

Rexam precision metering valves thoroughly consistent

Rexam offers a metering valve platform for inhalation treatments combining different gasket materials and plastic resin choices. The valves have been validated to operate with HFA gas and they demonstrate very consistent performance up to 30% alcohol formulation.

Rexam expands the range of its proprietary metering valves.

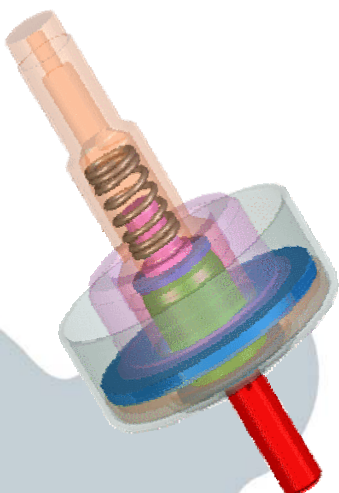
The right valve, for inhalation drug treatment, combines:

- **Reliable performance** through product life (shot weight, priming)
- Drug compatible gasket and plastic material. Rexam has selected the best materials (plastics and elastomeric seals) in terms of mechanical performances and **extractables control**
- **Seal performance** (leakage, moisture ingress). Rexam did not only select upgraded gaskets and plastic materials but also validated valve performances for optimum pMDI delivery

Validation tests are performed based on **international regulatory requirements** including FDA Guidance, Guideline EMEA, ISO 20072, European Pharmacopoeia 2.9.18, European Pharmacopoeia 2.9.27 and US Pharmacopoeia <601>

Testing conditions of valves combines different criteria:

- **Filling combination** (HFA, HFA and 30% alcohol)
- **Storage conditions** of canister and valves: positions (upright, sideways, upside down) and temperature of controlled environment (at room temperature, at 40°C - 70% humidity rate)
- **Duration of storage**: 2 weeks, 1 month, 3 months, 6 months



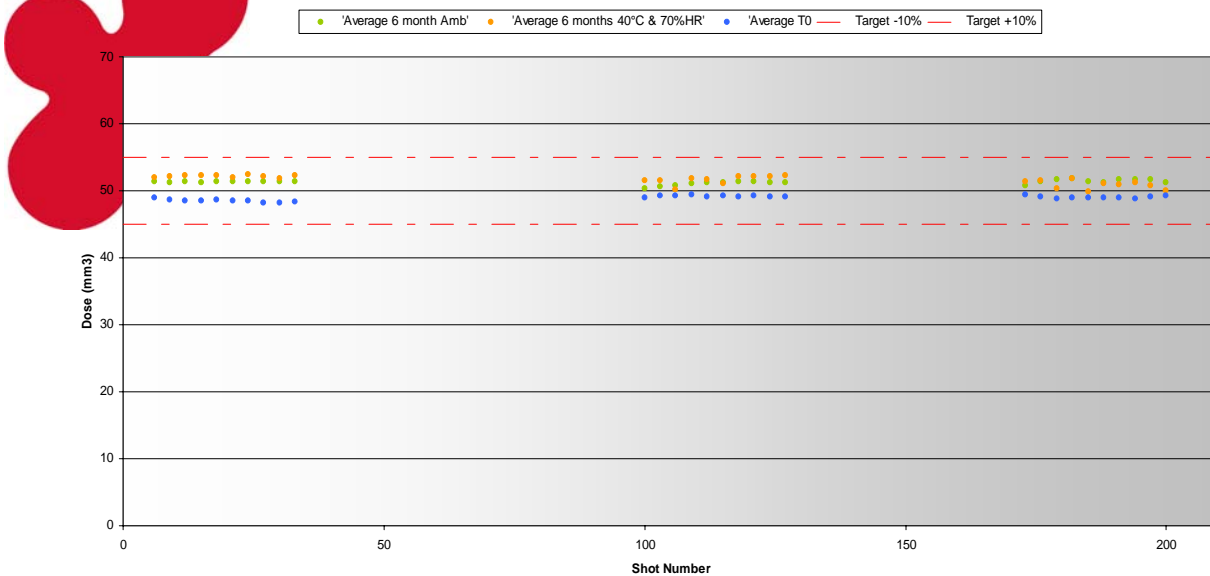
Rexam has 25µl, 50µl and 100µl valves available; 63µl dose is under qualification.

Examples of Rexam standard testing for metering valve performance:

- **Shot weight consistency** up to 200 doses – even with 30% alcohol formulation and after 6 months storage at ambient or 40°C – 70% humidity rate storage conditions.

Measures presented were manually recorded with up to 10 different testing users. These good results not only proves excellent shot weight consistency of the valve performance but also the **user independent** feature of the valve itself.

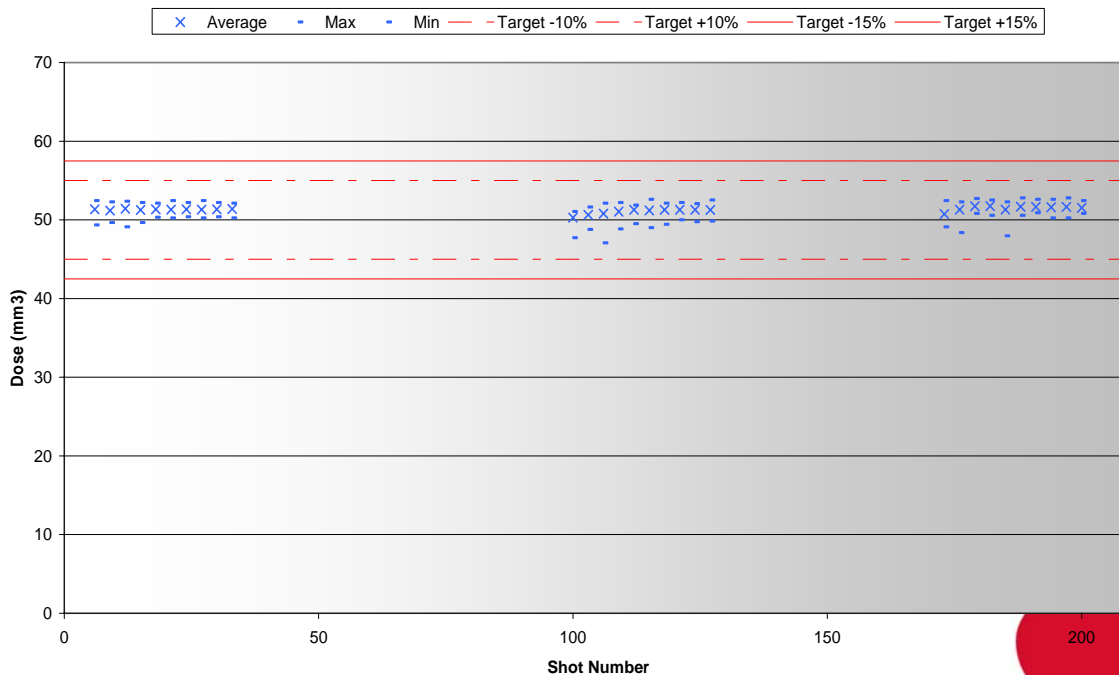
Shot Weight – 100% HFA
Average measures at initial and after 6 months storage
(ambient temperature and 40°C)



The valve performance is very reproducible and present, within regulatory criteria, little individual dose variations (see below maxi and mini values).

Shot Weight – 100% HFA after 6 months storage
Mean on 25 valves, with maximum and minimum values

Shot Weight - 100%HFA - Test T = 6 months T°Ambiant - Individual values for 25 valves



- Rexam valves present an **excellent prime retention** (see graph below even after 6 months storage at 40°C). No need to prime or reprime the valve after storage not only guaranties the constancy of dose delivery but also ensures patients' best compliance with treatments.

Prime retention- 100% HFA 6 months storage 40°C - 70%HR



Please consult us for details of proprietary valves portfolio.
Our development teams and our laboratory will assist you in your choice.

mailboxpharma@rexam.com
www.rexam.com/pharma