Lot-to-Lot Variability Study, 2024

2024 Annual Report · Effective 2025-02 · Quality Assurance Department

Executive Summary

This report summarizes the results of a year-long internal study evaluating lot-to-lot consistency across the Peptilune catalog during calendar year 2024. A total of 412 lots representing 38 distinct sequences were included. The study demonstrates that catalog material consistently meets release specifications with a comfortable margin, and that observed variability between lots is dominated by routine analytical noise rather than process drift.

Methods

For each lot, the following parameters were retrieved from production records: HPLC purity (% area at 220 nm), mass-spectrometric mass error (ppm), residual moisture by Karl Fischer titration, residual TFA content, and bacterial endotoxin (EU/mg). Descriptive statistics and process-capability indices were calculated for each parameter at the catalog-sequence level.

Key Results — HPLC Purity

Statistic	Value (% area, 220 nm)
Mean	98.2
Median	98.4
Standard deviation	0.71
Minimum observed	96.1
Maximum observed	99.6
Lots failing release (< 95%)	0 of 412

Key Results — Mass Accuracy

Across all lots, observed monoisotopic mass agreed with theoretical mass within a mean error of 0.3 ppm (standard deviation 1.1 ppm). The maximum observed deviation was 4.8 ppm, well within the ±100 ppm internal acceptance criterion.

Endotoxin & Moisture

Endotoxin levels remained below the detection limit (< 0.05 EU/mg) for 96% of lots; the highest observed value was 0.31 EU/mg, still well below the 0.5 EU/mg release limit. Residual moisture by Karl Fischer

titration averaged 2.1% with a maximum observation of 4.4%.

Conclusions

Lot-to-lot consistency was excellent across all measured parameters. No statistically significant trend was observed across calendar quarters, indicating stable process control. The data support the continued use of Peptilune material in long-running research programs where reproducibility between batches is critical.

Methodology Note

This report represents an aggregated retrospective analysis of routine release data and is not a prospective stability study. For sequence-specific stability data, please contact the Peptilune QA team.

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