Validation data for the new MAS-100 Sirius

MBV AG showcases the MAS-100 Sirius as the advanced successor to the MAS-100 NT®, offering significantly enhanced capabilities for quantitative monitoring of airborne viable particles in cleanrooms.

The MAS-100 Sirius® is the successor of the microbial air sampler MAS-100 NT®. It is designed for reliable monitoring of viable airborne particles in GMP-compliant cleanroom environments in pharmaceutical manufacturing.

To go beyond standard requirements of air sampler qualification according to ISO 14698 Annex B and EN 17141 Annex E and to ensure comprehensive validation of the instrument's performance, MBV AG applied an extended validation strategy inspired by guidelines for alternative and rapid microbiological methods (ARMM), including Ph. Eur. 5.1.6, USP <1223> and PDA Technical Report No. 33. It included the validation of the four parameters: equivalence, ruggedness, robustness, and specificity. Although the MAS-100 Sirius is not classified as an ARMM, these guidelines offer a sound scientific basis for performance validation akin to chemical method validation as per ICH Q2(R2).

To confirm the MAS-100 Sirius's reliability in routine cleanroom monitoring, the following tests were performed (**Table 1**):

Table 1: Overview of the different performance characteristics applied to the new MAS-100 Sirius.

TESTING	TEST DESCRIPTION	PERFORMANCE CHARACTERISTICS
Equivalence to predecessor instrument	Side-by-side air sampling of the MAS-100 Sirius and its predecessor the MAS-100 NT to show that both instruments enumerate the same number of colony-forming units (CFUs).	Equivalence
Instrument-to-instrument reproducibility	Demonstrate that different MAS-100 Sirius units yield equivalent CFU counts when operated side by side under identical environmental conditions.	Ruggedness
Lid interchangeability	Verify that using different perforated lids of the same type does not significantly affect CFU recovery, ensuring consistent results regardless of the specific lid used.	Ruggedness
Lid orientation independence	Confirm that the orientation (angle) of the magnetic perforated lid has no effect on microbial recovery, validating the robustness of the design in everyday handling.	Ruggedness
Agar-plate-type compatibility	Ensure that different agar plate formats (90mm settle plates, 55mm contact plates, and Growth Direct® cassettes) do not affect CFU recovery, allowing users to be flexible in their choice of media for routine monitoring.	Ruggedness
Flow rate independence	Show that the flow rates of 100 and 200 SLPM produce the same results, while allowing for different measuring times (10 minutes versus 5 minutes).	Robustness
Sampling volume comparability	Confirm that varying air sample volumes (500 L, 1000 L, 1500 L) have no impact on viable air counts.	Robustness
Microbial flora comparability	Parallel air sampling of the MAS-100 Sirius and the MAS-100 NT to assess concordance in microbial air flora detection.	Specificity

Material and methods

Test environment

The study was performed in an ISO Class 8 laboratory corridor of the pharmaceutical manufacturer F. Hoffmann-La Roche AG at Kaiseraugst (Switzerland). The corridor (approximately 3m wide and 56m long) was pre-characterised by conducting air sampling at three locations over a period of three days, with microbial concentrations ranging up to 150 CFU/m3, providing a representative and suitable environment for evaluating air sampler performance.

Study design

To ensure accurate airflow performance, all instruments were calibrated before and after the measurement series using a MAS-100 Regulus anemometer. All calibrations were within the required acceptance criterion.

Prior to testing, all air samplers and their respective perforated lids were thoroughly sanitised using 70 percent isopropanol and sterile wipes. To avoid positional bias, the devices were placed approximately one meter apart and randomly repositioned between sampling runs.

All tests were performed using CASO agar plates. After sampling, agar plates were incubated in a two-stage protocol under controlled conditions. The plates were first incubated at 20–25°C for three to five days, followed by a second incubation phase at 30–35°C for an additional three days. Colony forming units (CFUs) were subsequently counted and recorded for statistical evaluation.

Statistical analysis

For each sampling run, CFU recovered on the agar plates were first corrected using Feller's table to account for multiple-particle impaction and then normalised to CFU per 500 L of sampled air. Statistical analysis was performed using analysis of covariance (ANCOVA) or non-inferiority testing. Test power requirement was 80 percent.

Results

A comprehensive series of equivalence, ruggedness, robustness, and specificity studies was conducted to evaluate the MAS-100 Sirius for use in GMP-regulated cleanroom environments.

All tests were passed. Detailed results are presented in the corresponding Application Notes on the MBV website (MAS-100 Sirius). The following is a summary of the test outcome:

- **Equivalence:** Side-by-side comparison with the MAS-100 NT confirmed comparable sampling efficiency and variance. Both instruments gave the same number of CFU, and the variance of measurement did not differ between instruments. Statistical analysis demonstrated robust power, supporting the MAS-100 Sirius as a direct replacement for the MAS-100 NT in routine viable air monitoring.
- **Robustness:** The MAS-100 Sirius maintained consistent microbial recovery across two flow rates (100 SLPM, 200 SLPM) and three air volumes (500 L, 1000 L, 1500 L). Neither parameter had a significant effect on performance, confirming flexibility in sampling settings without compromising data integrity or reliability.
- **Ruggedness:** Microbial recovery was unaffected by the choice of MAS-100 Sirius instrument, interchangeable perforated lids of the same type, lid orientation, or agar plate type (90mm settle plates, contact plates, Growth Direct® cassettes). This demonstrates reliable and reproducible results under varied operational conditions.
- **Specificity:** The spectrum of airborne microorganisms collected was consistent with typical pharmaceutical cleanroom flora and showed no significant differences between MAS-100 Sirius and MAS-100 NT.

Conclusion

Across all evaluated parameters – equivalence, ruggedness, robustness, and specificity – the MAS-100 Sirius consistently delivered results comparable to the MAS-100 NT. Statistical analyses confirmed that variations in flow rate, sampling volume, instrument, perforated lid, lid orientation, or agar plate type had no meaningful impact on CFU recovery or measurement variability. The MAS-100 Sirius also demonstrated a comparable microbial spectrum, reflecting typical cleanroom flora.

These findings confirm that the MAS-100 Sirius is a reliable, flexible, and scientifically validated choice for routine quantitative monitoring of airborne viable particles in GMP-regulated cleanrooms, and it can be confidently implemented as a direct replacement for the MAS-100 NT.

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Main image: Use of the MAS-100 Sirius in a cleanroom environment in combination with a Growth Direct® cassette. The self-aligning magnetic lid with handle supports aseptic handling from the side and requires less force to open.

We would like to thank MGP Consulting for their valuable support in the design and execution of this study.

Our sincere thanks go to F. Hoffmann-La Roche AG for the great opportunity to conduct this study at the Kaiseraugst site.

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Corina Keller holds a master's degree in biochemistry from the University of Zurich and an MBA from the Lucerne University of Applied Sciences and Arts. She has many years of experience in product management, focusing on translating customer needs into targeted portfolio strategies and collaborating with interdisciplinary teams to develop effective solutions for microbial air monitoring in pharmaceutical cleanrooms.