

# sunbather

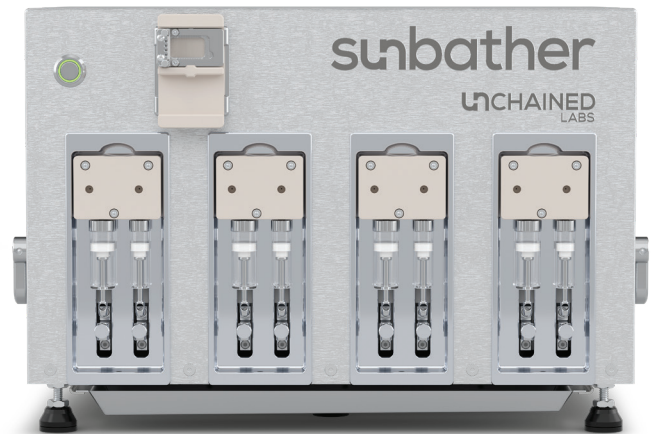


**UNCHAINED**  
LABS

## Jump to GMP in a jiff

Transferring your LNPs to GMP can be a costly, messy process. It usually means switching equipment, using a different flow path and mixer – basically a painful re-development and re-validation of all your hard work. Sunbather makes the move to GMP a walk in the park with the documentation, replaceable flow path and easy transfer built right in. It uses the same mixing process and protocol as its Sunny Suite family members Sunscreen and Sunshine, so you can take your dialed in formulation into GMP without all the fuss.

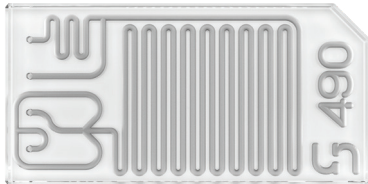
- Up to 1.8 L/h
- Integrated in-line dilution
- Fully replaceable flow path
- Range of mixer types
- 21 CFR Part 11 compliant software
- Transferrable process from Sunshine



## Mix it up big time

Prep one input channel with payloads, the other with lipids and you're ready to mix them up with a Sunny. For a simple, well-known T-mixing approach grab a Sunny T, or to increase fluid contact area for particle formation with a cross-junction, use a Sunny X. To use Sunbather's full range of flow rates, ratios and integrated in-line dilution, choose a Sunny Trident. GMP-ready Sunnies are made with quick-change, top connection points into the flow path, keeping their microfluidic channels pristinely clean and making it easy to sub them in and out of Sunbather.

**Sunny Trident**



- Reverse-angle mixing
- In-line dilution

**Sunny X**



- Cross-type mixing
- Multiple channel sizes

**Sunny T**



- T-mixing
- Multiple channel sizes

## GMP-ready when you are

Sunbather comes available with an installation qualification and operational qualification (IQ/OQ), and comprehensive user training so that you can get up and running as fast as possible. With fully traceable wetted materials, extractables data, and a manufacturing process grounded in by our Quality Management System (QMS), you'll be ready to dive straight into GMP with Sunbather.



## No-nonsense, compliant software

Sunbather's software serves up Administrator and Operator access levels, a 21 CFR Part 11 compliant audit trail, and password signoff for process critical actions. The software's simple user interface means fast familiarization, and the touchscreen kiosk keeps things clean and makes setting up a new run a breeze.

The screenshot displays the Sunbather software interface. At the top, there is a green header with the logo 'UNCHAINED LABS' on the left and 'Sunbather' in the center. Below the header, the main section is titled 'Run Parameters'. It contains a table with columns for 'Enable Channel', flow rate units, 'Input Volume', and 'Current State'. The flow rate units are set to 'mL/min'. The 'Input Volume' column shows values for each channel and a total volume. The 'Current State' column shows 'Idle' for channels 1-3 and 'Not Initialized' for channel 4. Below the table, there are fields for 'Total Volume' (500 mL), 'Total Time' (0:25:00), and 'Batch ID' (UL\_Test\_Batch). At the bottom left, there are icons for 'CFR', 'Log Out', and 'Power Off'. In the center bottom, there are four buttons: 'Initialize', 'Empty', 'Fill', and 'Stop'. On the right side, there is a large green circular button labeled 'START'. At the very bottom, there is a status bar with 'Device Status:' on the left and an 'About' button on the right.

	Enable Channel	mL/min <input checked="" type="radio"/> $\mu$ L/min <input type="radio"/>	Input Volume	Current State
Channel 1	<input checked="" type="checkbox"/>	7.5 mL/min	187.5 mL	Idle
Channel 2	<input checked="" type="checkbox"/>	2.5 mL/min	62.5 mL	Idle
Channel 3	<input checked="" type="checkbox"/>	10 mL/min	250 mL	Idle
Channel 4	<input type="checkbox"/>	<i>Channel 4 flow rate</i>	0 mL	Not Initialized
Total Volume		500 mL		
Total Time		0:25:00		
Batch ID		UL_Test_Batch		

CFR  
Log Out  
Power Off

Initialize Empty Fill Stop

START

Device Status: About

## The Sunny Suite

The Sunny Suite has a killer solution for every step of your LNP development. Sunscreen automates high-throughput screening of up to 96 formulations at a time to help you quickly discover your winning LNP formulations. Sunshine then takes your best formulations and hones in on the perfect mixing process conditions, with both automated experiments and continuous flow modes. When you're ready for clinical trials, Sunbather dials up your particles in a fully GMP-compliant environment.



Screen



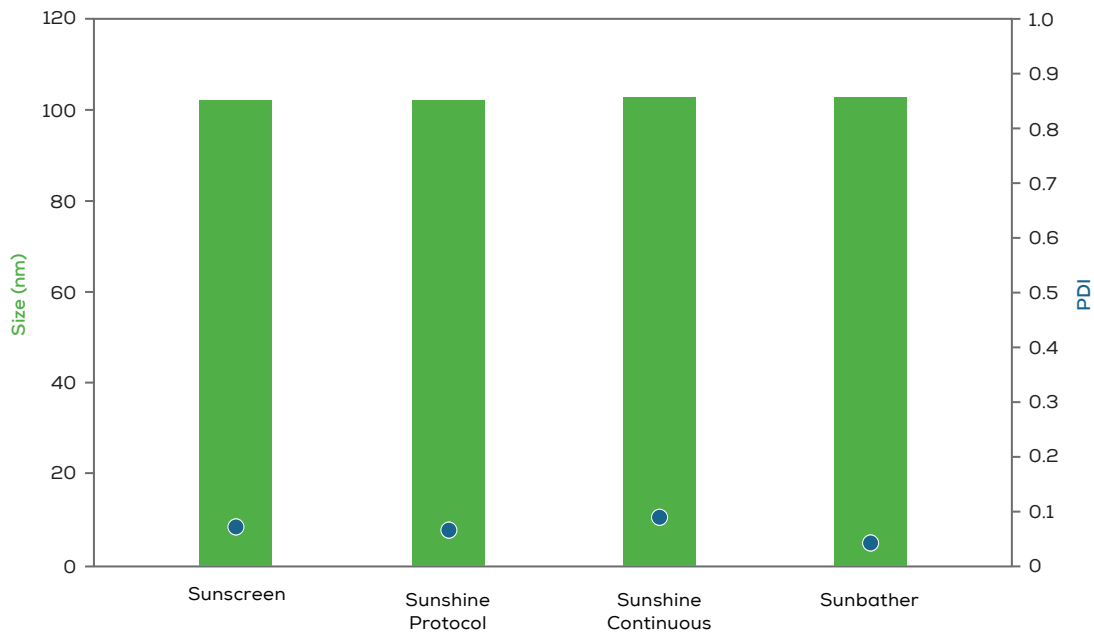
Optimize



Produce

## Trust the process

Using the same pumps for fluid delivery, and same range of Sunnies for mixing up your formulations, the Sunny Suite makes the transition from formulation screening to process development to GMP production smooth sailing. Whether you're screening through hundreds of 200  $\mu$ L formulations or producing liters of particles for clinical trials, you can trust the Sunny Suite to deliver the same consistent results at any scale.



# Specifications

Application	
Throughput	10 mL/min per channel
Total flow rate range	0.1–30 mL/min (configuration dependent)
Flow rate ratio (aqueous to organic) range	1:1 to 10:1
Typical particle size range	40–200 nm*
PDI	<0.2*
Encapsulation efficiency	>90%*
Instrument	
Physical	
Weight and dimensions (instrument only)	19 kg, 29 cm H x 41 cm W x 32 cm D
Operating pressure	0-10 bar
Electrical	
Voltage Input	100 V–240 V AC, 50–60 Hz
Power consumption (peak/average)	1A/500 mA
Other information	
Fluidic port sizes	¼"-28 threaded nut, luer fitting (male and female)
Wetted materials	PEEK, FEP, Glass, PTFE, Silicone
Computer	Windows 11 Enterprise Touchscreen PC with Kiosk-mode operation
Consumables	
GMP Sunnies	GMP-ready glass microfluidic mixing devices of various geometries and channel sizes
Available types	Sunny 490 Trident T, Sunny 100 X, Sunny 100 T, Sunny 190 X, Sunny 190 T, Sunny 275 X, Sunny 275 T, Sunny 150 3D, Sunny 50 Micromixer
Sunbather 1-Sunny Flowpath Pack	A complete wetted flowpath for use with the Sunbather instrument running a 1-Sunny configuration.
Sunbather 2-Sunny Flowpath Pack	A complete wetted flowpath for use with the Sunbather instrument running a 2-Sunny configuration.

\* Formulation dependent





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Rev A