

Nemera





...with Nemera delivery devices for ear, nose, throat formulations

Nemera offers standard delivery devices for nasal, buccal and auricular routes for both OTC and prescription drugs. They are recognized and valued by patients and pharmaceutical companies alike. We guarantee precision and dose consistency, to ensure an optimal treatment. The development of the new Nemera multidose nasal spray, Advancia®, illustrates perfectly our patient-oriented innovation process. The new technology pump provides outstanding performance responding to increasing regulatory requirements for nasal sprays.



Standard devices portfolio

- Metered pumps
- Metered valves
- Continuous valves



Customized solutions



Industrialization and manufacturing of customers' solutions

Quality for patients

Accurate dosing and ergonomics contribute to patients' adherence. That is why at Nemera, we put patients first when designing, developing and manufacturing drug delivery devices. Nemera proprietary products benefit from the utmost care because we know how critical they are for patients' health.

With over 50 years of experience in packaging development and industrialization, Nemera provides customers with a thorough spray expertise, and ensures the highest standards of product performance.

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

HOW TO CHOOSE FROM OUR SOLUTIONS?

Nemera proposes a comprehensive range of non-pressurized (pumps) and pressurized (valves) dispensing systems, compatible with a wide choice of actuators suitable for each delivery route (nasal, buccal, auricular, etc.).

Millions of people suffering from allergic rhinitis rely everyday on nasal sprays manufactured by Nemera.

			Pumps					Valves												
		Adv	/anci	a [®] *			SP	270/	SP27	0+				SI	P3		CV20	6668	6685	2D
	Doses (µl)	50	100	140	45	50	70*	80	90	100	130	140	130	180	200	230	CC	ntinuo	us	100
	Crimp-On																			
(4)	FEA 13 mm				•	•	•	•	•	•	•	•								
	FEA 20 mm	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
	Screw-On																			
	DIN 18/10				•	•	•	•	•	•	•	•	•	•	•	•				
	DIN 18/13				•	•	•	•	•	•	•	•	•	•	•	•				
	GCMI 18/415				•	•	•	•	•	•	•	•	•	•	•	•				
	GCMI 20/400				•	•	•	•	•	•	•	•	•	•	•	•				
	GCMI 20/410				•	•	•	•	•	•	•	•	•	•	•	•				
	Snap-On																			
	M17												•	•	•	•				
	FEA 20 mm	•	•	•	•	•	•	•	•	•	•	•								
	standard (indust in development	rial)	• pilo	ot																

We have qualified a number of rigid bottles compatible with our standard range of pumps, for a full solution.

FITMENTS



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



Screw-on

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



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

This system is tamper-proof.

NEW PRODUCTS

Advancia[®]

dvancia® is the high performing metering pump platform that patients can count on.

With accurate dosing, patients can be confident that each dose is fully delivered.

Advancia® offers a new alternative to improve treatment compliance in an increasingly demanding nasal spray market. Designed to be a step ahead of today's pumps, Advancia® is based on a new system combining user-independence and preservative-free features in one single system.

Moreover, its closing tip prevents clogging with formulations prone to crystallization.





Key product features

- User-independence
- Excellent dose consistency
- Long prime retention
- Mechanical **closing tip** to prevent clogging issues
- No metal part in contact with the formulation
- Plastic components made of **polyolefins only** (PE and PP) which comply with EP-USP-FDA regulations
- **DMF** available
- One-step snap-on process to boost productivity on filling lines
- Preservative-free version in development

As a platform, Advancia[®] offers different options (2 pump engines, 2 fitments, 3 doses) suitable for:

- Lifecycle management of off-patent allergic rhinitis products and OTC decongestants
- New combination treatments that target nasal allergies (e.g. steroids + antihistamines)
- Pipeline allergy molecules
- New drugs in development through the nasal route

	Advancia® Std	Advancia® PF*	
Fitment	Crimp-on 20 mm	Crimp-on 20 mm	
ritment	Snap-on 20 mm*	Snap-on 20 mm	
Doses (μl)	50, 100, 140	50, 100, 140	
Raw materials in contact with the formulation	PE, PP, gasket raw materials, silicone	PE, PP, silicone	
Nasal actuators	Crimp-on:	AD5701	
ivasai actuators	Snap-on: /	AD5705	

* in development



The patients' voice is the key driver of Nemera product development. Patient insights and human factor studies are at the heart of our Innovation process.

We conduct user-studies to make sure our products respond to patients' needs, and to benchmark Nemera delivery systems versus competition.

Two user studies were performed with Advancia® in 2011 and 2013 with 30 patients, including children, adults and seniors, with a double objective:

- Demonstrate the user-independence feature of Advancia®
- Benchmarck Advancia® vs. competition on dose consistency

RESULTS

Advancia® is the best performing pump, both on dose accuracy and reproducibility, independently of the user.

Users also highlighted Advancia®'s integrated Snap-on design, well-suited to today's on-the-go lifestyle.



PUMPS

SP270

The **SP270** pump platform has been used worldwide for drug delivery for more than 20 years and has a successful track record of large scale GMP production.

We continue to optimize it to respond to patients' needs and customers' requirements.

SP270

The New optimized **SP270+** pump is the result of continuous improvements to the SP270 pump platform.

The extensive range of actuators available makes these pumps easily adaptable for nasal, buccal and auricular liquid formulations, for the convenient and safe delivery of drugs to patients of all ages. The SP270 is ideal for delivering liquid solutions and suspensions.



Key product features

- Good priming and **dose consistency** through life
- Built-in pre-compression provides a fine and reproducible spray
- Materials compliant with FDA and EU regulations
- **DMF** available
- Wide range of doses (45 μl to 140 μl)
- Broad range of actuators
- Full polyolefins version upon request

BIOEQUIVALENCE

Nemera has established a Device Equivalence Program in order to respond to market enquiries in terms of nasal spray equivalence and secondsourcing needs.

Nemera proposes appropriate delivery systems to companies wishing to save time in their nasal spray development programs.

Please contact us for any request.



	SP270	SP270+
Stated doses (µl)	45, 50, 80, 90, 100, 130	50, 70*, 80, 90, 100, 130, 140
	Crimp: FEA 13 mm - FEA 20 mm	Crimp: FEA 13 mm - FEA 20 mm
Fitment	Snap: FEA 20 mm	Snap: FEA 20 mm
Fitment	Screw: DIN 18/10 - DIN 18/13 - GCMI	Other fitments under development.
	18/415 - GCMI 20/400 - GCMI 20/410	Please contact us.
Raw materials in contact	HDPE, LDPE, gasket raw materials,	LDPE, PP, gasket raw materials,
with the formulation	polyoxymethylene, stainless steel	polyoxymethylene, stainless steel

Nominal dose with distilled water may differ slightly from the stated dose.

SP3

The SP3, oversized pharmacy format, is produced to the same standards as the SP270 pump, and gives a comparable performance. All actuators for nasal, buccal, auricular and other applications suitable for SP270 platform are also compatible with SP3.

SP3 is ideal for delivering liquid solutions and suspensions, requiring higher doses than SP270.



	SP3				
Stated doses (µl)	130, 180, 200, 230				
	Crimp: FEA 20 mm				
Fitus a set	Snap: M17				
Fitment	Screw: DIN 18/10 - DIN 18/13				
	GCMI 18/415 - GCMI 20/400 - GCMI 20/410				
Raw materials in contact with the formulation	LDPE, PP, gasket raw materials, polyoxymethylene, stainless steel				

Nominal dose with distilled water may differ slightly from the stated dose.

^{*} in development



ACTUATORS

NASAL

The right shape and size for your local or systemic nasal sprays.

Fitments		L		1			1	
Reference	4345	2371 4290 - 9130	AA5733	AB3959	AB3960	4095	AA8238	8841
CRIMP-ON						<u> </u>		
SNAP-ON	-	-	-			-	-	-
SCREW-ON	-	-	-			-	-	-
Pediatric use	Х	-	X	-	-	Х	-	Х





Blue safety clip - Screw-on, Dose 100

BUCCAL

Different arms lengths for fighting buccal-pharyngeal infection.

Fitments			<u>-</u>			
Reference	9180	8940	4234	AA9994	5860	4325
CRIMP-ON		(4)		<u></u>		<u></u>
SNAP-ON		-	-		-	A
SCREW-ON		-	-		-	



AURICULAR

The right combination of actuators for ear treatment.

Fitments					
Reference	5860	9180	AA8238	AA9994	4234
CRIMP-ON				(4)	
SNAP-ON	-		-		-
SCREW-ON	-		-		-





OTHERS

Other actuators suitable for buccal, dental applications.



VALVES

CONTINUOUS VALVES



CV₂0

for liquid formulation

Valve 6668

for viscous products such as gels

Valve 6685

for pharmaceutical powders

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

ACTUATORS

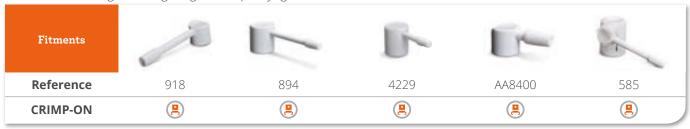
NASAL

The right shape and size for your local or systemic nasal sprays.

Fitments	1	
Reference	AA4238	AA8541
CRIMP-ON	<u> </u>	<u> </u>
Pediatric use	-	X

BUCCAL

Different arms lengths for fighting buccal-pharyngeal infection.



AURICULAR

The right combination of actuators for ear treatment.





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 customer formulations on nasal, buccal and auricular sprays.

The following tests can be performed by our specialists:

Pump performance

- dose accuracy
- strokes to prime/re-prime
- weight loss
- gasket swelling
- actuation/assembly force
- leakage test
- ageing

Spray characterization

- spray pattern
- plume geometry
- droplet size distribution



Spray pattern analysis: determination of the spray impact



Plume geometry analysis: determination of the spray angle

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
- · Buffalo Grove, IL, USA

OUR PORTFOLIO





