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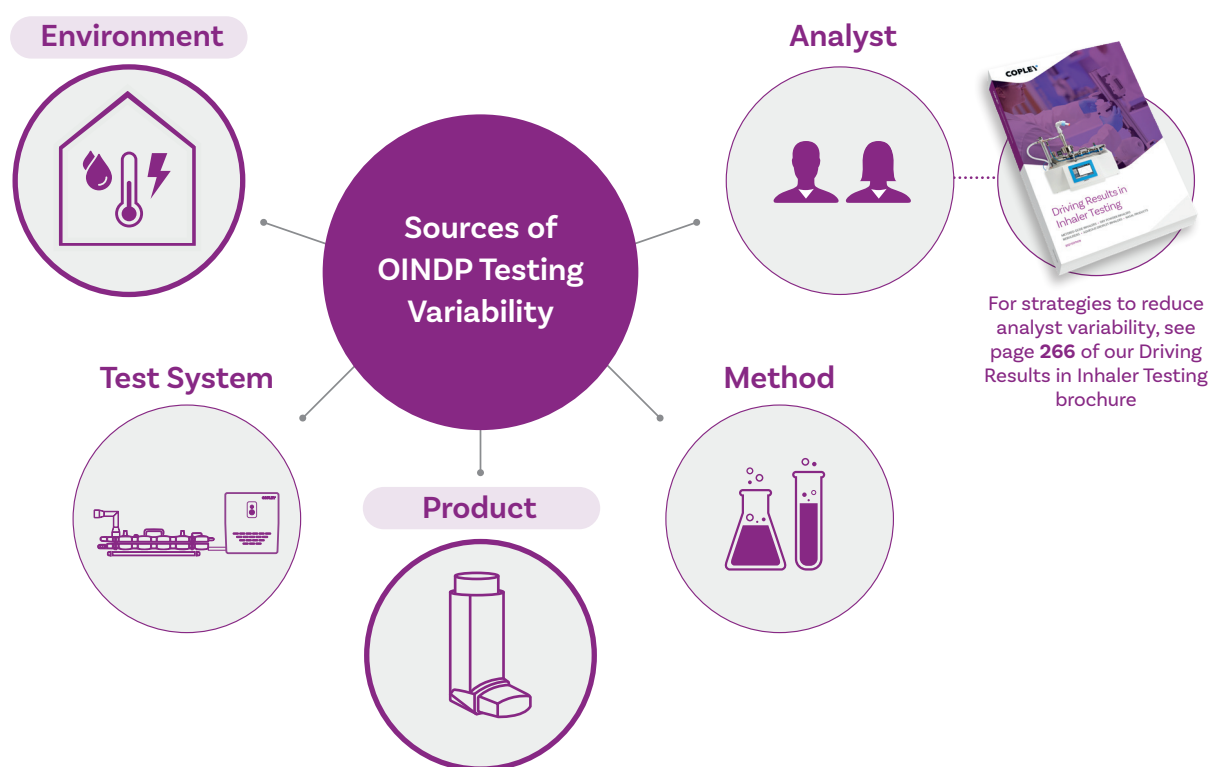
EnviroMate™

Benchtop Environmental Chamber

2023 Edition

OINDP Testing Variability and Environmental Conditions

Many factors have been identified that could give rise to variability in the testing of orally inhaled and nasal drug products (OINDPs). Each of these factors reduces the discriminatory power of tests to accurately determine product variability. Effective strategies to mitigate sources of variability in delivered dose uniformity (DDU) testing and aerodynamic particle size distribution (APSD) measurement have been the focus of rigorous investigation for many years. Environmental conditions is one key area.



Localised changes in laboratory temperature and humidity, and also the presence of electrostatic charge, are known to have a direct influence on the dose emission and aerosol generation performance of OINDPs, thereby compromising DDU and APSD test data integrity.



TEMPERATURE

- Particle/droplet evaporation effects for MDIs, nebulisers, ADIs, nasal sprays and aerosols
- Accuracy of volumetric air flow rate measurements during testing



HUMIDITY

- Particle/droplet evaporation effects for MDIs, nebulisers, ADIs, nasal sprays and aerosols
- Water absorption effects for hygroscopic powder-based DPI formulations
- Electrostatic charge-related issues exacerbated by low humidity



ELECTROSTATIC CHARGE

- Device generated triboelectrification of particles (via drug, propellant, metering valve system, inhaler materials, packaging etc.)
- Analyst-induced electrostatic effects (via clothing, handling)

Use of proper control mechanisms

Ph. Eur. and USP specifically reference the control of environmental conditions in cases where temperature and/or humidity limits are stated on the product label and/or it is specified in the relevant monograph.

However, it is also good practice to implement environmental controls across all DDU and APSD testing applications to reduce variability and improve the accuracy, sensitivity and reproducibility of data.

EnviroMate™

Inadequate control of environmental conditions can affect the dose emission and aerosol generation performance of OINDPs, leading to erroneous data and costly testing delays. EnviroMate is a cost-effective, compact, benchtop solution that addresses these issues with considerable value for scientists faced with:

- variable laboratory conditions or inadequate climate control
- OINDPs with high sensitivity to temperature, humidity and/or electrostatic charge
- poor reproducibility and unexplained out-of-specification (OOS) results
- achieving better environmental control, in a cost-effective manner, without investing in a dedicated climatically-controlled laboratory for testing

Accommodating all types of dose uniformity sampling apparatus and cascade impactor, EnviroMate controls and maintains uniform temperature and humidity throughout the chamber, whilst the built-in anti-static system helps minimise the unwanted effects of electrostatic charge.

Ideal for those struggling to achieve stable conditions for delivered dose uniformity (DDU) and aerodynamic particle size distribution (APSD) testing, EnviroMate provides users with consistent environmental control, in the immediate test area, enhancing data accuracy and repeatability.



Designed specifically for OINDP testing



Evenly distributes temperature and humidity throughout



Minimises electrostatic charge



Environmental control referenced in Ph. Eur. and USP



Compact, benchtop solution



No routine maintenance required

Key Features:



Sensitive temperature and relative humidity sensor ensures accurate performance
Adjacent holder for BAC 100i/TPK 100i Temperature and Relative Humidity Sensor included



Anti-static system minimises electrostatic-induced variability



Internal light maximises visibility



Easy-to-remove water supply/waste reservoirs



Temperature and relative humidity parameters are easily set and clearly visible to users



Large, slot-sealed entry ports enable easy handling of test equipment



A large, hinged door provides easy access



Access ports and built-in quick-release connectors accommodate a wide range of ancillaries, such as flow controllers and vacuum pumps



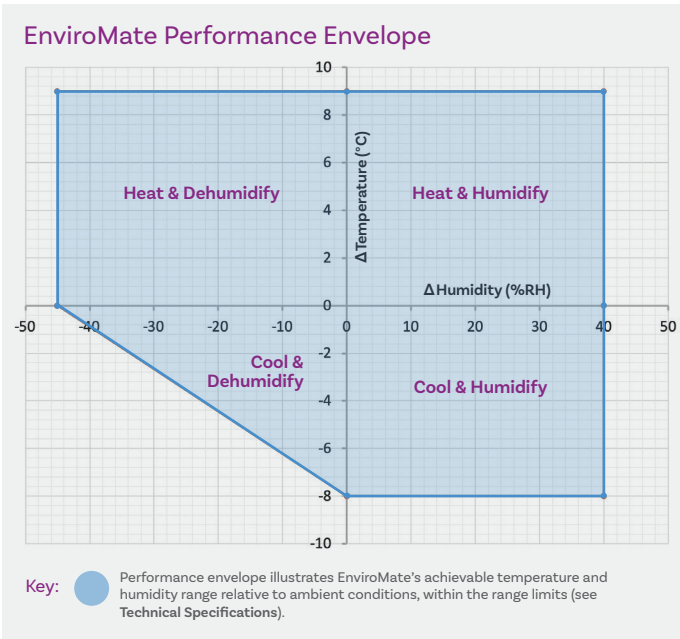
EnviroMate™ Performance Data

EnviroMate has been specifically designed to accommodate a wide range of inhaler testing apparatus, including:

- Next Generation Impactor (NGI) and Glass Twin Impinger (GTI)
- Inhaler Testing Workstation™ ITW with DUSA for MDIs and DPIs, Waste Shot Collector WSC2, Andersen Cascade Impactor (ACI) and Multi-Stage Liquid Impinger (MSLI)

EnviroMate can also interface with the BRS 200i and NGI Cooler™ for nebuliser testing, and flow controllers and vacuum pumps for testing of other OINDPs.

The graph opposite shows the performance envelope of the EnviroMate, with the shaded area defining the optimal performance range.



EnviroMate™ Technical Specifications

User Interface	Digital display with set-point control buttons
Ambient Temperature	16 - 28°C
Temperature Control Range	17 - 35°C
Temperature Control Accuracy	Typically ±2°C
Ambient Humidity	35 - 85% RH
Humidity Control Range	15 - 85% RH
Humidity Control Accuracy	Typically ±5% RH
Electrostatic Minimisation System	Included as standard
Ancillary Connector Ports	2 x ports for quick-release connectors (left and right) 2 x ports for cables (left and right) 2 x ports for interface with BRS 200i and NGI Cooler™ (right)
Sound Level	63 dBA at 1m
Power Supply	Mains supply: 230V, 50Hz or 115V, 60Hz
Compressed Air Supply Fitting	6 mm OD Push-Fit
Pressure	5 to 8 bar (G)
Capacity	280 litres
Unit Dimensions (w x d x h)	1258 x 761 x 890 mm



EnviroMate with Next Generation Impactor (NGI)



EnviroMate with Inhaler Testing Workstation™ ITW and DUSA for DPIs



EnviroMate with Andersen Cascade Impactor (ACI)



EnviroMate with Breathing Simulator BRS 200i for nebuliser testing



EnviroMate with NGI Cooler for nebuliser testing

EnviroMate™

Cat. No.	Description
5040	EnviroMate™ Environmental Chamber
5042	IQ/OQ Documentation for EnviroMate™
5043	Qualification Tools for EnviroMate™
5044	Recalibration of EnviroMate™ Qualification Tools




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