Drug Development & Delivery

Respiratory Drug Development

eBook
Respiratory Drug Development Edition
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Drug Development & Delivery
2025 Inhalation & Nasal Delivery eBook

New Devices and Drugs Enhance Compliance & Facilitate Improved Disease Management

By: Cindy H. Dubin, Contributor

In March, the FDA approved epinephrine nasal spray (ARS Pharma's neffy) for emergency treatment of allergic reactions, including those that are life-threatening (anaphylaxis), in adult and pediatric patients who weigh at least 66 pounds. This made the nasal spray the first and only needle-free epinephrine treatment indicated for younger children, according to Contemporary Pediatrics. Then in May, the FDA approved a 1mg neffy nasal spray for children ages 4 and older weighing between 33 and 66 pounds. Neffy was first approved in August 2024. FDA stated that neffy provides an "important treatment option and addresses an unmet need."

According to Kelly Stone, MD, PhD, Associate Director of the Division of Pulmonology, Allergy and Critical Care in the FDA's Center for Drug Evaluation and Research. "The availability of epinephrine nasal spray may reduce barriers to rapid treatment of anaphylaxis."

neffy may also reduce delays in administering treatment, as is common with needle-based options as many children fear needles. Eric Karas, Chief Commercial Officer of ARS Pharma, states that neffy may also eliminate the risk of adverse events, such as accidental injections into the hands or fingers of a child or caregiver, which he says happens about 3,500 times each year.

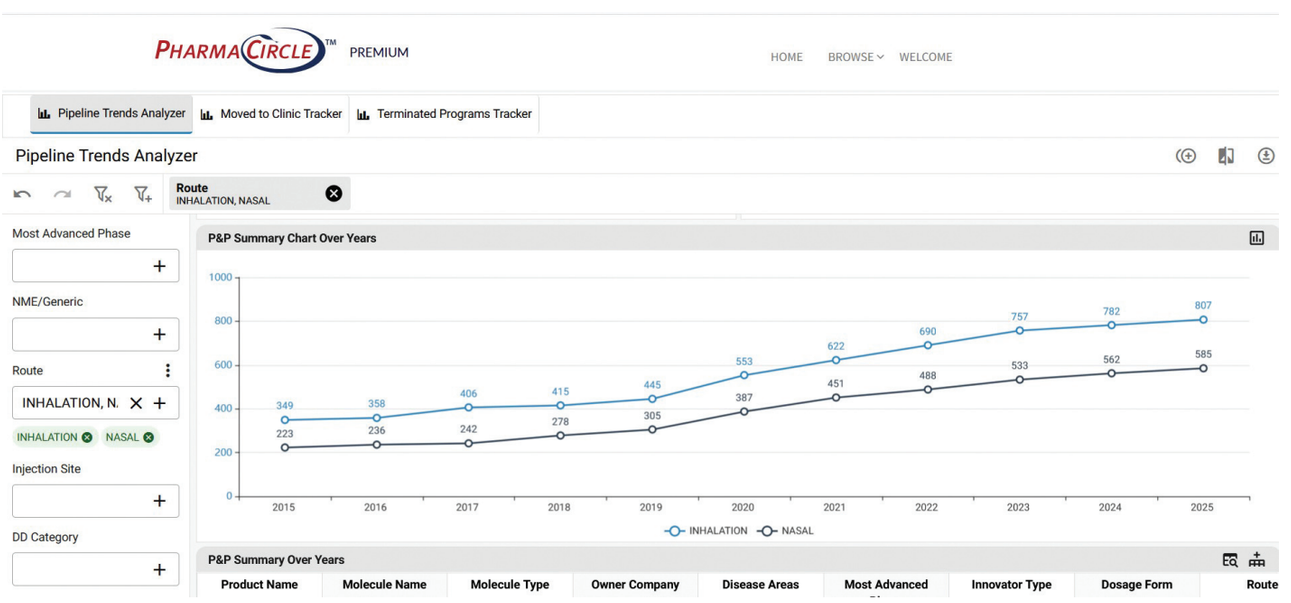
In a printed announcement, ARS states that human factor studies show 100% of users dosed neffy successfully by following instructions, compared with up to 35% error rates with injection devices.

This year has also marked several FDA approvals for inhaled delivery treatments. Liquidia Corp. received approval in May for Yutrepia ™ (treprostinil) inhalation powder for adults with pulmonary arterial hypertension. This marks the first prostacyclin dry-powder formulation enabled by Liquidia's proprietary PRINT ™ technology, which yields uniform particles designed to enhance deep-lung delivery. Ritedose Pharmaceuticals gained approval to manufacture and market generic formoterol fumarate inhalation solution (20mcg/2mL), a treatment for chronic obstructive pulmonary disease (COPD) and other respiratory ailments.

Inhalation and nasal spray therapies offer site-specific pulmonary or nasal drug delivery with rapid onset of action, improved bioavailability, and reduced systemic side effects. Innovations like smart inhalers, breath-actuated inhalers, and dose monitoring systems are transforming the market scenario, enhancing patient compliance and facilitating improved disease management. Additionally, the growth of biologics and vaccines via nasal delivery and the emergence of combination inhalation therapies are driving the sector's growth. According to PharmaCircle, the pipeline in both Inhalation and nasal has doubled in the last 10 years (**Figure 1**).

Going forward, Emergen Research predicts the Inhalation and Nasal Spray Market size will more than double to $73.5 billion by 2034 up from $36.2 billion in 2024, fueled by the increasing incidence of respiratory diseases like asthma, COPD, and allergic rhinitis, coupled with a patient shift towards less invasive, instant-action drug delivery mechanisms.

Figure 1: Inhalation & Nasal Pipeline 2015-2025



Source: PharmaCircle Pipeline & Products Intelligence

In this exclusive Drug Development & Delivery eBook, you will learn how:

- Aptar's nasal drug delivery platform provides an opportunity to reposition existing drugs or bring new therapies to market;
- Bespak is partnering with propellant suppliers and investing in capabilities that support low-carbon pMDI propellant choices;
- Nemera brings its expertise to the design and manufacturing of complex metered-dose nasal delivery devices; and
- Nipro is addressing the challenge of contamination with a silicone-free prefillable glass syringe and plunger.

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Aptar Pharma: Setting the Standard in Single-Use Nasal Drug Delivery for the Last 30 Years

By: Reenal Gandhi, Director Business Development, Aptar Pharma

With more than 30 years of real-world use, the Unidose system (UDS) by Aptar Pharma remains the only nasal spray platform in use that is approved by both the US Food and Drug Administration (FDA) and European Medicines Agency (EMA). What began as a breakthrough in single-dose delivery has grown into a recognized standard in nasal drug delivery, with over 30 successful market references and hundreds of millions of units delivered worldwide. This unique method of administration offers a non-invasive, fast-acting route that supports patient preference and reduces barriers to treatment. Backed by consistent performance, rigorous quality standards, and a proven regulatory track record, the UDS is the trusted solution for pharmaceutical and biotechnology companies seeking to provide life-changing therapies with confidence.

The Nasal Drug Delivery System Behind Some of the World's Most Impactful Therapies

When every second counts, the reliability and simplicity of nasal systems delivering life-saving medications are critical. Designed with these needs in mind, the UDS enables intuitive one-handed administration in any position with no priming, shaking or specialized handling required. Its compact, ready-to-use format eliminates the need for medical training, making it suitable for caregivers, patients or even bystanders.

The UDS is engineered to deliver every dose with precision for optimal drug efficacy, supporting partners in achieving 99.999% reliability. Designed with safety in mind, the UDS is backed by rigorous testing to ensure microbiological integrity of the product. Additionally, it features tamper-evident design and clear actuation indicators to support confidence in emergency scenarios – like opioid overdose, hypoglycemic episode, or anaphylactic shock – where simplicity and speed can save lives.

Flexible by Design and Adaptable Across Indications

More than a drug delivery system, the UDS represents a scalable, adaptable platform that supports a wide range of therapeutic applications – from chronic central nervous system and endocrine disorders to acute, life-threatening conditions. Its adaptability has enabled successful collaborations across diverse indications, with each therapy benefiting from a tailored approach that considers both patient needs and regulatory expectations.

Aptar Pharma's nasal drug delivery platform offers a variety of customization options, including liquid or powder formulations, unidose or bidose formats, and design flexibility to suit specific clinical and patient use cases, such as systemic delivery or pediatric administration. This versatility provides a unique opportunity to reposition existing drugs or bring new therapies to market, enabling partners to extend the lifecycle of their products, respond to unmet patient needs, and achieve meaningful brand differentiation.
Looking ahead, Aptar Pharma remains committed to investing in innovation, with a strong focus on nose-to-brain potential and next-generation solutions that expand what's possible for partners.

A Proven Path to Market

The UDS's long-standing regulatory and commercial success offers a reliable and validated path to market. Approvals of various active pharmaceutical ingredients by both the US FDA and EMA demonstrate compliance with the highest global standards, while the system's proven machinability ensures seamless integration into existing manufacturing operations.

Beyond the platform itself, Aptar Pharma provides comprehensive support throughout the product lifecycle. Services include formulation development support, regulatory guidance, and post-launch support such as device training, patient onboarding, and ongoing digital health solutions. This full-spectrum support helps derisk every stage of development to accelerate time to market while ensuring long-term product success.

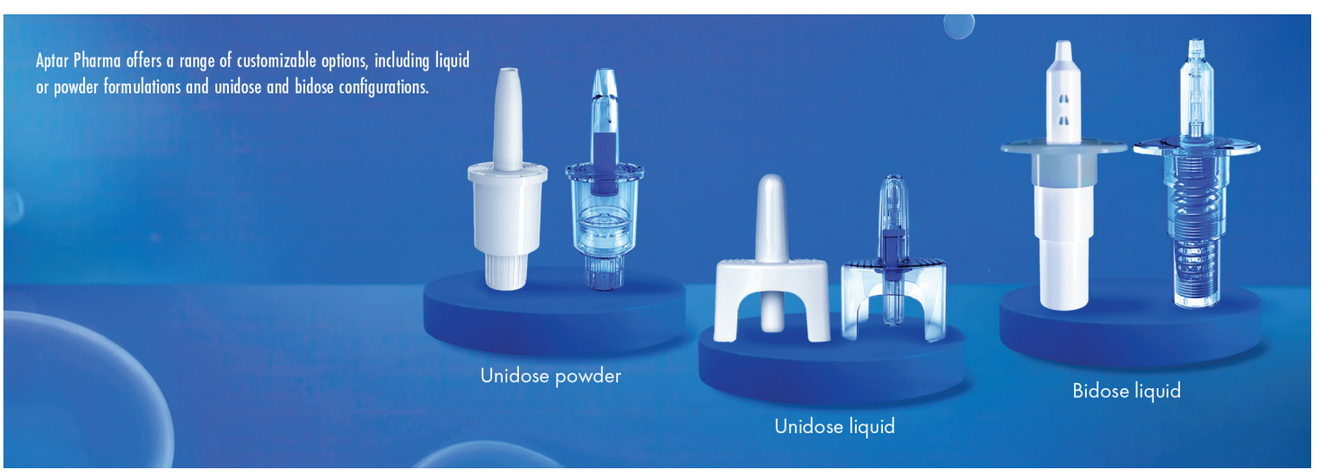
Aptar Pharma's global, dual-sourced manufacturing network ensures consistent supply and quality assurance across markets. Through strategic collaborations with a broad network of partners, including contract development and marketing organizations (CDMOs) and contract manufacturing organizations (CMOs), Aptar Pharma offers flexible production capabilities, from clinical-scale batches to high-volume commercial supply.

When Performance Matters, Expertise Leads

As therapies become more complex and patient expectations rise, dependable delivery systems play a central role in successful treatment outcomes. Whether repurposing a well-established molecule or launching a novel therapy, the UDS offers a regulatory-approved platform that has helped leading developers bring critical treatments to market safely and efficiently.

Backed by decades of nasal drug delivery expertise, Aptar Pharma continues to offer partners with not only a trusted, field-proven technology, but also a comprehensive path to successful product development and commercialization.

Learn more about the UDS platform by reaching out to the experienced Aptar Pharma team! Contact us at reenal.gandhi@aptar.com.



Decades of proven **Unidose delivery**

Trust the first single-dose nasal spray system used in U.S. FDA- and EMA-approved Unidose products; the only system with decades of successful delivery on the market.

100s OF MILLIONS
of units delivered worldwide

30+ MARKET
references

1000s
used daily

30+ YEARS
on the market*

*First-generation product.

The Unidose system (UDS) by Aptar Pharma is a market-proven platform, chosen by the world's leading pharmaceutical companies.

What began as a breakthrough in single-dose delivery has become a global nasal delivery platform. Engineered for safety, quality, and performance, Aptar Pharma's Unidose system can support you in achieving 99.999% reliability with every dose.

Aptar Pharma's nasal delivery platform accommodates a wide range of needs – from liquid or powder formulations to unidose or bidose delivery, for adult or pediatric use, whether in routine or emergency situations – making it adaptable for most indications.

Backed by decades of manufacturing expertise and a robust quality management system, Aptar Pharma helps derisk development at every stage, effectively supporting market approval and patient adoption.

When performance matters, experience leads.
Explore the Unidose platform at aptar.com/pharmaceutical.

From formulation to patient.

Aptar pharma

BESPAK

Industry Challenges in Low Carbon pMDI Manufacturing

By: Richard Turner, Head of Business Development, and Simon Gardner, Business Development Director

There is growing pressure to transition to low Global Warming Potential (GWP) propellants in pressurised Metered Dose Inhalers (pMDIs), fuelled by evolving regulations, patient and prescriber demand, and shifting market dynamics. Two next-generation propellants with significantly lower GWP than current options provide available solutions, but several manufacturing considerations must be addressed for their successful adoption. Contract Development and Manufacturing Organizations (CDMOs), such as Bespak®, can streamline the transition and help pMDI developers tackle these key challenges, outlined below.

1. Shifting regulations

The regulatory route to market for new low carbon pMDIs varies depending on the formulation and product. For example, if the only change to an approved pMDI is the propellant, clinical trials may not be needed. However, changing the propellant may necessitate changes to other device components, in which case regulators may require additional testing. The European Medicines Agency (EMA) has been in dialogue with the industry for some years to refine its regulations, whereas the US Food and Drug Administration (FDA) has only more recently opened the conversation with stakeholders. As a specialist inhalation CDMO, Bespak participates in these discussions directly, sharing insights between developers, industry bodies, and regulators to shape a clear regulatory framework that accelerates the commercialization of low carbon pMDIs.

2. Propellant choice

Selecting one of the two next-generation propellants is a key consideration for developers. HFO-1234ze has a near-zero GWP, making it a strong alternative. However, it may fall under PFAS regulation, and it is not known if there will be an exemption. On the other hand, HFA-152a has a GWP of ~138 – still significantly lower than current propellants – but is flammable and, while safe, therefore requires specific engineering controls in manufacturing facilities. Bespak has partnered with the suppliers of HFO-1234ze and HFA-152a, investing in capabilities and expertise to support customers with low carbon pMDI propellant choice, development, and commercialization.

In addition, through collaboration with HFA-152a manufacturer, Orbia Fluor & Energy Materials, DH Industries (a leading pMDI manufacturing equipment supplier), and the British Aerosol Manufacturers' Association (BAMA), Bespak has developed safe handling guidelines for the flammable propellant to support the transition.

3. Product performance

When developing pMDIs that incorporate either of the low GWP propellants, drug developers may be concerned about achieving equivalent performance compared to current products. To streamline the process of refining a formulation for high performance with a low GWP propellant, Bespak's market-leading valves, actuators, and dose counters have been optimized for both next-generation propellants during more than five years of research and development. In particular, utilizing advanced simulation tools alongside physical testing, the optimized valve platform delivers good shot weight reproducibility, low leakage, and low-moisture ingression with both propellants. As well as offering a range of components suitable for low GWP propellants, the Bespak teams have extensive knowledge of pMDI development from start to finish with both low GWP options.

4. Clinical pathways and scale-up

Ensuring supply of suitable GMP batches for clinical trials represents a critical stage in any pMDI development programme. Bespak's pilot filling capability can produce GMP batches suitable for clinical studies with both low GWP propellants. With development, pilot, and manufacturing capabilities co-located at Bespak's Holmes Chapel, UK site, the company is well positioned to support pMDI scale-up. In addition, through a collaboration with the Medicines Evaluation Unit (MEU), Bespak can provide customers with an integrated route to rapidly complete clinical trials.

5. Supply chains

As current propellants are phased down across industries, availability will decrease and prices will rise, accelerating the transition to low GWP propellants for pMDIs. In addition, geopolitical events can disrupt global supply chains, so long-term supply security is a priority. Bespak has taken steps to shorten and on-shore the pMDI supply chain through strategic, local collaborations, creating a robust network within the UK. This also decreases the carbon emissions associated with transportation, contributing to the industry's wider efforts towards decarbonisation.

Tackling challenges together

With the green transition progressing at pace, pMDI developers must prepare to navigate a low GWP propellant future. By partnering with a CDMO at the forefront of the transition, developers can leverage the groundwork already in place to accelerate life-saving, low carbon inhalers to those who need them.

BESPAK

UNCOVER NEW POSSIBILITIES

Discover our development, clinical and commercial capability for low carbon pMDIs with HFA-152a & HFO-1234ze.

THE SPECIALIST INHALATION CDMO
LEADING THE GREEN TRANSITION

- Analytical and formulation
- Drug product development
- Device design and development
- Regulatory support
- Clinical supply
- Scale up and tech transfer
- Commercial supply

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we put patients first

Precision, Safety, & Speed: UniSpray for Acute, Crisis & Emergency Nasal Drug Administration

By: Séverine Duband
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Nemera
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Nasal drug delivery offers a non-invasive alternative that empowers patients to self-administer medication quickly and conveniently, eliminating the need for healthcare professional intervention typically required with injectables. The needle-free nature of nasal devices improves patient acceptance, which in turn fosters better adherence and compliance, and can ultimately improve therapeutic outcomes.

The nasal drug delivery field is experiencing significant evolution with growing interest and further research on targeting the nasal turbinates – highly vascularized structures with extensive surface area – to facilitate efficient systemic drug delivery via the nasal route.

An expanding range of systemically acting drugs have been successfully formulated as non-invasive metered unit-dose nasal sprays, enabling rapid and user-friendly administration with fast-onset of therapeutic action. Examples include naloxone in Narcan® and nalmefene in OPVEE® for opioid overdose; epinephrine in Neffy® for anaphylactic shock; and Zavegepant in Zavzpret™ for migraine relief. These patient-centric medicines, enable patients and caregivers to administer one-shot sprays easily and rapidly to manage emergency and crisis situations, such as overdoses, seizures and migraines.

UniSpray, Nemera's single-dose nasal spray device, delivers a metered 100µL dose, and provides a platform solution for new, repurposed, or generic drug formulations. Designed for acute, crisis and emergency use, UniSpray is a ready-to-use, primeless device featuring 360° actuation and ergonomic one-handed operation, ensuring ease and reliability under critical conditions.

To ensure device reliability and robustness, as well as compliance with regulatory requirements, UniSpray has undergone comprehensive human factors studies, design verification and rigorous processes, assuring both patient safety and ease of use. The device has an ergonomic and intuitive design to ensure its correct use. Upon activation, the device's plunger locks securely, preventing accidental re-use and providing a clear visual confirmation that the dose has been delivered – an essential safety feature for emergency administration. The final locking also prevents device disassembly after activation.

UniSpray is compatible with existing marketed primary drug containers and has been adapted to fit conventional filling lines. It also provides a customizable platform, offering flexibility for spray adjustment for reposed drugs, new formulations, and generics
Regulatory agencies enforce stringent standards for nasal drug-device combination therapies, demanding specific performance reliability criteria and in the case of generics – bioequivalence to the original market reference form – both aspects are particularly critical for life-saving therapies – to guarantee patient safety and therapeutic efficacy. UniSpray is compliant with the FDA's strict reliability specifications for rescue and emergency medicines. In addition, Nemera's *in vitro* testing capabilities deliver the analytical data required to support in vitro bioequivalence dossier registration filing for generics.

In line with the fundamental principle of integrating patients into combination product development, Nemera places patient needs at the heart of its process. The company leverages extensive human factors expertise to conduct thorough usability studies, ensuring each device is intuitive, safe, and effective for its intended population. By mapping the patient journey and tailoring user instructions to specific groups, both safety and the overall user experience for every drug-device combination is optimized.

We support our partners by adapting instructions for use to meet the needs of diverse target populations and by guiding human factors activities in accordance with the chosen regulatory pathway, whether for Abbreviated New Drug Applications (ANDA) or New Drug Applications (NDA). Such support helps ensure that the selected device, when paired with the drug, is not only appropriate but also meets the highest standards of safety and efficacy for end users.

Nemera brings extensive expertise in the design and manufacturing of complex metered-dose nasal delivery devices, supported by a state-of-the-art GMP facility producing millions of metered-dose nasal spray pumps annually. Our expertise in spray characterization and bioequivalence has made it possible to commercialize a wide variety of combination products, ultimately enabling the delivery of vital medicines and therapeutic relief to millions of patients.

Amid growing interest in systemic therapies delivered via the nasal route, our robust device platforms – combined with an integrated, end-to-end development approach – empower pharmaceutical partners to bring innovative drug-device solutions to patients efficiently. With its comprehensive capabilities and commitment to quality, Nemera is a trusted partner, accelerating the successful development and market launch of advanced nasal drug-device combination therapies.

Note: NARCAN® is a registered trademark of Emergent Operations Ltd. OPVEE® is a registered trademark of Opiant Pharmaceuticals Inc. Neffy® is a registered trademark of ARS Pharmaceuticals, Inc. ZAVZPRET™ is a registered trademark of Pfizer Ireland Pharmaceuticals.

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Metered-dose nasal spray for seamless delivery of life-saving and crisis therapies.

UniSpray

Live Longer. Live Better.

Less Material for More Stability: D2F™ Pre-fillable Glass Syringes – Silicone Oil Free

By: Charlotte Ostrowski-Leconte, Product Portfolio Manager, Pre-fillable Syringes/Product Development, Nipro PharmaPackaging

As the pharmaceutical landscape continues to evolve, biologic drugs have emerged as the dominant force in injectable therapies, now accounting for over 80% of the drug pipeline.[1] These complex, cell-derived molecules offer targeted treatment for various chronic and life-threatening conditions. However, their structural complexity and sensitivity to environmental factors, such as temperature, light, pH, mechanical stress, and contamination, pose significant challenges for drug formulation and delivery.

One potential source of contamination arises from the use of different materials within the primary packaging system, which may lead to interactions with the filled drug product. Pre-filled glass syringes are widely used for biologics due to their inherent advantages, including a ready-to-use format, reduced risk of dosing errors, and user-friendly handling. However, pre-filled syringes contain several materials that come into direct contact with the drug product. For example, silicone oil, often used as a lubricant for smooth plunger movement, can interact with biologic molecules. This interaction may lead to protein aggregation, immunogenic responses, and the formation of visible or subvisible particulates, all of which can compromise drug safety and efficacy. [2,3,4,5,6,7]

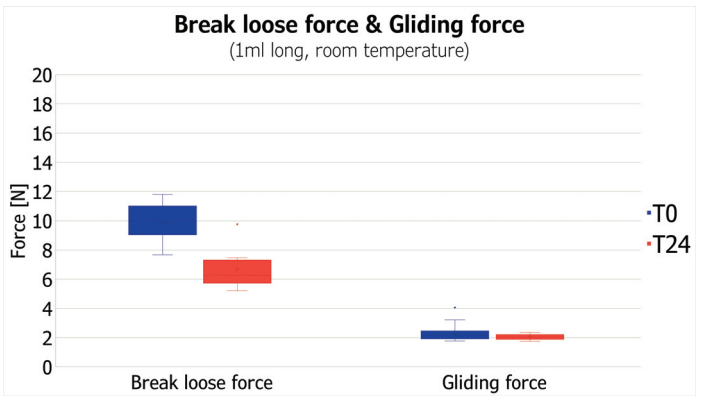
A Silicone-Free Solution for Sensitive Biologics

To address these challenges, Nipro has introduced the D2F™ Pre-fillable Glass Syringe – Silicone Oil Free, that incorporates a silicone-oil-free elastomeric plunger, creating a fully silicone-free system that minimizes interaction risks while maintaining high performance.

Performance Without Compromise

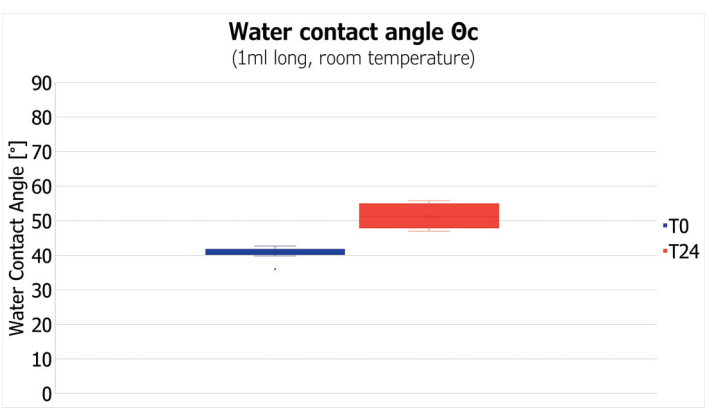
Removing silicone oil from the syringe barrel could potentially affect key functional attributes. To ensure performance integrity, the D2F™ system has undergone rigorous testing across several critical quality parameters:[8]

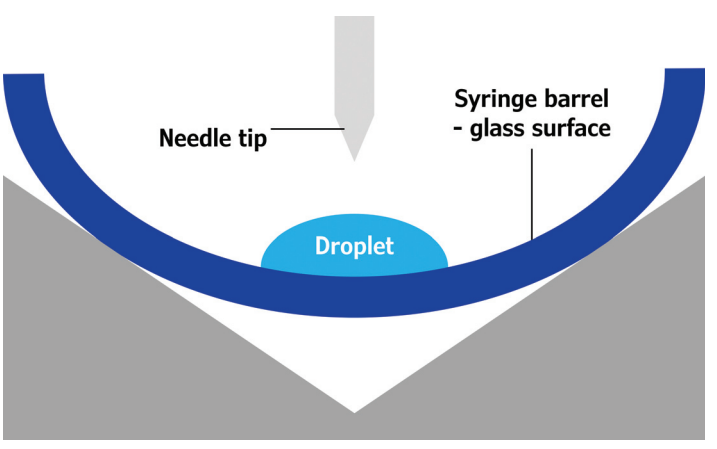
1. Smooth Plunger Movement[9]
Despite the absence of silicone oil, D2F™ syringes demonstrated consistent break-loose and gliding forces, ensuring reliable and smooth plunger performance.

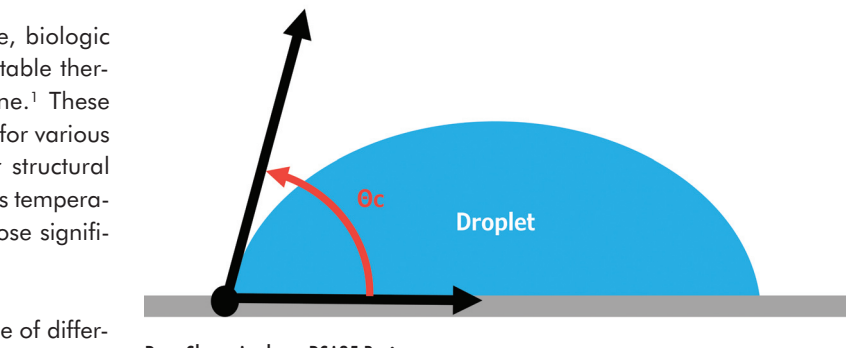


This is achieved through:
- Plunger stopper characteristics; the stopper design, combined with the fluoropolymer barrier on the coated plunger, contribute to smooth and consistent gliding performance; and
- Hydrophilic glass surface with high wettability, controlled by water contact angle[10] measurement.

The data confirms that the water contact angle does not exceed 90° and hereby confirms a hydrophilic glass surface over time.







Drop Shape Analyzer DSA25 Basic
A droplet of water (WFI) is generated on the tip of the needle Amount: 1–2 µl (DIN 55660-2:2011-12, 2-6 µl recommended). After the water (WFI) droplet is on the glass surface, the water contact angle (θc) is immediately measured.

These characteristics ensure reliable and smooth plunger operation, essential for both manual and automated injection systems.

2. Lower Particulate Burden (absence of silicone)

Light Obscuration Particle Count Test					
Syringe 1ml long, staked needle (particulate free water)	≥ 2 µm	≥ 5 µm	≥ 10 µm UTL 600 particles	≥ 25 µm UTL 60 particles	> 50 µm Visible
T0 n=100 **silicone oil free**	**612**	**115**	**29**	**0**	**0**
T0 n=160 **silicone oil** 0.55 mg ± 0.15 mg	**2,122**	**768**	**109**	**2**	**0**

Using light obscuration testing, the D2F™ syringes showed significantly reduced visible and subvisible particles, well below the limits defined in European Pharmacopoeia (EP) 2.9.20 and 2.9.19. This is a critical advantage for biologics, where even minimal particulate contamination can trigger immune responses or reduce therapeutic efficacy.

3. Container Closure Integrity[11]
All tested syringes have passed stringent leakage tests, verifying container closure integrity (CCI). This ensures long-term sterility and protection from environmental contaminants.

ENHANCE Quality for Demanding Applications

The D2F™ Pre-fillable Glass Syringe – Silicone Oil Free is delivered in ENHANCE quality, a standard developed to meet the stringent requirements of sensitive drug products. Key benefits include:
- Excellent Drug-Container Compatibility: Minimizes the risk of chemical interaction and drug degradation, contributing to product stability and safety;
- Seamless Integration with Auto-Injectors: Designed for compatibility with auto-injection devices, supporting patient-friendly and reliable drug delivery;
- Optimized Processability: Engineered to reduce drug loss during filling and handling, enhancing efficiency across the supply chain; and
- Comprehensive Data Package: Facilitates faster regulatory approval and smoother market entry, backed by extensive validation and testing.

Conclusion

As biologics continue to dominate the injectable drug market, the need for adapted primary packaging solutions have become increasingly urgent. Nipro's D2F™ Pre-fillable Glass Syringe – Silicone Oil Free offers a robust solution for drug products that are sensitive to silicone oil. By eliminating silicone oil and offering a solution in ENHANCE quality, D2F™ Pre-fillable Glass Syringe Silicone Oil Free delivers enhanced stability, safety, and reliability – supporting that sensitive drugs reach patients in an effective form.

Delivering trust with each primary packaging solution.

More information on our D2F™ Pre-fillable Glass Syringes – Silicone Oil Free

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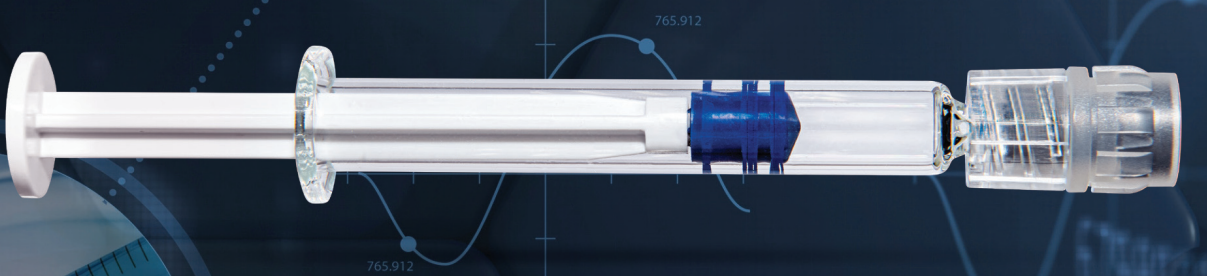
9. NPG protocol 3_QC_T_8_515_01 | LF Plus tensile force tester | Speed: 200 mm/min
10. DIN 55660-2:2011-12 | Drop Shape Analyzer DSA25 Basic
11. Nipro Internal protocol | LF Plus tensile force tester | Speed until pressure build-up: 60 mm/min | Test pressure: 6 N | Test period: 20 sec

SILICONE OIL-FREE

D2F™ Pre-fillable Glass Syringes

SILICONE OIL-FREE



For Biotech & Ophthalmic drug products

Excellent drug-container compatibility

Smooth integration into auto-injection devices

Optimized processability for minimal drug loss

successful testing of key quality attributes: break loose force,gliding force, particle count, container closure integrity, leakage, water contact angle

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