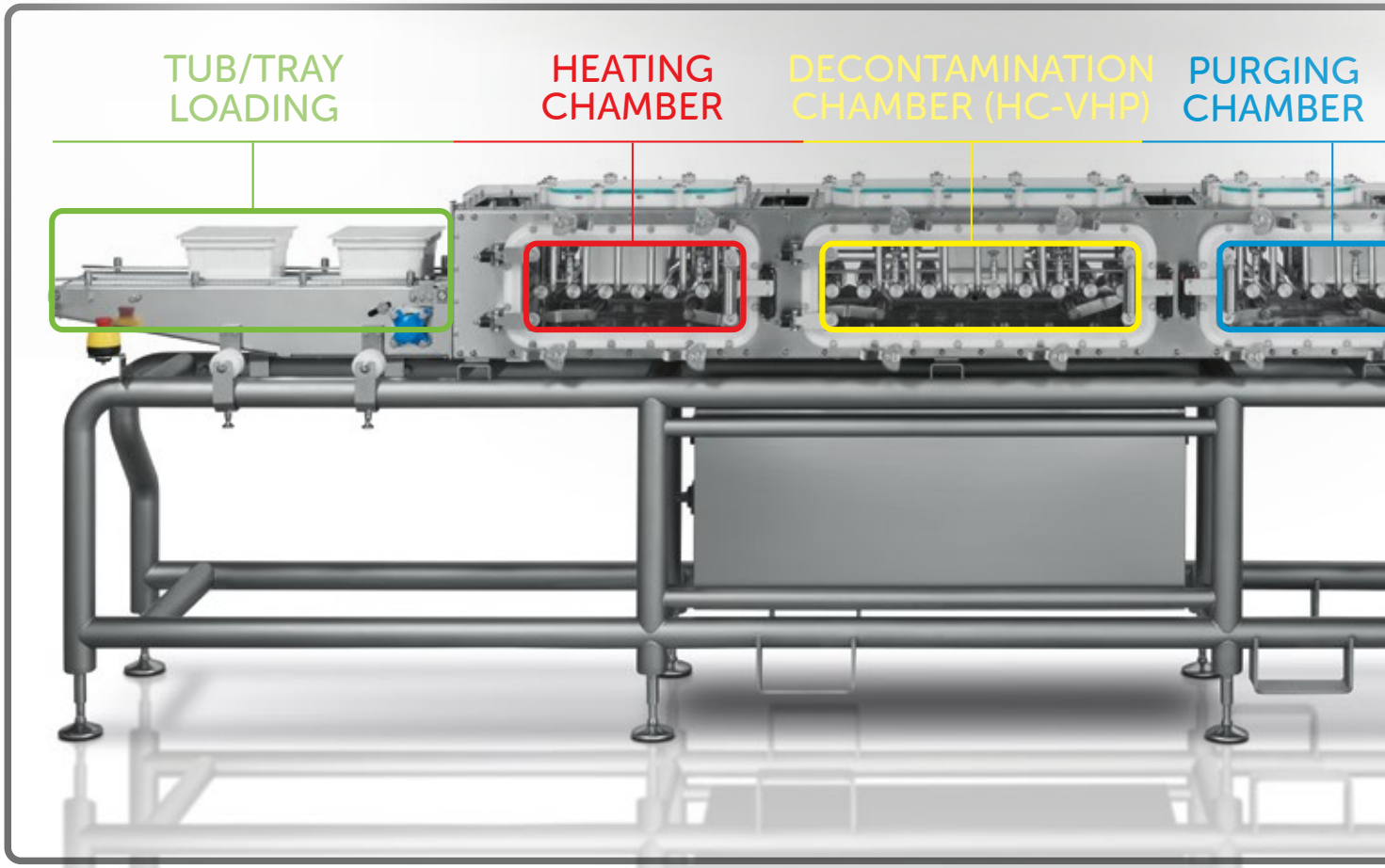
Phase 3.
Tub purging

In the purging chamber, the system reduces the concentration of residual hydrogen peroxide within the container to avoid possible impact on the pharmaceutical product dispensed downstream. The chamber utilises a combination of time, temperature and ventilation to achieve a rapid purging effect of the residual concentration to levels below 1 PPM. The purging chamber is set at a positive pressure to ensure a dual purpose: to prevent the diffusion of VPHP towards the isolator and to protect the aseptic zone connected to NEBULA from possible contamination. Inside the chamber, in addition to environmental parameters, particle contamination can be monitored with an appropriate integrated instrument.

ACHIEVES RESIDUAL HYDROGEN PEROXIDE LEVELS BELOW 1 PPM

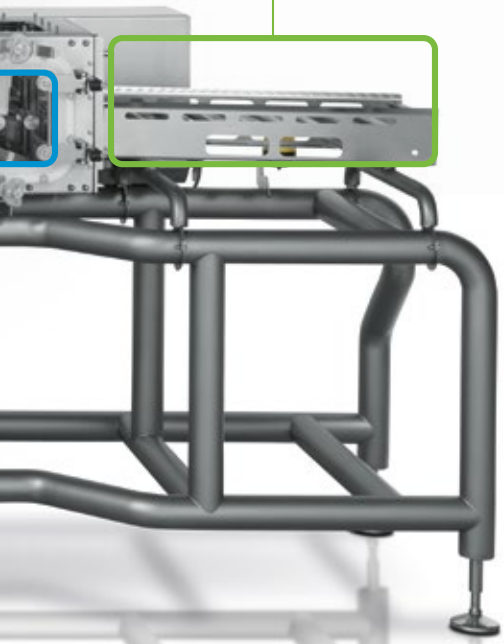
Seamless integration with aseptic fill-finish lines

NEBULA is a high-speed decontamination tunnel **which integrates seamlessly with IMA Life aseptic fill-finish lines.** Speed can be regulated to adapt to the subsequent processing parameters of the line, and in particular the tub/tray opening module which can be anything from semi-automatic to fully robotized. Peeling then takes place in a Grade A environment.


TUB/TRAY LOADING
HEATING CHAMBER
DECONTAMINATION CHAMBER (HC-VHP)
PURGING CHAMBER

TECHNICAL DATA

GRADE A
(PEELING)



Features	Dimensions
Decontamination Tunnel Dimensions (Cleanroom)	3.7 m (L) x 0.9 m (W) x 1.5 (H) + inlet/outlet piping up to the ceiling
Power Supply & Ventilation Skid Dimensions (Technical Area)	2.3 m (L) x 1.2 m (W) x 2.8 m (H)
AHU Dimensions (Technical Area)	2.0 m (L) x 0.8 (W) x 2 m (H)
H_2O_2 Cabinet (Cleanroom/Technical Area)	1.2 m (L) x 0.5 (W) x 1.6 m (H)
Ready-To-Use Tub/Trays	3-4" (Standard Nebula) 6" tubs, vial trays (to be requested)
Outlet H_2O_2 Catalyser	included
Output	Up to RTU/min (max speed@30sec 6-log decontamination time)
Expected 35% H_2O_2 Solution Consumption in Production	6l/hr
H_2O_2 Storage	2x 20L Tank - 35% aqueous hydrogen peroxide solution high purity - low residues
Requested Utilities	Ventilation inlet airflow:450m3/h from technical area Compressed air: 10 Nm3/h @ 8 bar Cold water for UTA: 2.5 m3/h @ 7°C Industrial steam 10 Kg/h @ 5 bar

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