Crysta'days November 8 2023

Introduction to the new SCT-LAB

Secaya FLUIDIFY PHARMA

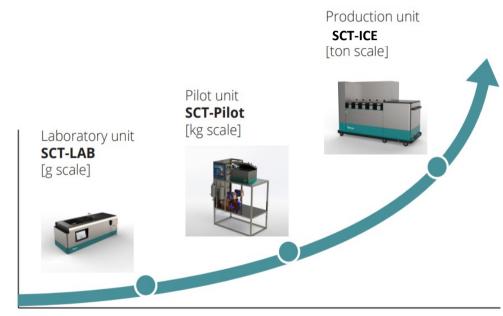




3 temperature zones:

Solution: RT to 85°C
Antisolvent: 5 to 85°C
Reactor: 0 to 70°C

- Delivered with dedicated cooling/heating thermostat
- Single use inserts and reactors
  - 6 different inserts for cooling and antisolvent crystallization
  - 6 different integrated reactors with different volumes: 1 to 7mL
  - 1 specific reactor execution for highly viscous solutions
- Pump flow rates 1 to 60 mL/min
- Simplified collection of slurries
- Stand-alone 21 CFR part 11 software

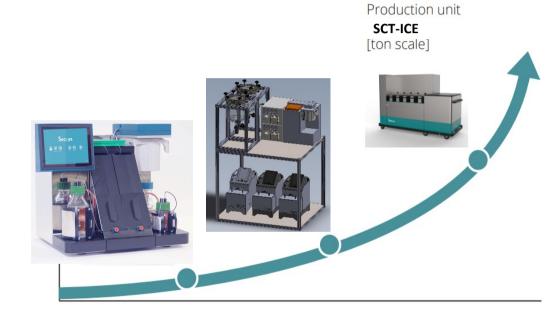




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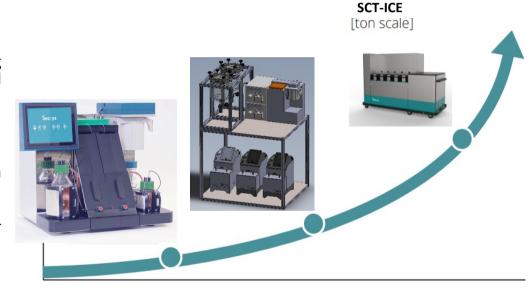




## Why make the changes:

- « Not always very user friendly: lots of screws, blocking syringes, not very happy with thermal properties overall design »
- « takes up a lot of space in the fume hood »
- « external bottles with own heating make it difficult with space in the fume hood »
- « cannot reach well the back side and replacing the reactor and insert is difficult »

« once the user gets to know the philosophy behind the system, the user increase development speed »

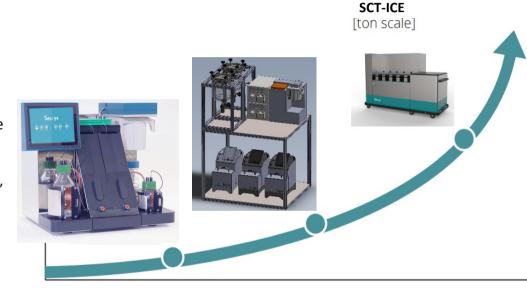


Production unit

The PID and philosophy is OK, execution and customer experience needs to be increased



- On-site mixing and dissolution
- « No screw fixing » and unfixing syringe
- Homing device for syringes
- No hustle in changing the reactor and insert
- New reactor design with other way of homogenizing the temperature
- No more closing the reactor chamber with screws
- Software controlled temperature of stock solution, syringe, and reactor (by thermostat)
- Stand-alone instrument, no PC needed



Production unit



• specifications



,	
Temperature antisolvent	from 5 to 85 °C (antisolvent precooled in fridge)
Temperature solution	from 25 to 85 °C
Temperature reactor	from 0 to 75 °C, agitated
Volume stock solution	100 mL, agitated and heated in place
Volume stock antisolvent	250 mL, agitated and heated in place
Volume solution per test	from 1 to 20 mL, syringes are preheated and precooled
Flow rate solution and antisolvent	from 1 to 50 mL/min
6 mixing inserts for cooling and antisolvent crystallization	
7 different reactors for cooling and antisolvent crystallization	
Unit dimensions	45 x 45 x 45 cm (L x W x H)
Weight	28 kg



- Stand-alone 21 CFR part 11 software
- Data structure: data integrity is key







- Stand-alone 21 CFR part 11 software
- Data structure



UserID Temperature solution

Project name Temperature antisolvent

Series number Insert

Sample number reactor

Molecule name Solution flow rate

Acronym Solution volume

Solvent Antisolvent flow rate

concentration Antisolvent volume

Concentration unit Reactor temperature

Antisolvent Sample posttreatment

**Temperature solution** 

**Temperature antisolvent**