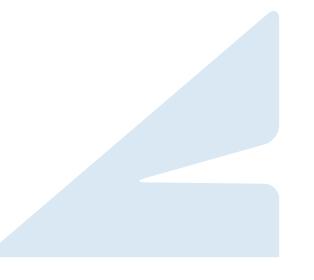






CPS Technology Platform





CPS Technology Platform

CPS is a versatile spray pump. It is designed for the multi-dose delivery of preserved or nonpreserved drug formulations for the nasal route. CPS can be used for a range of other applications which include intra-nasal vaccination.

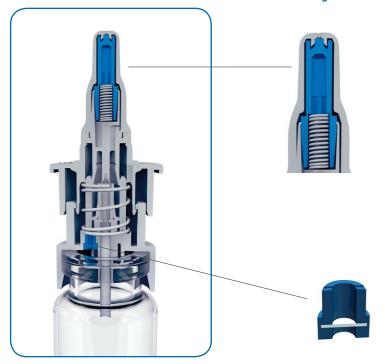
Key Benefits

- Wide range of dose volumes: 50 µl to 140 µl
- No re-priming needed even when not used regularly
- Can be sterilized by irradiation
- Gentle alternative to injection for intra-nasal vaccination applications
- One-shot mass vaccination cap available

Key Differentiators

- Anti-clogging tip seal technology to minimize crystallization with high-viscosity and high-volatile formulations
- Proven CPS filter technology avoids entrance of contaminated air into the container
- Fully validated and tested microbiological integrity
- No anti-microbial additives within the pump components
- Metal-free fluid pathway

Air Filtered Preservative Free System



Spring loaded tip seal

- no re-priming
- no crystallization

0.2 µm filter membrane filters the air flow and protects the product from contamination

Proven Microbiological Integrity Protects Your Preservative-free Formulation

- Aptar Pharma's Tip-Seal technology has been qualified by microbial challenge tests and has passed relevant worst-case simulation
- Comprehensive data package





TSIT 2.0

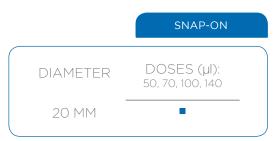
(Tip Seal Integrity Test)
Submersed actuation in
challenge suspension
containing Pseudomonas
aeruginosa, Staphylococcus
aureus and Candida
albicans. Reflects most
recently updated guidelines
in highly regulated markets.



CVIT

(Closure Ventilation Integrity Test) Closure and filter challenge with *Bacillus atrophaeus* spores in aerosol chamber.

Available Closure Types / Doses



DIAMETER DOSES (μl): 50, 70, 100, 140

Pump / Actuator / Cap Cross-Reference



The CPS spray pump is supported by the following associated Services to expedite your drug product development:



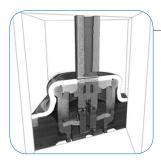
Customized Drug Delivery Solutions

- Specific designs for Rx and OTCs
- Designed and developed by multi-disciplinary project teams with a customer-centric approach
- Quality-by-Design



Analytical Laboratories

- Elastomer and plastic extractables, bioburden, silicone oil assay
- Full extractable and toxicology packages to support regulatory filing



Physical Laboratories

- Aerodynamic sizing and spray characterization
- Mechanical, stress and content uniformity testing, moisture content
- Non-destructive 3D tomography imaging
- IV BE Testing
- Fully validated Nasal Casts



Regulatory Expertise

- Dedicated regulatory affairs experts
- 30 DMFs and over 50 pass NDAs and ANDAs generated
- Fast approval data packages



Elastomer Center Research & Development

- Ultra clean, highly inert elastomer gaskets supported by validated testing and manufacturing processes
- Optimization of chemical purity
- Surface treatment for improved gasket inertness

