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Application Note

Equivalence Validation of the MAS-100 Sirius® Microbial Air Sampler

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Abstract

The MAS-100 Sirius® Microbial Air Sampler is the successor of the MAS-100 NT® Microbial Air Sampler. It is designed for reliable monitoring of viable airborne particles in cleanroom environments.

In addition to validation according to ISO 14698 Annex B and EN 17141 Annex E, MBV AG performed additional testing to ensure comprehensive validation of the instrument's performance.

This application note is part of a series and focuses on the parameter EQUIVALENCE between the MAS-100 Sirius® Air Sampler and its predecessor the MAS-100 NT® Air Sampler.

Results show no statistically significant differences in microbial recovery or variability, confirming the MAS-100 Sirius® Air Sampler is as a robust and equivalent successor to the MAS-100 NT® Air Sampler.

Introduction

Reliable monitoring of airborne microbial contamination is fundamental for maintaining GMP-compliant clean room 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 ensure the MAS-100 Sirius® Air Samplers functional reliability, MBV AG applied an extended validation strategy which was 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 4 parameters RUGGEDNESS, ROBUSTNESS, EQUIVALENCE and SPECIFICITY. Although the MAS-100 NT® Air Sampler is not classified as an ARMM, these guidelines offer a sound scientific basis for performance validation akin to chemical method validation per ICH Q2(R1).

The focus of this application note is the parameter EQUIVALENCE. The goal was to verify the MAS-100 Sirius® Air Samplers capability to replace the MAS-100 NT® Air Sampler in routine cleanroom monitoring by demonstrating statistical similarity in microbial recovery performance.

Material & Methods

Test Environment:

The study was performed in an ISO Class 8 laboratory corridor of the pharmaceutical manufacturer Hoffmann-La Roche AG at Kaiseraugst (Switzerland). The corridor (approximately 3 m wide and 56 m long) was precharacterized 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.

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Materials Used:

- MAS-100 Sirius® Air Sampler (100 SLPM): 3 units (Serial numbers 220060, 220062, 220063) with matching 300 x 0.6 mm perforated lids (ANS830352, ANS830353, ANS830354)
- MAS-100 NT® Air Sampler (100 SLPM): 3 units (Serial numbers 103549, 103550, 103552) with matching 300 x 0.6 mm perforated lids
- Anemometer MAS-100® Regulus Anemometer (serial no. 18126) for "as-found" calibration
- Agar Media: 90 mm CASO + LT ICR plates (Merck KGaA, Darmstadt, Germany, article number 14605000120, batch: 207763)

Study Design:

Prior to testing, all air samplers and their respective perforated lids were thoroughly sanitized using 70% isopropanol and sterile wipes. The instruments ran in parallel. To minimize positional bias, the instruments were placed approximately one meter apart and randomly repositioned between sampling runs.

Air sampling was conducted using a flow rate of 100 SLPM (standard liters per minute) over a fixed sampling duration of 5 minutes per run, resulting in a sampled air volume of 500 liters per measurement. Each of the six instruments (three MAS-100 Sirius® Air Samplers and three MAS-100 NT® units) completed ten independent sampling runs, yielding a total of 60 data points for analysis.

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.

After sampling, CASO agar plates were incubated in a two stage protocol under controlled conditions. The plates were first incubated at 20–25 °C for 4 days, followed by a second incubation phase at 30–35 °C for an additional 3 days. Colony forming units (CFU) were subsequently counted and recorded for statistical evaluation.

Statistical Analysis and Acceptance Criteria:

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 normalized to CFU per 500 L of sampled air. Statistical analysis was performed using Analysis of Covariance (ANCOVA), with "Instrument" (MAS-100 Sirius® Air Sampler versus MAS-100 NT® Air Sampler) as the fixed factor of interest, and "Run" and "Position" as covariates to account for variability in air bioburden across time and sampling locations. A significance level of $p = 0.05$ was applied throughout.

To confirm the validity of the ANCOVA model assumptions as well as to check homogeneity among the two instruments, homoskedasticity was assessed using Bartlett's Test. The normality of residuals was verified using the Shapiro Wilk test. Statistical power of the ANCOVA was calculated using MATLAB based on the methodology described by Zar (1999), enabling quantitative assessment of the ability to detect meaningful differences between instrument types.

The following predefined acceptance criteria were applied to determine equivalence between the MAS-100 Sirius® Air Samplers and MAS-100 NT® Air Samplers:

- No statistically significant difference in CFU recovery between instrument types (ANCOVA, $p \geq 0.05$)
- No significant difference in variance between instrument types (homogeneity of variance, Bartlett's Test, $p \geq 0.05$)
- A statistical power of at least 80% for the ANCOVA model
- Meeting all three criteria would demonstrate that the MAS-100 Sirius® Air Sampler performs equivalently to the MAS-100 NT® Air Sampler in terms of both mean recovery and measurement precision under ISO Class 8 conditions

Results & Discussion

The analysis of the air sampling conducted with both the MAS-100 Sirius® Air Sampler and the MAS-100 NT® Air Sampler demonstrated highly comparable microbial recovery. The mean colony count per 500 liters of air was 20 CFU for the MAS-100 Sirius® Air Sampler and 22 CFU for the MAS-100 NT® Air Sampler, indicating a negligible difference in overall performance (**Figure 2**). This is further supported by the results of the ANCOVA model, which showed no statistically significant difference in CFU counts between instruments (**Table 1**, $p = 0.821$), confirming that the MAS-100 Sirius® Air Sampler delivers performance equivalent to the MAS-100 NT® Air Sampler under real world cleanroom conditions (**Figure 2**).

As expected, the sampling run had a statistically significant effect on CFU counts (**Table 1**), reflecting the inherent variability of airborne microbial loads over time. In contrast, the position of the instruments within the corridor did not significantly influence the results, suggesting a relatively homogeneous distribution of airborne bioburden across the sampling area.

Additionally, Bartlett's Test confirmed no significant difference in variance between the two instruments ($p = 0.867$), supporting the conclusion that both instruments exhibit consistent measurement variation, further reinforcing the homogeneity of performance.

The calculated statistical power exceeded 99%, well above the commonly accepted criterion of 80%, confirming the validity of the statistical analysis.

In conclusion, all three acceptance criteria were successfully met, demonstrating that the MAS-100 Sirius® Air Sampler delivers equivalent microbial collection performance to the MAS-100 NT® Air Sampler with no significant differences in sampling efficiency or result variability.

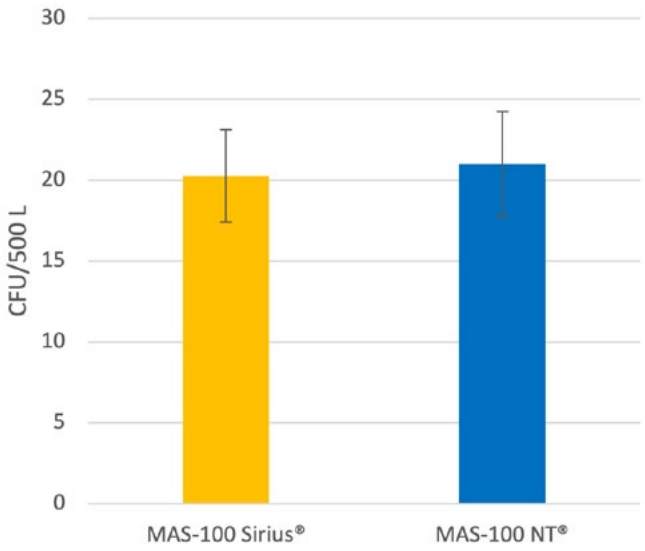

Figure 2: Direct comparison of the MAS-100 Sirius® Air Sampler with its predecessor MAS-100 NT® Air Sampler showing summarized (pooled) data (CFU/500 L, mean ±SEM, N = 60).

Table 1: Summary of the ANCOVA and power tests used for comparing the MAS-100 Sirius® and MAS-100 NT® instruments.

Factor	DF	SS	MS	F-Ratio or θ	p or Power
Modell	19	16504.768	868.672	28.009	<0.001
Error	40	1240.565	31.014		
Total	59	17745.333	300.768		
Run	9	16160.667	1795.630	57.897	<0.001
Position	5	243.568	48.714	1.571	0.191
Instrument	5	67.568	13.514	0.436	0.821
Power				4.744	>99%

Conclusion

This EQUIVALENCE study confirms that the MAS-100 Sirius® Air Sampler performs on par with the MAS-100 NT® Air Sampler. Both acceptance criteria comparable sampling efficiency and variance were met, and the statistical analysis demonstrated robust power.

Based on these findings, the MAS-100 Sirius® Air Sampler can be confidently adopted as a direct replacement for the MAS-100 NT® Air Sampler in routine viable air monitoring applications within GMP-regulated environments.

Abbreviations

Abbreviation	Term
ANCOVA	Analysis of Covariance
ARMM	Alternative or Rapid Microbiological Method
CASO	Casein Soya Bean Digest
DF	Degree of Freedom
EN	European Norm
ICH	International Conference on Harmonization
ISO	International Organization for Standardization
CFU	Colony Forming Unit
MS	Mean Squares
N	Sample Size
p	Significance level
PDA	Parenteral Drug Association
Ph. Eur.	European Pharmacopoeia
SEM	Standard Error of the Mean
SLPM	Standardliter per Minute
SS	Sum of Squares
TR	Technical Report
USP	United States Pharmacopeia

References

- EN 17141:2020. Cleanrooms and associated controlled environments - Biocontamination control.
- ICH Q2(R1) (2005). Validation of Analytical Procedures: Text and Methodology. ICH Harmonised Tripartite Guideline.
- ISO 14698-1 (2003). Cleanrooms and associated controlled environments — Biocontamination control. Part 1: General principles and methods, Annex B: Guidance on validating air samplers.
- PDA Technical Report No. 33 (Revised 2013). Evaluation, Validation and Implementation of Alternative and Rapid Microbiological Methods. ISBN: 978-0-939459-63-6, Parenteral Drug Association, Inc.
- Ph. Eur. Chapter 5.1.6 (current edition). Alternative Methods for Control of Microbiological Quality. European Pharmacopeia.
- USP Chapter <1223> (current edition). Validation of Alternative Microbiological Methods. United States Pharmacopeia.
- Zar J.H. (1999). Biostatistical Analysis. Fourth Edition, PHIPE, Prentice Hall.

Further Information

Speak to our specialists for more information or request a demo of the MAS-100 Sirius® Air Sampler: **SigmaAldrich.com/sirius-contact**

Ordering Information

Article	Article Number
MAS-100 Sirius® Air Sampler (calibrated for 100 SLPM, incl. perforated lid type A (for 90mm agar, 100 SLPM))	**1178800001**
MAS-100 Sirius® Flex Air Sampler (calibrated for 100 and 200 SLPM flow rates, without perforated lid)	**1178810001**
Perforated lid type ANS for 90mm agar and 100 SLPM flow rate	**1178830001**
Perforated lid type BNS for 90mm agar and 200 SLPM flow rate	**1178840001**

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About MBV AG MBV AG stands for air - nothing eise. The family-run company is the global market leader in air samplers and has been a reliable partner to the pharmaceutical, cosmetics and food industries as weil as research laboratories and medical device manufacturers for nearly 40 years. The MAS-100 microbial air samplers are synonymous with innovation, quality and excellence. MBV researches, develops and produces all its instruments in Switzerland. The headquarters are in Stäfa on Lake Zurich, where also R&D, the accredited calibration laboratory and customer service are located.

For more information, please visit: https://www.mbv.ch/en/

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