

R05 ANONYMIZED TECHNICAL EDITION

Public release | anonymized technical record

This edition preserves all 27 technical source pages at native scale and adds this preface. Identifying text was removed through PDF redaction; identifying pixels in photographs, plot legends, raw-data headers, and signatures were removed before a clean non-incremental save. The confidential original is unchanged and is not embedded.

Alias policy

Test Article A is the client group; A1-A3 are its three PSD products. Comparator B has B1-B3, Comparator C has C1-C3, and Comparator D has D1. Chamber representatives are A3, B1, C2, and D1. The identity map is retained outside this PDF.

Editorial limits

- Phase 1 group sizes are unequal: 3/3/3/1 products. No inferential group comparison is reported.
- Phase 2 uses one representative product per group. A3 was actuated for about 750 ms; B1, C2, and D1 for one second. Starting counts differ by orders of magnitude.
- Figure 12 shows raw logarithmic counts, not normalized decay or equivalent-dose retention. Figure 11 is labelled APS and FMPS even though the method says APS was pretesting and FMPS supplied trial data.
- D10 and D90 are volume percentiles, not a standard deviation around D50.
- Source statements about aroma duration and lung deposition are historical interpretations, not measured findings. Particle residence does not establish odor longevity, safety, exposure, or clinical performance.
- Page 1 cites 21 CFR Part 58 while source page 10 cites 40 CFR Part 160. Dates also differ across the source. This edition does not resolve those conflicts or assert current certification, accredited scope, or publication timing.

Omissions and coverage

The identifying product photograph on source page 2 is omitted. Personnel names, signatures, signature dates, project number, brand/product names, raw source-file paths, plot timestamps, and sample/supplier/batch fields are removed or replaced by aliases. Plot curves, displayed values, technical narrative, tables, and appendices remain. Edition pages 2-28 map one-to-one to source pages 1-27.

This public release is an anonymized technical edition. Identifying material has been removed; scientific content is preserved subject to the omissions and editorial limits above.

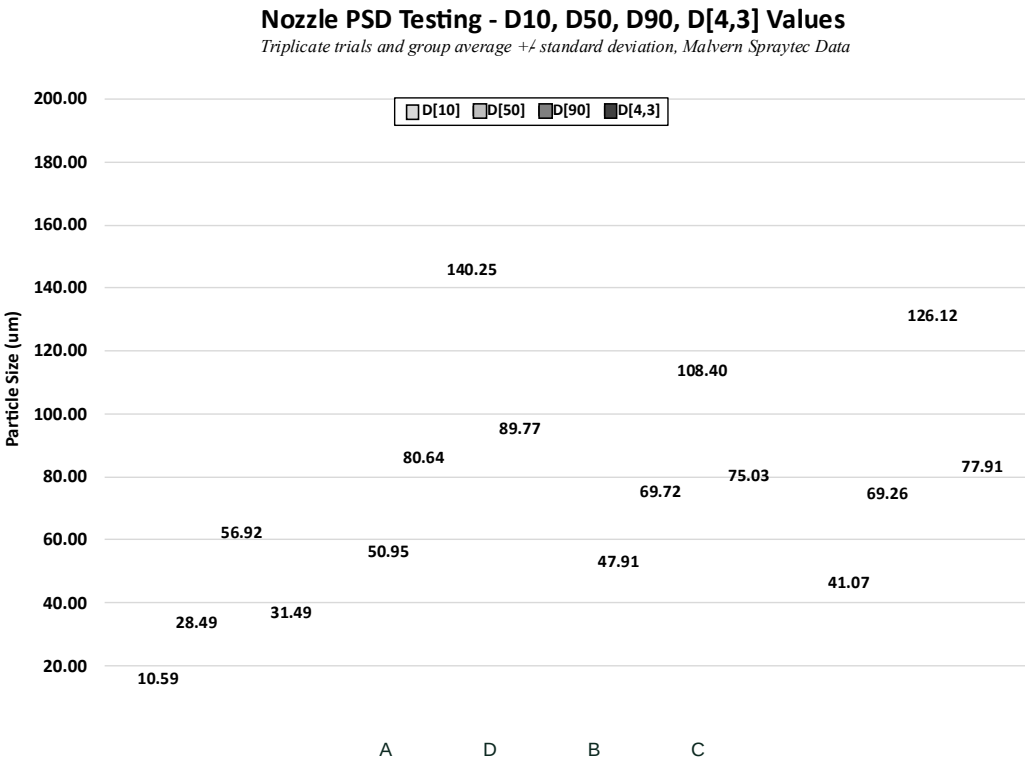


Figure 6. The D10, D50, D90, and D[4,3] averages for each brand tested

Summary of Particle Size Results

The results from the particle size distribution testing show that the A spray has a particle size distribution in a smaller range than that of the competitors tested and that all three of the A fragrances tested yielded very similar particle size distributions. All of

the D10, D50, D90, and D[4,3] values for the A sprays were much lower than those same values for the other sprays tested. Figure 6 above shows a graph depicting the average D values for each brand of spray tested. In theory, the smaller the particle the longer the particle will stay suspended in the air which leads to less deposition on surfaces and a more persistent aroma.

Analytical Testing Facility

Aerosol Research and Engineering Labs, Inc.
12880 Metcalf Ave.
Overland Park, KS 66213

Project #

R05

Study Director

Name withheld
Aerosol Research and Engineering Laboratories

GLP Statement

We, the undersigned, hereby certify that the work described herein was conducted by Aerosol Research and Engineering Laboratories in compliance with FDA Good Laboratory Practices (GLP) as defined in 40 CFR, Part 160.

PERSONNEL, SIGNATURES, AND SIGNATURE DATES WITHHELD

This anonymized technical edition is unsigned.

The source compliance references are retained above but conflict with the page
1 citation.

No current certification or accredited scope is asserted.



APPENDIX A

Supplemental Graphs



