

Stability analysis

ICH Q1E inspired
decision support
for **assay** at
25C/60RH. The
Python engine
owns the model,
confidence bound,
crossing estimate,
reproducibility
metadata, and
artifact record.

SUPPORTED SHELF LIFE

17 months

Statistical crossing 18.0 months. Rounded down to a whole month.

ATTRIBUTE assay	CONDITION 25C/60RH	DIRECTION decreasing	TERM shelf life for product
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Decision Summary

The headline decision is the earliest supported period implied by the selected model and one sided confidence bound. Internal ids are retained in badges for audit traceability.

SUPPORTED SHELF LIFE 17 months	STATISTICAL CROSSING 18.0 months	OBSERVED DATA 24.0 months	GOVERNING BATCH B2
MODEL SELECTED Common slope, batch-specific intercepts	POOLABILITY ALPHA 0.25	CONFIDENCE BOUND Lower one-sided 95% confidence bound on the mean response	EXTRAPOLATION No. Supported period is within observed data.

Dataset

Attribute	assay
Unit	not recorded
Condition	25C/60RH
Direction	decreasing
Number of batches	Not recorded in metadata
Time points (months)	Not recorded in metadata
Row count used in fit	42
Required-column validation	All required columns present (assumed)

Model

Model kind	Common slope, batch-specific intercepts common_slope_batch_intercepts								
Model formula	value ~ time + batch (common slope, batch-specific intercepts)								
Estimated parameters	<table><tr><td>b0_B1</td><td>99.8623</td></tr><tr><td>b0_B2</td><td>98.9486</td></tr><tr><td>b0_B3</td><td>100.802</td></tr><tr><td>b1</td><td>-0.488847</td></tr></table>	b0_B1	99.8623	b0_B2	98.9486	b0_B3	100.802	b1	-0.488847
b0_B1	99.8623								
b0_B2	98.9486								
b0_B3	100.802								
b1	-0.488847								
Residual df	38								
Residual standard error (s)	0.331206								
Batches in fit	B1, B2, B3								

Poolability

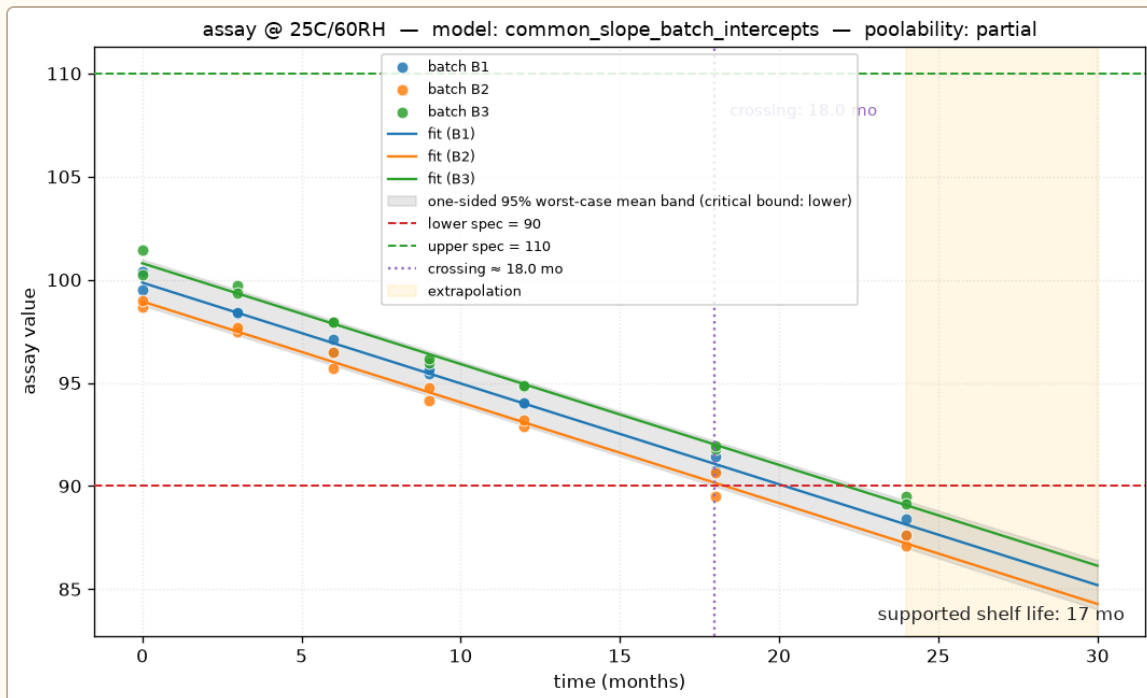
Decision	Partial pooling (common slope, batch-specific intercepts) partial
Alpha (significance level)	0.25 (ICH Q1E reference alpha = 0.25)
Guidance profile	Q1A_R2+Q1E (effective)
Guidance reference	ICH Q1A(R2) Step 4 + ICH Q1E Step 4
Step 1 p-value for slopes	$0.9056 \geq \alpha$, proceed to intercept test
Step 2 p-value for intercepts	$1.658e-16 < \alpha$, intercepts differ, common slope
Poolability notes	- step1 slopes: F-test on time:C(batch), $p=0.9056$ ($\alpha=0.25$) - step2 intercepts: F-test on C(batch), $p=1.658e-16$ ($\alpha=0.25$)

Shelf Life Estimate

Supported shelf life	17 months
Statistical crossing (months)	18.0
Observed long-term data (months)	24.0
Confidence bound used	Lower one-sided 95% confidence bound on the mean response lower_one_sided_95_mean (level = 0.95)
Crossing status	Crossed specification within the evaluated horizon crossed
Governing batch	B2
Extrapolation	No. Supported period is within observed data.

The supported shelf life is rounded *down* to the nearest whole month, per ICH Q1E.

Confidence Bound Plot



Observed data by batch, fitted regression, the lower one-sided 95% confidence bound on the mean response, and the relevant specification limit. Crossing point and extrapolation region are marked. Plot file: confidence_plot.png.

Diagnostics and Assumptions

Linearity: **ok**

Homoscedasticity: **ok**

Normality of residuals: **ok**

Influential points (Cook's d): **4**

Diagnostic notes

- Influence check: 4 observation(s) have Cook's distance $> 4.0/n = 0.0952$ (row indices [13, 24, 28, 29]). A single observation controls the fit. Consider a sensitivity analysis with and without these points; do not auto-exclude.

Warnings and Limitations

data_quality[info] duplicate_batch_time_no_replicate: 42 rows share (batch, time, attribute) ; no 'replicate' column

data_quality summary: 0 error(s), 0 warning(s), 1 info; can_analyze=True

step1 slopes: F-test on time:C(batch), p=0.9056 (alpha=0.25)

step2 intercepts: F-test on C(batch), p=1.658e-16 (alpha=0.25)

Influence check: 4 observation(s) have Cook's distance > 4.0/n = 0.0952 (row indices [13, 24, 28, 29]). A single observation controls the fit. Consider a sensitivity analysis with and without these points; do not auto-exclude.

Significant-change assessment (ICH Q1A)

Accelerated condition	not recorded
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Intermediate condition	not recorded
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Extrapolation allowed	yes
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Rationale	no accelerated data
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Criteria fired

Criterion	First change (months)	Evidence
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accelerated	not recorded
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intermediate	not recorded
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Model effects

Model	fixed (Q1E default fixed effect batch)
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Reproducibility

Tool version 1.1.0

Analysis timestamp (ISO-8601) 2024-06-01T00:00:00Z

Input file SHA-256 65138b8343548cfcc775d822e124c556ed47e62fdec455bc4ccd7d946f8a497e

Random seed (if any) none / deterministic core

Library versions	python	3.11.15
	pandas	3.0.3
	numpy	2.4.6
	scipy	1.17.1
	statsmodels	0.14.6
	matplotlib	3.11.0
	jinja2	3.1.6

Disclaimer. This report is ICH Q1E-inspired and intended for educational, exploratory, and reproducible decision-support use. It is not a substitute for qualified regulatory, statistical, or quality review. The toolkit does not provide 21 CFR Part 11 audit trails, electronic signatures, or data integrity controls, and is not a validated GxP system.

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