

Nemera





Nemera's delivery devices for fragile dermal & transdermal formulations

Nemera offers dermal delivery devices for both OTC and Prescription drugs which are recognised and appreciated by patients today. Our dermal delivery devices have been designed to ensure patient compliance thanks to precise and consistent dosing which is critical especially when applying formulations for systemic treatments. Our airless systems, pumps and valves are designed to handle a variety of formulations with different viscosities. We have extensive expertise in airless delivery systems which dispense and protect very sensitive products.



Standard dermal delivery device portfolio

- Metered pumps
- Airless systems
- Metered and continuous valves



Customised solutions based on existing dermal technologies



High volume industrialisation of your dermal delivery solutions

Quality for patients

Accurate dosing and ergonomics contribute to patient adherence to treatment. That is why, we put patients first when designing, developing and manufacturing drug delivery devices.

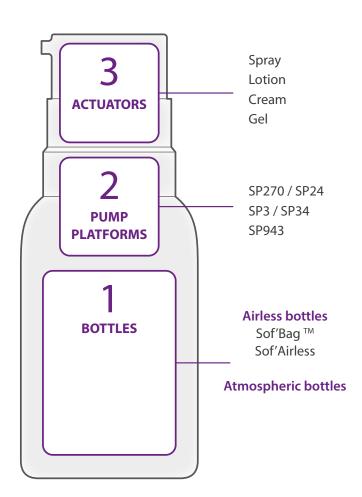
Thanks to our compliance with the most demanding specifications (EMA, FDA, USP...), our devices are well suited to deliver precise doses of topical or systemic drugs such as local anaesthetics, anti-inflammatories, hormones, antibiotics, antifungals or counterirritants for the skin.

We have dedicated facilities and GMP standards are at the core of our manufacturing and validation culture. We are committed to providing excellence in the quality of our products and services:

- Full traceability, 100% in-line controls
- ISO 9001, ISO 13485 and ISO 15378 certification
- Production according to GMP
- Manufacturing in ISO CLASS 8 clean rooms
- DMF available

OUR **RANGE**

COMBINE NEMERA'S STANDARD PRODUCTS INTO YOUR DERMAL DELIVERY SOLUTION



FITMENTS



Crimp-on

A classic solution for standard finishes, optimized to ensure easier assembly on filling lines.

This system is tamper-proof.



Reliable and easy-to-assemble option. The easy separation of the pump from the bottle supports recycling.



Snap-on

This attachment, known as an "outside neck" ensures that every container is tamper-proof and airtight.



WHAT IS AN AIRLESS SYSTEM?

- Anon-pressurised system combining a mechanical pump with an airless sealed container which dispenses the formulation without air intake
- The container is either equipped with a **piston or pouch**

WHY CHOOSE OUR AIRLESS SYSTEMS?

- Patients receive a **precise dose** and can operate the devices in **any position**
- Formulations contain only **little or no preservatives** and are **protected from oxygen, light and moisture**
- The package has an **excellent restitution rate** for optimal use of the product and **minimised waste**
- Our systems are **suitable for a wide range of viscosities** and products: fluid or viscous, creams, gels, lotions or pastes

Pouch-in-bottle technology

Upon actuation of the pump the formulation is dispensed through a collapsing pouch inside a rigid bottle.







Piston technology

Upon actuation of the pump the formulation is dispensed through the rise of a piston inside the bottle.





Complete airless packaging solutions, suitable for low viscosity solutions and highly viscous creams and gels

Sof'Bag™

A high performing airless pouch system for dermal and transdermal applications.

Sof'Airless XS

Our protective mini-airless system for small dose applications and sampling.

Sof'Airless XL

A customized dispenser for higher dose applications.







Technology	Pouch-in-bottle	Piston	Piston
Pump	SP943	SP24	SP943 customized
Dose (μl)	672, 1000, 1150 1420, 1500, 1550	45, 50, 80	1420*
Bottle (ml)	50, 100	2.05	59
Fitment	M32 Snap-on	M17E Snap-on 🚇	Screw 📳
Actuator	BP mono 4389	BP mono 9700	AB1544

^{*}Not available for anti-acne applications. Other doses available, contact us.

METERED **PUMPS**

Dermal pumps with consistent dosage for formulations with a wide range of viscosities

SP943Metered delivery for high dose applications



- Suitable for solutions and viscous formulations
- Total neutrality and compatibility:
 - no gasket
 - no contact between the bulk and the spring
- Available with the SofBag™ airless system
- Available with actuator BP mono 4389 (as shown)
- M32 snap fitment
- DMF available
- Bottle qualification support service available

Formulations	Doses (μl)		
Solutions/Oils/Gels/Creams/	672, 1000, 1150		
Lotions	1420, 1500, 1550		

SP2 AND SP3 TECHNOLOGY PLATFORMS

Precise delivery for lower doses and targeted areas

- Suitable for solutions and viscous formulations
- DMF available
- Bottle qualification support service available



	Solutions / Oil		Gel/Creams/Lotions		
	SP270 / SP270+	SP3	SP24	SP34	
DOSES (µl)	45, 50, 70*, 80, 90, 100 ,130, 140	130, 180, 200, 230	45, 50, 80	130, 180, 200, 230	
CRIMP-ON	•		•		
FEA 13mm					
FEA 20mm	•	•	•	•	
SNAP-ON					
FEA 20mm	•		•	•	
M17		•		•	
SCREW-ON					
DIN 18/10 DIN18/13 GCMI 18/415** GCMI 20/400 GCMI 20/410	•	•	•	•	

^{*}in development **pilot

ACTUATORS

DERMAL PUMPS



DERMAL VALVES

	18		5		6
Reference	918	894	4229	AA8400	585
CRIMP-ON					•

VALVES

CONTINUOUS VALVES



CV₂0

for liquid formulations

Valve 6668

for viscous products such as gels

Valve 6685

for pharmaceutical powders

A pressurized delivery solution with 2 different types of valves: continuous and metering.

KEY ADVANTAGES

- continuous valve with a neutral propellant agent (nitrogen) or liquid gases
- isolates the active ingredient from the aluminium ferrule
- fitting 🖺 FEA 20 mm

METERED VALVES



2D valves

KEY ADVANTAGES

- metered dose valve with a neutral propellant agent (nitrogen) or liquid gases
- ensures protection of active ingredients down to the last drop
- 100 µl metered dose
- fitting 🖺 FEA 20 mm

	Continuous valves Metered val			Metered valves
References	CV20	6668	6668	2D
Fitment	FEA 20 mm			
Doses (μl)	-	-	-	100
Raw materials in contact with the formulation	ion PE, polyoxymethylene, gasket raw materials, stainless steel			



The patient's voice is a key driver in Nemera's product development.

Patient insights and human factor studies are at the heart of our Innovation process.

Nemera performed a user-study to evaluate different child-resistant concepts for dermal delivery systems in 2014.

30 patients, including children, adults and seniors, took part in the study to:

- test the ergonomics, functionality and user preferences of different closure concepts
- prove that these concepts meet the regulatory requirements on child-resistance

RESULTS

Based on positive patient feedback, Nemera selected the Tab child-resistant closure for the SP9 dermal pump.

While it offers the required protection for children it is simple and intuitive to use.





- Dip tube adaptation to the selected container
- Recommendation of compatible bottle and introduction to bottle suppliers

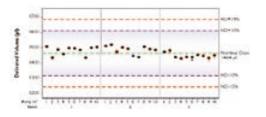
LABORATORY

Our highly qualified team has an extensive knowledge of pharmaceutical requirements to support your projects. Our laboratory is at the cutting edge of technology and is able to perform a wide range of tests related to the device performance with dermal and transdermal formulations.

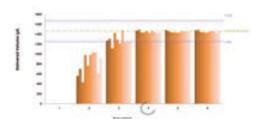
The following tests can be performed by our specialists:

- Weight loss testing according to regulatory requirements
- In-row and in-use dose testing
- Priming

DOSE CONSISTENCY ANALYSIS



PRIMING PROFILE ANALYSIS



FILLING AND PROCESSING

Filling and processing are critical to ensure good performance of our devices, especially our airless systems.

Please contact us for filling and processing advice.

OTHERS

Regulatory support at each stage of development to help obtaining market approval for your drug product

- US-DMF Type III available for our pumps
- Raw material expertise
- Pharma compliance for materials in contact with the formulation
- Extractable reports upon customer request

Nemera is a world leader in the design, development and manufacturing of drug delivery solutions.







50[†]

OVER 50 ENGINEERS IN DEVELOPMENT 30000+

OVER 30,000 SQM OF CLEAN ROOM MANUFACTURING 47

SALES IN 47 COUNTRIES *75*0

OVER
750 MILLION
DEVICES
PRODUCED YEARLY

1300⁺

OVER 1,300 EMPLOYEES

4 PLANTS IN EUROPE & THE USA



- · Neuenburg, Germany
- · La Verpillière, France
- · Le Tréport, France
- $\boldsymbol{\cdot}$ Buffalo Grove, IL, USA

OUR PORTFOLIO





ophthalmic

