



## Case study: Vacuum Drying of different active organic pharmaceuticals

### Application:

For development of active (organic) pharmaceuticals a dryer will be used for drying the wet filter cake coming out of a centrifuge.

The solvent to be evaporated is mostly water, acetone, ethanol, ethyl acetate or a mixture of these solvents.

Drying must be done under vacuum and heating and cooling by means of an external mono medium system (glycol/water).

After every batch the mixer/dryer and vacuum filter shall be cleaned by means of a pumping system and a cleaning robot to clean mixer/ dryer interior.

A vapour dust filter keeps the dust, which will occur during processing, within the dryer.

During processing critical process parameters have to be logged and communication between PLC and the above DCS must be possible.

Critical are batch integrity and process validation.



### Requirements product

Product	:	Organic solvent wet cake
Moisture content	:	Feed 20% W.B. Dry < 0,1 % W.B.
Max product temperature	:	100 °C
Particle size	:	d50 = 10 – 100 µm
Bulk density	:	1000 – 1200 kg/m <sup>3</sup> (wet cake) 400 - 700 kg/m <sup>3</sup> ( dry solids)
Sensitive for	:	High shear Elevated temperatures Oxidation

### Solution:

The following data are applicable:

<b>Dryer</b>	:	The Vrieco-Nauta® vacuum dryer to ensure: capability of handling of different products batch integrity good cleanability minimum of residue after discharge
<b>CIP Filter</b>	:	Special developed CIP filter with metallic filter bags and spray-nozzles on strategic places to ensure good clean ability. The filter housing is provided with a heating jacket and is isolated.
<b>Cyberjet</b>	:	The latest development on CIP is this cleaning robot . (RCIP- Robotised Cleaning In Place). Product recovery is possible when spraying with air or Nitrogen before using liquids.



## Controls

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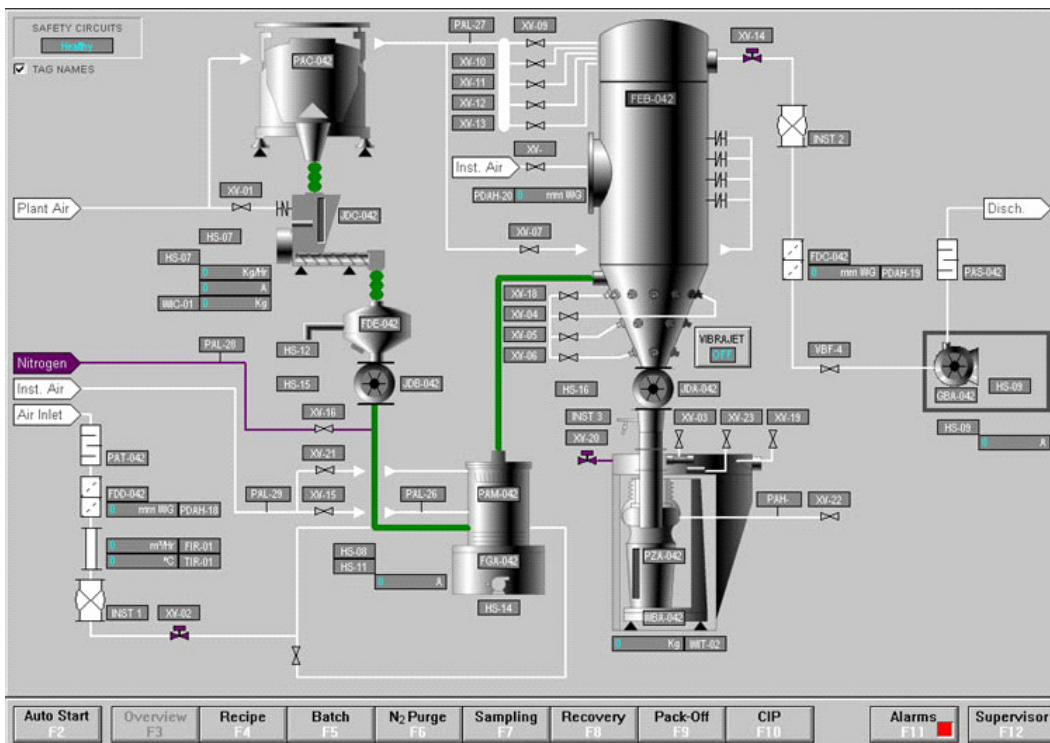
The control system is based on a PLC which contains the following automatic functions:

- drying program
- CIP program
- local trending of pressure and temperature visualization of the unit with key parameters.
- The software is written with respect to the FDA regulations (21-CFR-11, S88 and GAMP)

## Validation

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Validation documentation DQ / IQ and OQ to assist in the validation of the total system.



## Process Data

Content of the vacuum dryer	:	1.800 liters of product
Feed capacity	:	200 – 800 kg / batch (dry mass)
Feed moisture content	:	20 % W.B.
Product moisture content	:	< 0,1 % W.B.
Max. Product temperature	:	100 °C
Time available for CIP	:	2 hours between batches
Max. drying time	:	8 hours
Design pressure	:	Full vacuum / 4 barg
Design temperature	:	-35 / + 165 °C
Leakage rate at level of vacuum	:	< 1 kg/hour at 100 mbara

## Conclusion

The Vrieco-Nauta vacuum dryer is a universal **low temperature contact dryer**

The units is specially designed for processing pharmaceuticals and this dryer can cope with the higher requirements in terms of cleaning & CIP.