



DF30 Technology Platform



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Aptar Pharma is the world-leading supplier of aerosol metering valves. The metering valve is a key sub-system of a pMDI which enables an accurate and repeatable dose of drug to be delivered as a fine aerosol to the patient's airways.

Our DF30 metering valve platform has been the industry gold standard for more than 25 years and is constantly improved and optimized.

Aptar Pharma continues to set new standards in the design, use of materials, manufacture and control of metering valves. We offer a variety of off-the-shelf valve configurations and value-added services to meet all of our stakeholders' requirements.

Key Benefits

- Suitable for both solution and suspension-based formulations
- Compatible with all pMDI filling technologies
- Robust designs guaranteeing accurate and consistent performance (seal, dose, aerosol, etc.)
- Complete services and support to allow faster regulatory approval of your pMDI drug product
- Customer trust in our robust supply chain.

Key Differentiators

- [Proprietary elastomer](#) formulations designed for specific therapeutic applications
- Our dedicated in-house Elastomer Center which develops, improves and manufactures [ultra-clean elastomers](#)
- Three valve manufacturing facilities strategically located across Europe and Asia
- Extractable and toxicology dossiers to support/expedite your regulatory filings



Aptar Pharma's Elastomer Center

Elastomer Center

Elastomeric seals for valves are critical components that must maintain their function and chemical integrity within the challenging environment of the pMDI container closure system over the life-time of the drug product. To ensure these challenges are met, Aptar Pharma continues to develop and improve its elastomeric materials to offer the following benefits:

- A selection of ultra clean, highly inert elastomer gaskets, including: EPDM, thermoplastic elastomer (TPE) and [our novel COCe](#)
- Specific gasket designs (dynamic and static sealing)
- Extensive testing in our labs to challenge our gaskets and valves with a variety of drug formulations
- Customer trust: each year over 2.5 billion gaskets are manufactured at our Elastomer Center for subsequent use in Aptar Pharma valves and pumps

Our Novel COCe Material (static sealing gasket)

This novel Cyclic Olefin Copolymer sealing material presents a unique combination of properties which can be customized by varying the chemical structure of the copolymer. Aptar Pharma has developed and manufactures a component that offers ultra low extractables in conjunction with low water absorption and excellent static leakage barrier protection properties.

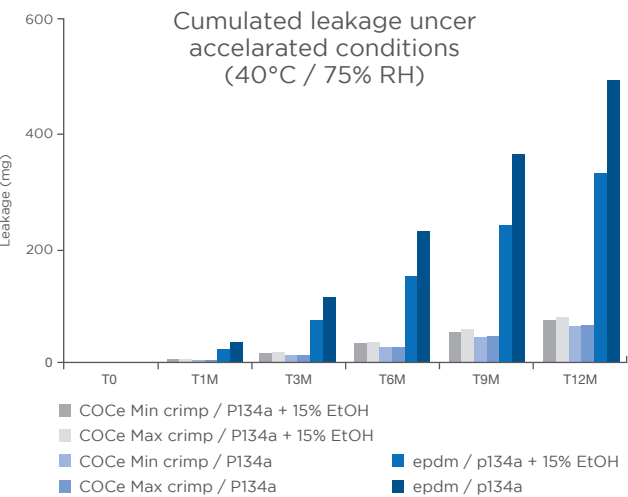


Fig. 1- Static leakage measured at various crimp parameters

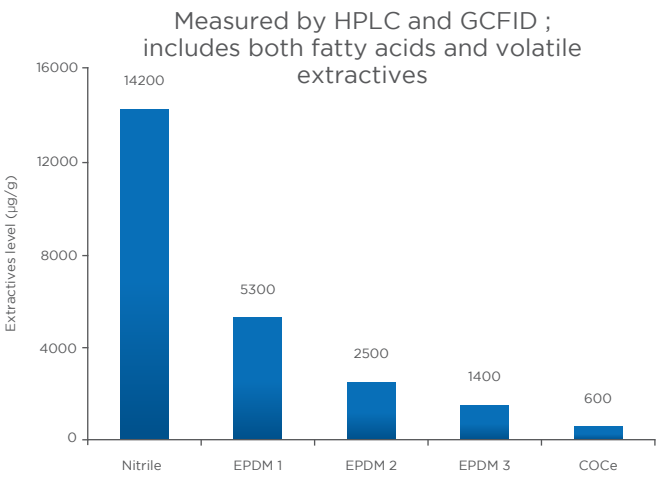
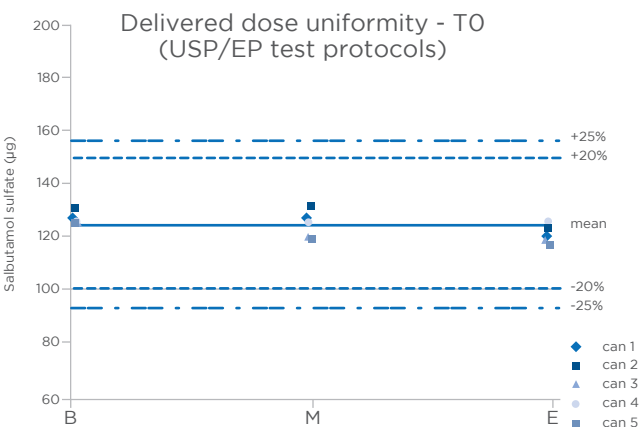
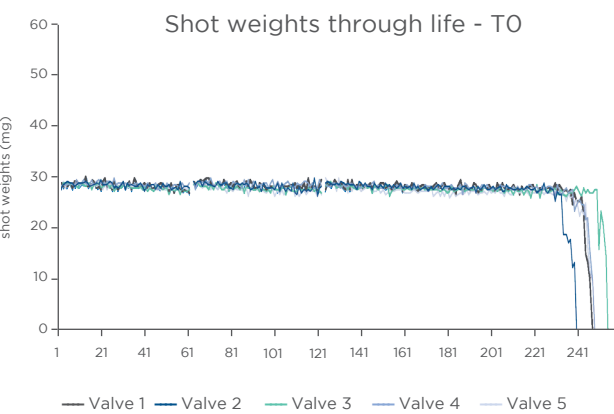


Fig. 2 - Extractable levels of various Aptar Pharma gasket materials

Df30 Product Range

Valve Ref. (20mm)	Stem Design + diameter (mm)	Metering Chamber (µl)	Materials				
			Metering Chamber & Body	Stem (upper/lower)	Elastomers (Dynamic)	Elastomer (Static)	Gathering Ring
DF316	RCU 3.16	25, 50, 61, 75	Acetal (POM)	POM	Nitrile or EPDM	Nitrile, EPDM or COCe	Polyamide
DF30Plus or DF316Hybrid		28, 50, 63	Polyester (PBT)	POM or PBT	EPDM	EDPM or COCe	Polyamide or Polyethylene

DF30 Performance



Figures 3 and 4: Shot weight and delivered dose uniformity from the beginning to the end of the lifespan - Salbutamol HFA 134a & 15%EtOH

The DF30 platform is supported by the following associated Services to expedite your drug product development:



Customized Drug Delivery Solutions

- Designed and developed by multi-disciplinary project teams with a customer-centric approach
- Quality-by-Design



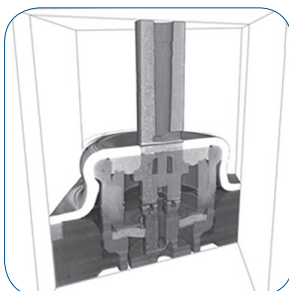
Formulation, Filling, Packaging And Valve Sampling

- Technical support in formulation development
- Pilot filling equipment for R&D studies
- Off-the-shelf formulation packages available
- Dedicated technical expert to support clients (on-site) with crimping & filling enquiries
- Dedicated sampling lab to expedite valve sampling enquiries



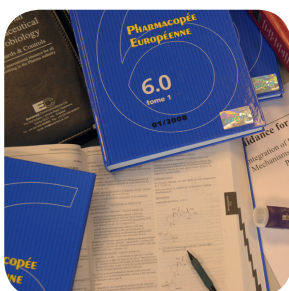
Analytical Laboratories

- Elastomer and plastic extractables, bioburden, silicon 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



Regulatory Expertise

- Dedicated regulatory affairs experts
- 30 DMFs and over 50 pass NDAs and ANDAs generated