CORVANE BIOLOGICS



CVB-0217 Drug Product

ICH stability study STB-0217-DP-01

24-month interim evaluation · report STR-0217-DP-24M

Study identification			
Product	CVB-0217 (humanised IgG1 monoclonal antibody), 100 mg/4 mL concentrate for solution for infusion		
Container closure	6R type I glass vial, 20 mm chlorobutyl stopper, flip-off aluminium seal		
Manufacturer	Corvane Biologics AG, Industriezone Rottenmatte, filling line FL-3		
Batches	CVB0217-DP-24-011, CVB0217-DP-24-012, CVB0217-DP-24-014		
Protocol / guidelines	STP-0217-DP-003 v2.0 · ICH Q1A(R2), Q1B, Q1E, Q5C		
Storage conditions	5 °C ± 3 °C; 25 °C/60 % RH; 40 °C/75 % RH; ICH Q1B photostability		
Data cut-off	15 mai 2026	**Report date**	12 juin 2026

Key results				
Proposed shelf life at 2–8 °C	Statistical estimate (pooled, Q1E)	Rows with OOS · long-term 5 °C	Rows with OOS · all arms	Rows with OOT · all arms
30 months	**47 months**	**0**	**13**	**10**

Conclusion

All long-term (5 °C) results of the three batches remain within the acceptance criteria up to 24 months; no out-of-trend behaviour was observed at 5 °C. Assay decreases by about 0.1 % LC per month; the batches can be pooled (ANCOVA p > 0.25). The pooled one-sided 95 % lower confidence bound reaches 95.0 % LC after 47 months; with the Q1E extrapolation limit for refrigerated products a shelf life of 30 months at 2–8 °C is proposed, to be confirmed with the 36-month data (due April 2027). At 25 °C/60 % RH one HMW result (batch DP-24-012, 12 months) exceeded 2.0 % (investigation INV-26-0118, confirmed, no impact). At 40 °C/75 % RH the expected degradation leads to OOS results from 3 months onwards.

Contents

Protocol	Batches, storage conditions, testing matrix, pull schedule, chamber performance
Results 5°C	Long-term results with specification check, sparklines and margin icons
Results 25°C	Accelerated results (12 months)
Results 40°C	Stress results (6 months)
Regression	ICH Q1E regression, ANCOVA poolability, confidence bounds
Charts	Eight trend charts with acceptance limits
Sample inventory	Inventory table (183 sample sets) with totals and filters
Sign-off	Review checklist, comments and approval signatures

Outlook and proposed storage statement			
Next scheduled pull	**jeu 18 mars 2027**	**Pulls outstandin**	3 (36-month time point)
Storage statement	*Store in a refrigerator (2 °C – 8 °C). Do not freeze. Keep the vial in the outer carton in order to protect from light. Shelf life: 30 months.*		

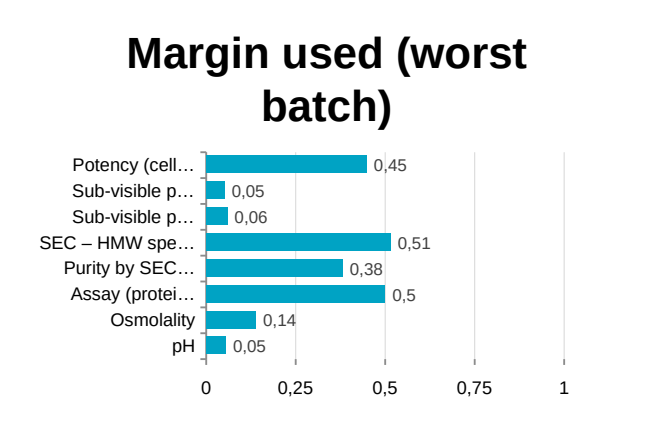
Status by attribute and storage condition (worst batch)

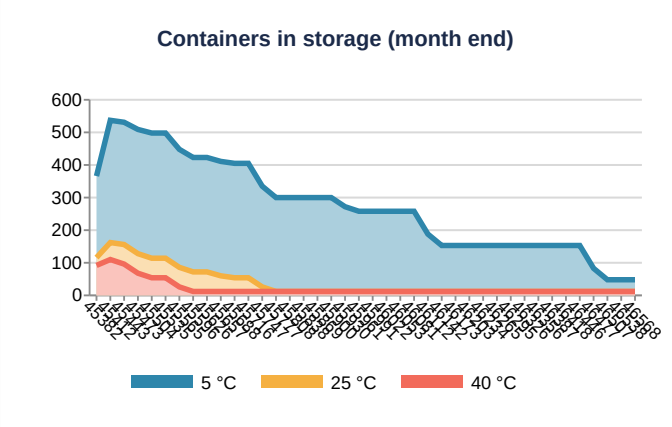
Attribute	5 °C	25 °C/60 % RH	40 °C/75 % RH
Appearance	Within spec	Within spec	Within spec
Visible particles	Within spec	Within spec	Within spec
pH	Within spec	Within spec	Within spec
Osmolality	Within spec	Within spec	Within spec
Assay (protein content)	Within spec	Out of trend	OOS
Purity by SEC – monomer	Within spec	Out of trend	OOS
SEC – HMW species	Within spec	OOS	OOS
Sub-visible particles >= 10 µm	Within spec	Within spec	Out of trend
Sub-visible particles >= 25 µm	Within spec	Within spec	Out of trend
Potency (cell-based bioassay)	Within spec	Within spec	OOS

Out-of-specification results (click to open the result; OOT results are flagged on the result sheets)

Arm · attribute	Batch	Time point	Result	Limit	Flag
25 °C/60 % RH · SEC – HMW species	DP-24-012	12 M	**2,06 %**	<= 2	OOS
40 °C/75 % RH · Assay (protein content)	DP-24-011	3 M	**93,5 %**	>= 95	OOS
40 °C/75 % RH · Assay (protein content)	DP-24-011	6 M	**87,8 %**	>= 95	OOS
40 °C/75 % RH · Assay (protein content)	DP-24-012	3 M	**94,2 %**	>= 95	OOS
40 °C/75 % RH · Assay (protein content)	DP-24-012	6 M	**87,9 %**	>= 95	OOS
40 °C/75 % RH · Assay (protein content)	DP-24-014	3 M	**93,6 %**	>= 95	OOS
40 °C/75 % RH · Assay (protein content)	DP-24-014	6 M	**87,7 %**	>= 95	OOS
40 °C/75 % RH · Purity by SEC – monomer	DP-24-011	3 M	**95,7 %**	>= 97	OOS
40 °C/75 % RH · Purity by SEC – monomer	DP-24-011	6 M	**92,2 %**	>= 97	OOS
40 °C/75 % RH · Purity by SEC – monomer	DP-24-012	3 M	**95,6 %**	>= 97	OOS
40 °C/75 % RH · Purity by SEC – monomer	DP-24-012	6 M	**92,1 %**	>= 97	OOS
40 °C/75 % RH · Purity by SEC – monomer	DP-24-014	3 M	**95,8 %**	>= 97	OOS
40 °C/75 % RH · Purity by SEC – monomer	DP-24-014	6 M	**92,3 %**	>= 97	OOS
40 °C/75 % RH · SEC – HMW species	DP-24-011	3 M	**3,31 %**	<= 2	OOS
40 °C/75 % RH · SEC – HMW species	DP-24-011	6 M	**6,08 %**	<= 2	OOS
40 °C/75 % RH · SEC – HMW species	DP-24-012	3 M	**3,33 %**	<= 2	OOS
40 °C/75 % RH · SEC – HMW species	DP-24-012	6 M	**6,08 %**	<= 2	OOS
40 °C/75 % RH · SEC – HMW species	DP-24-014	3 M	**3,23 %**	<= 2	OOS
40 °C/75 % RH · SEC – HMW species	DP-24-014	6 M	**5,95 %**	<= 2	OOS
40 °C/75 % RH · Potency (cell-based bioassay)	DP-24-011	6 M	**75 %**	>= 80	OOS
40 °C/75 % RH · Potency (cell-based bioassay)	DP-24-012	6 M	**71 %**	>= 80	OOS
40 °C/75 % RH · Potency (cell-based bioassay)	DP-24-014	6 M	**74 %**	>= 80	OOS

Specification margin used at the last long-term time point





Stability protocol STP-0217-DP-003 (version 2.0)

◄ Summary

Study design, testing matrix and pull schedule according to ICH Q1A(R2) and Q5C · effective 01-Mar-2024

1. Batches on study

Batch	Manufactured	Line	DS batch	Fill (mL)	Vials placed	Placement (T0)	36 M due	Remarks
DP-24-011	04-mars-2024	FL-3	DS-23-207	4,0	612	18-mars-2024	18-mars-2027	Primary stability batch; process validation PPQ-1
DP-24-012	11-mars-2024	FL-3	DS-23-207	4,0	612	25-mars-2024	25-mars-2027	PPQ-2; same drug-substance batch as DP-24-011
DP-24-014	08-avr-2024	FL-3	DS-24-019	4,0	588	22-avr-2024	22-avr-2027	PPQ-3; drug substance from campaign 2024-A
Data cut-off (status date)		15-mai-2026						

2. Storage conditions

Study arm	Set point	Tolerance	Chamber	Orientation	Time points (months)
Long-term (ICH Q5C)	5 °C	± 3 °C	CH-05	Upright	0, 1, 3, 6, 9, 12, 18, 24, 36
Long-term, inverted	5 °C	± 3 °C	CH-05	Inverted	6, 12, 24, 36 (physicochemical, particles, CCI)
Accelerated	25 °C / 60 %	± 2 °C / ± 5 %	CH-12	Upright	0, 1, 3, 6, 9, 12
Stress	40 °C / 75 %	± 2 °C / ± 5 %	CH-14	Upright	0, 1, 3, 6
Photostability (ICH Q1B, option 2)	1.2 Mlx·h / 2	–	LC-02	Horizontal	Single exposure; dark control wrapped in foil

3. Testing matrix (• = tested; blank = not tested at this time point)

Study arm	Time point	Appearance	Visible particles	pH	Osmolality	Assay (protein content)	Purity by SEC – monomer	SEC – HMW species	Sub-visible particles >= 10 µm	Sub-visible particles >= 25 µm	Potency (cell-based bioassay)
5 °C	0 months	•	•	•	•	•	•	•	•	•	•
	1 months	•	•	•		•	•	•			
	3 months	•	•	•		•	•	•	•	•	
	6 months	•	•	•	•	•	•	•	•	•	•
	9 months	•	•	•		•	•	•			
	12 months	•	•	•	•	•	•	•	•	•	•
	18 months	•	•	•		•	•	•	•	•	•
	24 months	•	•	•	•	•	•	•	•	•	•
	36 months	•	•	•	•	•	•	•	•	•	•
25 °C/60 % RH	0 months	•	•	•	•	•	•	•	•	•	•
	1 months	•	•	•		•	•	•			
	3 months	•	•	•		•	•	•	•	•	•
	6 months	•	•	•	•	•	•	•	•	•	•
	9 months	•	•	•		•	•	•			
	12 months	•	•	•	•	•	•	•	•	•	•
40 °C/75 % RH	0 months	•	•	•	•	•	•	•	•	•	•
	1 months	•	•	•		•	•	•	•	•	•
	3 months	•	•	•	•	•	•	•	•	•	•
	6 months	•	•	•	•	•	•	•	•	•	•
Tests per arm		*19*	*19*	*19*	*11*	*19*	*19*	*19*	*15*	*15*	*14*

4. Pull schedule (planned dates computed from placement date; weekends moved to the next working day)

Batch	Study arm	Months	Placement	Nominal pull	Planned pull	Window ± d	Window from	Window to	Actual pull	Deviation (d)	Status
Batch CVB0217-DP-24-011 — placed 18-Mar-2024, 17 pulls											
DP-24-011	Initial	0	18-mars-24	18-mars-24	**lun 18-mars-24**	±0	18-mars-24	18-mars-24	18-mars-24	0	Completed
DP-24-011	5 °C	1	18-mars-24	18-avr-24	**jeu 18-avr-24**	±3	15-avr-24	21-avr-24	19-avr-24	+1	Completed
DP-24-011	5 °C	3	18-mars-24	18-juin-24	**mar 18-juin-24**	±7	11-juin-24	25-juin-24	18-juin-24	0	Completed
DP-24-011	5 °C	6	18-mars-24	18-sept-24	**mer 18-sept-24**	±7	11-sept-24	25-sept-24	17-sept-24	-1	Completed
DP-24-011	5 °C	9	18-mars-24	18-déc-24	**mer 18-déc-24**	±7	11-déc-24	25-déc-24	20-déc-24	+2	Completed
DP-24-011	5 °C	12	18-mars-24	18-mars-25	**mar 18-mars-25**	±7	11-mars-25	25-mars-25	18-mars-25	0	Completed
DP-24-011	5 °C	18	18-mars-24	18-sept-25	**jeu 18-sept-25**	±14	04-sept-25	02-oct-25	19-sept-25	+1	Completed
DP-24-011	5 °C	24	18-mars-24	18-mars-26	**mer 18-mars-26**	±14	04-mars-26	01-avr-26	18-mars-26	0	Completed
DP-24-011	5 °C	36	18-mars-24	18-mars-27	**jeu 18-mars-27**	±14	04-mars-27	01-avr-27			Scheduled
DP-24-011	25 °C	1	18-mars-24	18-avr-24	**jeu 18-avr-24**	±3	15-avr-24	21-avr-24	16-avr-24	-2	Completed
DP-24-011	25 °C	3	18-mars-24	18-juin-24	**mar 18-juin-24**	±7	11-juin-24	25-juin-24	19-juin-24	+1	Completed
DP-24-011	25 °C	6	18-mars-24	18-sept-24	**mer 18-sept-24**	±7	11-sept-24	25-sept-24	18-sept-24	0	Completed
DP-24-011	25 °C	9	18-mars-24	18-déc-24	**mer 18-déc-24**	±7	11-déc-24	25-déc-24	23-déc-24	+5	Completed
DP-24-011	25 °C	12	18-mars-24	18-mars-25	**mar 18-mars-25**	±7	11-mars-25	25-mars-25	18-mars-25	0	Completed
DP-24-011	40 °C	1	18-mars-24	18-avr-24	**jeu 18-avr-24**	±3	15-avr-24	21-avr-24	17-avr-24	-1	Completed
DP-24-011	40 °C	3	18-mars-24	18-juin-24	**mar 18-juin-24**	±7	11-juin-24	25-juin-24	19-juin-24	+1	Completed
DP-24-011	40 °C	6	18-mars-24	18-sept-24	**mer 18-sept-24**	±7	11-sept-24	25-sept-24	18-sept-24	0	Completed
Batch CVB0217-DP-24-012 — placed 25-Mar-2024, 17 pulls											
DP-24-012	Initial	0	25-mars-24	25-mars-24	**lun 25-mars-24**	±0	25-mars-24	25-mars-24	25-mars-24	0	Completed
DP-24-012	5 °C	1	25-mars-24	25-avr-24	**jeu 25-avr-24**	±3	22-avr-24	28-avr-24	26-avr-24	+1	Completed
DP-24-012	5 °C	3	25-mars-24	25-juin-24	**mar 25-juin-24**	±7	18-juin-24	02-juil-24	25-juin-24	0	Completed
DP-24-012	5 °C	6	25-mars-24	25-sept-24	**mer 25-sept-24**	±7	18-sept-24	02-oct-24	25-sept-24	0	Completed
DP-24-012	5 °C	9	25-mars-24	25-déc-24	**mer 25-déc-24**	±7	18-déc-24	01-janv-25	23-déc-24	-2	Completed
DP-24-012	5 °C	12	25-mars-24	25-mars-25	**mar 25-mars-25**	±7	18-mars-25	01-avr-25	26-mars-25	+1	Completed
DP-24-012	5 °C	18	25-mars-24	25-sept-25	**jeu 25-sept-25**	±14	11-sept-25	09-oct-25	25-sept-25	0	Completed
DP-24-012	5 °C	24	25-mars-24	25-mars-26	**mer 25-mars-26**	±14	11-mars-26	08-avr-26	30-mars-26	+5	Completed
DP-24-012	5 °C	36	25-mars-24	25-mars-27	**jeu 25-mars-27**	±14	11-mars-27	08-avr-27			Scheduled
DP-24-012	25 °C	1	25-mars-24	25-avr-24	**jeu 25-avr-24**	±3	22-avr-24	28-avr-24	24-avr-24	-1	Completed
DP-24-012	25 °C	3	25-mars-24	25-juin-24	**mar 25-juin-24**	±7	18-juin-24	02-juil-24	26-juin-24	+1	Completed
DP-24-012	25 °C	6	25-mars-24	25-sept-24	**mer 25-sept-24**	±7	18-sept-24	02-oct-24	25-sept-24	0	Completed
DP-24-012	25 °C	9	25-mars-24	25-déc-24	**mer 25-déc-24**	±7	18-déc-24	01-janv-25	25-déc-24	0	Completed
DP-24-012	25 °C	12	25-mars-24	25-mars-25	**mar 25-mars-25**	±7	18-mars-25	01-avr-25	26-mars-25	+1	Completed
DP-24-012	40 °C	1	25-mars-24	25-avr-24	**jeu 25-avr-24**	±3	22-avr-24	28-avr-24	25-avr-24	0	Completed
DP-24-012	40 °C	3	25-mars-24	25-juin-24	**mar 25-juin-24**	±7	18-juin-24	02-juil-24	24-juin-24	-1	Completed
DP-24-012	40 °C	6	25-mars-24	25-sept-24	**mer 25-sept-24**	±7	18-sept-24	02-oct-24	27-sept-24	+2	Completed
Batch CVB0217-DP-24-014 — placed 22-Apr-2024, 17 pulls											
DP-24-014	Initial	0	22-avr-24	22-avr-24	**lun 22-avr-24**	±0	22-avr-24	22-avr-24	22-avr-24	0	Completed
DP-24-014	5 °C	1	22-avr-24	22-mai-24	**mer 22-mai-24**	±3	19-mai-24	25-mai-24	22-mai-24	0	Completed
DP-24-014	5 °C	3	22-avr-24	22-juil-24	**lun 22-juil-24**	±7	15-juil-24	29-juil-24	25-juil-24	+3	Completed
DP-24-014	5 °C	6	22-avr-24	22-oct-24	**mar 22-oct-24**	±7	15-oct-24	29-oct-24	22-oct-24	0	Completed
DP-24-014	5 °C	9	22-avr-24	22-janv-25	**mer 22-janv-25**	±7	15-janv-25	29-janv-25	21-janv-25	-1	Completed
DP-24-014	5 °C	12	22-avr-24	22-avr-25	**mar 22-avr-25**	±7	15-avr-25	29-avr-25	23-avr-25	+1	Completed
DP-24-014	5 °C	18	22-avr-24	22-oct-25	**mer 22-oct-25**	±14	08-oct-25	05-nov-25	22-oct-25	0	Completed
DP-24-014	5 °C	24	22-avr-24	22-avr-26	**mer 22-avr-26**	±14	08-avr-26	06-mai-26	22-avr-26	0	Completed
DP-24-014	5 °C	36	22-avr-24	22-avr-27	**jeu 22-avr-27**	±14	08-avr-27	06-mai-27			Scheduled
DP-24-014	25 °C	1	22-avr-24	22-mai-24	**mer 22-mai-24**	±3	19-mai-24	25-mai-24	22-mai-24	0	Completed
DP-24-014	25 °C	3	22-avr-24	22-juil-24	**lun 22-juil-24**	±7	15-juil-24	29-juil-24	22-juil-24	0	Completed
DP-24-014	25 °C	6	22-avr-24	22-oct-24	**mar 22-oct-24**	±7	15-oct-24	29-oct-24	24-oct-24	+2	Completed
DP-24-014	25 °C	9	22-avr-24	22-janv-25	**mer 22-janv-25**	±7	15-janv-25	29-janv-25	22-janv-25	0	Completed
DP-24-014	25 °C	12	22-avr-24	22-avr-25	**mar 22-avr-25**	±7	15-avr-25	29-avr-25	23-avr-25	+1	Completed
DP-24-014	40 °C	1	22-avr-24	22-mai-24	**mer 22-mai-24**	±3	19-mai-24	25-mai-24	22-mai-24	0	Completed
DP-24-014	40 °C	3	22-avr-24	22-juil-24	**lun 22-juil-24**	±7	15-juil-24	29-juil-24	22-juil-24	0	Completed
DP-24-014	40 °C	6	22-avr-24	22-oct-24	**mar 22-oct-24**	±7	15-oct-24	29-oct-24	21-oct-24	-1	Completed

5. Stability chamber performance during the reporting period

Chamber	Set point	Mean	Min	Max	Mean RH	Excursions	Last excursion start	Last excursion end	Duration
CH-05 walk-in	5 °C	4,9 °C	3,6 °C	6,8 °C	–	2	14-août-2025 02:17	14-août-2025 03:05	**0:48 h**
CH-12 reach-in	25 °C / 60 %	25,1 °C	24,2 °C	26,4 °C	59,6%	1	03-févr-2025 22:40	04-févr-2025 00:52	**2:12 h**
CH-14 reach-in	40 °C / 75 %	40,0 °C	38,9 °C	41,2 °C	74,8%	0	none	–	–
LC-02 light cabinet	Q1B option 2	24,6 °C	22,8 °C	26,1 °C	–	0	none	–	–

6. Analytical reference data and programme cost

Reference standard (bioassay)	RS-CVB0217-002, assigned potency 100 %
Reference EC50 (mean of qualification runs)	3,15E-08 g/mL
Starting dilution of test samples	0
Serial dilution step (three-fold)	1/3
System suitability: slope ratio test vs reference	0.80–1.25
SEC column lot (current)	TSK-G3000SWxl, lot 0021-77
Testing cost per full pull (3 batches)	CHF 14 850
Programme cost to date (completed pulls)	**CHF 237 600**

7. Pull workload by quarter (from the pull schedule)

Quarter	From	Pulls	Completed	Scheduled	Share of programme
Q1 2024	01-janv-24	2	2	–	3,9%
Q2 2024	01-avr-24	16	16	–	31,4%
Q3 2024	01-juil-24	9	9	–	17,6%
Q4 2024	01-oct-24	7	7	–	13,7%
Q1 2025	01-janv-25	6	6	–	11,8%
Q2 2025	01-avr-25	2	2	–	3,9%
Q3 2025	01-juil-25	2	2	–	3,9%
Q4 2025	01-oct-25	1	1	–	2,0%
Q1 2026	01-janv-26	2	2	–	3,9%
Q2 2026	01-avr-26	1	1	–	2,0%
Q3 2026	01-juil-26	0	0	–	0,0%
Q4 2026	01-oct-26	0	0	–	0,0%
Q1 2027	01-janv-27	2	0	2	3,9%
Q2 2027	01-avr-27	1	0	1	2,0%

Sampling and testing rules

- Samples are removed from the chamber on the planned pull date within the window shown; results are reported against the nominal time point.
- Physicochemical testing starts within 5 working days of the pull; the bioassay within 15 working days (samples held at 5 °C).
- Any result outside the acceptance criteria at the long-term or accelerated condition triggers an OOS investigation per SOP QA-0412. Out-of-trend results are evaluated by QC Stability within 10 working days.
- The protocol may be amended to add time points; deletion of time points requires QA approval and a change request.

Results — long-term storage, 5 °C ± 3 °C

◄ Summary

Batches DP-24-011, DP-24-012, DP-24-014 · 6R glass vials, upright · chamber CH-05 · data cut-off 15 May 2026 · results as reported (LIMS)

Attribute · method	Unit	Acceptance min	Acceptance max	Batch	Time point (months) 0 M	1 M	3 M	6 M	9 M	12 M	18 M	24 M	36 M	Trend	Last result	Margin used	Status
Appearance Visual, Ph. Eur. 2.2.1/2.2.2	–	Clear to slightly opalescent, colourless to slightly yellow		DP-24-011	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms			Conforms		**Conforms**
				DP-24-012	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms			Conforms		**Conforms**
				DP-24-014	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms			Conforms		**Conforms**
Visible particles Visual inspection, Ph. Eur. 2.9.20	–	Practically free from visible particles		DP-24-011	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms			Conforms		**Conforms**
				DP-24-012	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms			Conforms		**Conforms**
				DP-24-014	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms			Conforms		**Conforms**
pH Potentiometry, Ph. Eur. 2.2.3	–	**5,50**	**6,50**	DP-24-011	6,00	6,02	6,02	6,01	6,04	6,04	6,00	6,02			**6,02**	✓ 4%	**Within spec**
				DP-24-012	5,95	6,01	6,02	5,96	5,93	5,95	5,91	5,98			**5,98**	✓ 5%	**Within spec**
				DP-24-014	6,03	6,06	6,05	6,03	6,06	6,05	6,02	6,01			**6,01**	✓ 4%	**Within spec**
Osmolality Freezing-point depression	mOsm/kg	**270**	**330**	DP-24-011	294			302		294		299			**299**	✓ 14%	**Within spec**
				DP-24-012	301			301		297		300			**300**	✓ 3%	**Within spec**
				DP-24-014	295			298		296		292			**292**	✓ 12%	**Within spec**
Assay (protein content) UV A280, SOP QC-0217-03	% LC	**95,0**	**105,0**	DP-24-011	101,0	100,6	100,1	99,8	99,5	98,7	99,5	98,0			**98,0**	✗ 50%	**Within spec**
				DP-24-012	100,5	100,8	100,2	100,6	99,5	99,0	98,4	99,0			**99,0**	! 27%	**Within spec**
				DP-24-014	100,1	100,4	100,6	99,8	99,3	99,1	98,6	97,7			**97,7**	✗ 47%	**Within spec**
Purity by SEC – monomer SE-HPLC, SOP QC-0217-05	%	**97,0**	–	DP-24-011	99,2	99,2	98,9	98,9	98,9	98,7	98,6	98,4			**98,4**	✗ 36%	**Within spec**
				DP-24-012	99,1	99,0	98,9	98,8	98,7	98,6	98,4	98,3			**98,3**	✗ 38%	**Within spec**
				DP-24-014	99,2	99,2	99,1	99,1	99,0	98,9	98,6	98,5			**98,5**	! 32%	**Within spec**
SEC – HMW species SE-HPLC, SOP QC-0217-05	%	–	**2,00**	DP-24-011	0,57	0,60	0,81	0,78	0,81	0,92	1,11	1,27			**1,27**	✗ 49%	**Within spec**
				DP-24-012	0,66	0,72	0,75	0,83	0,95	1,01	1,26	1,35			**1,35**	✗ 51%	**Within spec**
				DP-24-014	0,55	0,52	0,62	0,68	0,73	0,83	1,07	1,14			**1,14**	✗ 41%	**Within spec**
Sub-visible particles >= 10 µm Light obscuration, Ph. Eur. 2.9.19	per container	–	**6 000**	DP-24-011	165		213	265		277	261	398			**398**	✓ 4%	**Within spec**
				DP-24-012	259		235	251		290	460	450			**450**	✓ 3%	**Within spec**
				DP-24-014	170		154	230		300	393	514			**514**	✓ 6%	**Within spec**
Sub-visible particles >= 25 µm Light obscuration, Ph. Eur. 2.9.19	per container	–	**600**	DP-24-011	9		13	23		19	27	39			**39**	✓ 5%	**Within spec**
				DP-24-012	26		18	23		17	33	38			**38**	✓ 2%	**Within spec**
				DP-24-014	8		15	11		26	13	38			**38**	✓ 5%	**Within spec**
Potency (cell-based bioassay) Reporter-gene assay, QC-0217-11	% rel.	**80**	**125**	DP-24-011	106			106		102	101	95			**95**	✗ 42%	**Within spec**
				DP-24-012	109			96		98	91	96			**96**	✗ 45%	**Within spec**
				DP-24-014	101			101		103	98	93			**93**	✗ 38%	**Within spec**

Legend

Margin used = change from initial divided by the distance from the initial value to the limit in the direction of change (icons: green < 50 %, amber 50–100 %, red >= 100 %). Green values at T0 on the accelerated and stress sheets are linked from the 5 °C sheet.

12.3	Out of specification (OOS)
12.3	Out of trend: change from initial exceeds the attribute OOT limit
	Not tested at this time point per testing matrix (Protocol §3)
	Scheduled, result pending
	Time point not part of this storage arm

Results — accelerated storage, 25 °C ± 2 °C / 60 % RH ± 5 %

◄ Summary

Batches DP-24-011, DP-24-012, DP-24-014 · 6R glass vials, upright · chamber CH-12 · data cut-off 15 May 2026 · results as reported (LIMS)

Attribute · method	Unit	Acceptance min	Acceptance max	Batch	Time point (months) 0 M	1 M	3 M	6 M	9 M	12 M	18 M	24 M	36 M	Trend	Last result	Margin used	Status
Appearance Visual, Ph. Eur. 2.2.1/2.2.2	–	Clear to slightly opalescent, colourless to slightly yellow		DP-24-011	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms					Conforms		**Conforms**
				DP-24-012	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms					Conforms		**Conforms**
				DP-24-014	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms					Conforms		**Conforms**
Visible particles Visual inspection, Ph. Eur. 2.9.20	–	Practically free from visible particles		DP-24-011	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms					Conforms		**Conforms**
				DP-24-012	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms					Conforms		**Conforms**
				DP-24-014	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms					Conforms		**Conforms**
pH Potentiometry, Ph. Eur. 2.2.3	–	**5,50**	**6,50**	DP-24-011	6,00	6,02	6,04	6,00	5,99	5,99					**5,99**	✓ 2%	**Within spec**
				DP-24-012	5,95	5,97	5,97	5,92	5,96	5,94					**5,94**	✓ 2%	**Within spec**
				DP-24-014	6,03	6,03	6,00	6,01	6,04	5,98					**5,98**	✓ 9%	**Within spec**
Osmolality Freezing-point depression	mOsm/kg	**270**	**330**	DP-24-011	294			289		298					**298**	✓ 11%	**Within spec**
				DP-24-012	301			298		299					**299**	✓ 6%	**Within spec**
				DP-24-014	295			295		297					**297**	✓ 6%	**Within spec**
Assay (protein content) UV A280, SOP QC-0217-03	% LC	**95,0**	**105,0**	DP-24-011	101,0	99,9	100,3	98,6	98,0	96,8					**96,8**	! 70%	**OOT**
				DP-24-012	100,5	100,1	99,7	99,0	97,7	97,3					**97,3**	! 58%	**Within spec**
				DP-24-014	100,1	100,5	99,8	98,2	97,3	96,7					**96,7**	! 67%	**Within spec**
Purity by SEC – monomer SE-HPLC, SOP QC-0217-05	%	**97,0**	–	DP-24-011	99,2	99,0	98,7	98,3	97,9	97,5					**97,5**	✗ 77%	**OOT**
				DP-24-012	99,1	98,9	98,6	98,2	97,7	97,3					**97,3**	✗ 86%	**OOT**
				DP-24-014	99,2	99,0	98,8	98,4	98,0	97,5					**97,5**	✗ 77%	**OOT**
SEC – HMW species SE-HPLC, SOP QC-0217-05	%	–	**2,00**	DP-24-011	0,57	0,72	0,97	1,32	1,60	1,91					**1,91**	✗ 94%	**OOT**
				DP-24-012	0,66	0,78	1,05	1,35	1,69	2,06					**2,06**	✗ 104%	**OOS**
				DP-24-014	0,55	0,67	0,90	1,21	1,52	1,89					**1,89**	✗ 92%	**OOT**
Sub-visible particles >= 10 µm Light obscuration, Ph. Eur. 2.9.19	per container	–	**6 000**	DP-24-011	165		420	543		847					**847**	✓ 12%	**Within spec**
				DP-24-012	259		442	586		737					**737**	✓ 8%	**Within spec**
				DP-24-014	170		290	349		1 016					**1 016**	✓ 15%	**Within spec**
Sub-visible particles >= 25 µm Light obscuration, Ph. Eur. 2.9.19	per container	–	**600**	DP-24-011	9		31	35		53					**53**	✓ 7%	**Within spec**
				DP-24-012	26		36	36		47					**47**	✓ 4%	**Within spec**
				DP-24-014	8		23	30		51					**51**	✓ 7%	**Within spec**
Potency (cell-based bioassay) Reporter-gene assay, QC-0217-11	% rel.	**80**	**125**	DP-24-011	106		93	95		92					**92**	! 54%	**Within spec**
				DP-24-012	109		100	93		92					**92**	! 59%	**Within spec**
				DP-24-014	101		97	98		92					**92**	! 43%	**Within spec**

Legend

Margin used = change from initial divided by the distance from the initial value to the limit in the direction of change (icons: green < 50 %, amber 50–100 %, red >= 100 %). Green values at T0 on the accelerated and stress sheets are linked from the 5 °C sheet.

12.3	Out of specification (OOS)
12.3	Out of trend: change from initial exceeds the attribute OOT limit
	Not tested at this time point per testing matrix (Protocol §3)
	Scheduled, result pending
	Time point not part of this storage arm

Results — stress storage, 40 °C ± 2 °C / 75 % RH ± 5 %

◄ Summary

Batches DP-24-011, DP-24-012, DP-24-014 · 6R glass vials, upright · chamber CH-14 · data cut-off 15 May 2026 · results as reported (LIMS)

Attribute · method	Unit	Acceptance min	Acceptance max	Batch	Time point (months) 0 M	1 M	3 M	6 M	9 M	12 M	18 M	24 M	36 M	Trend	Last result	Margin used	Status
Appearance Visual, Ph. Eur. 2.2.1/2.2.2	–	Clear to slightly opalescent, colourless to slightly yellow		DP-24-011	Conforms	Conforms	Conforms (slightly yellow)	Conforms (slightly yellow)							Conforms (slightly yellow)		**Conforms**
				DP-24-012	Conforms	Conforms	Conforms (slightly yellow)	Conforms (slightly yellow)							Conforms (slightly yellow)		**Conforms**
				DP-24-014	Conforms	Conforms	Conforms (slightly yellow)	Conforms (slightly yellow)							Conforms (slightly yellow)		**Conforms**
Visible particles Visual inspection, Ph. Eur. 2.9.20	–	Practically free from visible particles		DP-24-011	Conforms	Conforms	Conforms	Conforms							Conforms		**Conforms**
				DP-24-012	Conforms	Conforms	Conforms	Conforms							Conforms		**Conforms**
				DP-24-014	Conforms	Conforms	Conforms	Conforms							Conforms		**Conforms**
pH Potentiometry, Ph. Eur. 2.2.3	–	**5,50**	**6,50**	DP-24-011	6,00	5,99	5,94	5,86							**5,86**	28%	**Within spec**
				DP-24-012	5,95	5,96	5,93	5,79							**5,79**	36%	**Within spec**
				DP-24-014	6,03	6,00	5,96	5,88							**5,88**	28%	**Within spec**
Osmolality Freezing-point depression	mOsm/kg	**270**	**330**	DP-24-011	294		302	303							**303**	25%	**Within spec**
				DP-24-012	301		304	301							**301**	0%	**Within spec**
				DP-24-014	295		296	299							**299**	11%	**Within spec**
Assay (protein content) UV A280, SOP QC-0217-03	% LC	**95,0**	**105,0**	DP-24-011	101,0	98,1	93,5	87,8							**87,8**	220%	**OOS**
				DP-24-012	100,5	98,3	94,2	87,9							**87,9**	229%	**OOS**
				DP-24-014	100,1	97,9	93,6	87,7							**87,7**	243%	**OOS**
Purity by SEC – monomer SE-HPLC, SOP QC-0217-05	%	**97,0**	–	DP-24-011	99,2	98,0	95,7	92,2							**92,2**	318%	**OOS**
				DP-24-012	99,1	97,8	95,6	92,1							**92,1**	333%	**OOS**
				DP-24-014	99,2	98,0	95,8	92,3							**92,3**	314%	**OOS**
SEC – HMW species SE-HPLC, SOP QC-0217-05	%	–	**2,00**	DP-24-011	0,57	1,51	3,31	6,08							**6,08**	385%	**OOS**
				DP-24-012	0,66	1,63	3,33	6,08							**6,08**	404%	**OOS**
				DP-24-014	0,55	1,50	3,23	5,95							**5,95**	372%	**OOS**
Sub-visible particles >= 10 µm Light obscuration, Ph. Eur. 2.9.19	per container	–	**6 000**	DP-24-011	165	515	1 534	4 128							**4 128**	68%	**OOT**
				DP-24-012	259	635	2 260	4 848							**4 848**	80%	**OOT**
				DP-24-014	170	795	2 044	3 881							**3 881**	64%	**OOT**
Sub-visible particles >= 25 µm Light obscuration, Ph. Eur. 2.9.19	per container	–	**600**	DP-24-011	9	49	106	223							**223**	36%	**Within spec**
				DP-24-012	26	72	192	271							**271**	43%	**Within spec**
				DP-24-014	8	94	222	455							**455**	76%	**OOT**
Potency (cell-based bioassay) Reporter-gene assay, QC-0217-11	% rel.	**80**	**125**	DP-24-011	106	101	85	75							**75**	119%	**OOS**
				DP-24-012	109	93	83	71							**71**	131%	**OOS**
				DP-24-014	101	97	85	74							**74**	129%	**OOS**

Legend

Margin used = change from initial divided by the distance from the initial value to the limit in the direction of change (icons: green < 50 %, amber 50–100 %, red >= 100 %). Green values at T0 on the accelerated and stress sheets are linked from the 5 °C sheet.

12.3	Out of specification (OOS)
12.3	Out of trend: change from initial exceeds the attribute OOT limit
	Not tested at this time point per testing matrix (Protocol §3)
	Scheduled, result pending
	Time point not part of this storage arm

Shelf-life evaluation — assay at 5 °C (ICH Q1E)

◄ Summary

Linear regression of assay (% LC) versus time, poolability by ANCOVA (α = 0.25), one-sided 95 % lower confidence bound for the mean

A. Data (linked to Results 5 °C)

Batch	Months	Assay % LC	Residual (pooled)
DP-24-011	0	101,0	+0,45
DP-24-011	1	100,6	+0,16
DP-24-011	3	100,1	-0,14
DP-24-011	6	99,8	-0,13
DP-24-011	9	99,5	-0,13
DP-24-011	12	98,7	-0,62
DP-24-011	18	99,5	+0,79
DP-24-011	24	98,0	-0,10
DP-24-012	0	100,5	-0,05
DP-24-012	1	100,8	+0,36
DP-24-012	3	100,2	-0,04
DP-24-012	6	100,6	+0,67
DP-24-012	9	99,5	-0,13
DP-24-012	12	99,0	-0,32
DP-24-012	18	98,4	-0,31
DP-24-012	24	99,0	+0,90
DP-24-014	0	100,1	-0,45
DP-24-014	1	100,4	-0,04
DP-24-014	3	100,6	+0,36
DP-24-014	6	99,8	-0,13
DP-24-014	9	99,3	-0,33
DP-24-014	12	99,1	-0,22
DP-24-014	18	98,6	-0,11
DP-24-014	24	97,7	-0,40

B. Regression statistics per batch and pooled

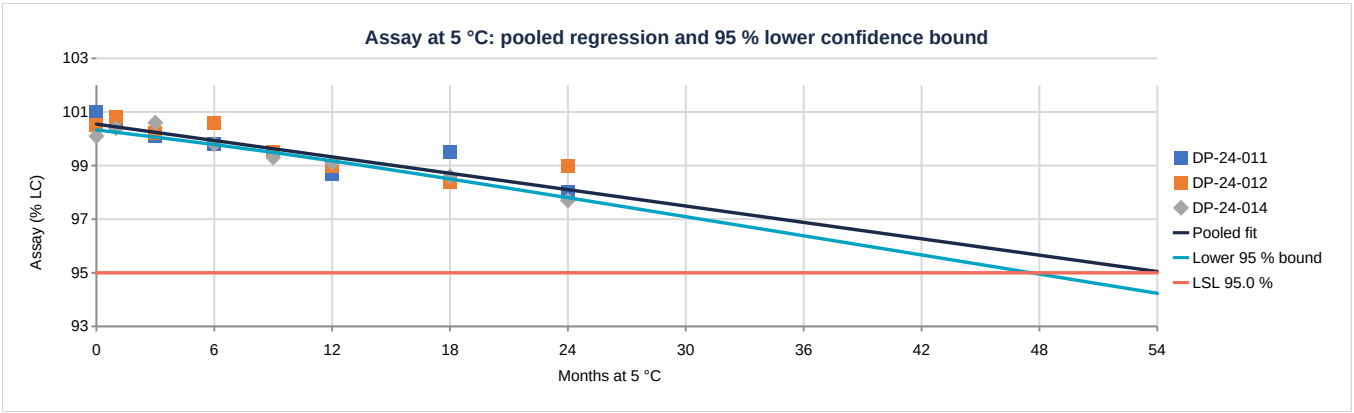
Statistic	DP-24-011	DP-24-012	DP-24-014	Pooled
Number of results n	8	8	8	24
Slope b (% LC per month)	-0,1027	-0,0912	-0,1116	-0,1018
Intercept a (% LC)	100,587	100,582	100,468	100,546
Coefficient of determination R²	0,804	0,750	0,939	0,814
Residual standard deviation s (STEYX)	0,4646	0,4830	0,2616	0,4036
Mean time x̄ (months)	9,125	9,125	9,125	9,125
Sxx = Σ(x − x̄)²	504,88	504,88	504,88	1514,63
Syy = Σ(y − ȳ)²	6,6200	5,6000	6,7000	19,2933
Sxy = b × Sxx	-51,8500	-46,0500	-56,3500	-154,2500
Residual sum of squares SSE = (n - 2) s²	1,2951	1,3997	0,4107	3,5845
t (one-sided 95 %, n - 2 df)	1,9432	1,9432	1,9432	1,7171
Shelf life where lower bound >= 95.0 % (month	**41**	**44**	**42**	**47**

C. Poolability test (ANCOVA, Q1E: pool if p > 0.25)

Model / test	SSE	df	F	p-value
Separate slopes and intercepts	3,1055	18		
Common slope, separate intercepts	3,2111	20		
Common slope and intercept (pooled)	3,5845	22		
Equality of slopes			0,306	**0,740**
Equality of intercepts (given common slope)			1,163	**0,333**
Decision	**Pool all batches**			

D. Shelf-life proposal (ICH Q1E, refrigerated product)

Statistical shelf life, pooled model (months)	47	*pooled model, see table E*
Long-term data available (months)	24	*all three batches*
Maximum extrapolation: min(1.5 × X, X + 6)	30	*Q1E Appendix A*
Proposed shelf life at 2–8 °C (months)	**30 months**	*subject to 36-month data*



E. Lower one-sided 95 % confidence bound for the mean assay (% LC) by month

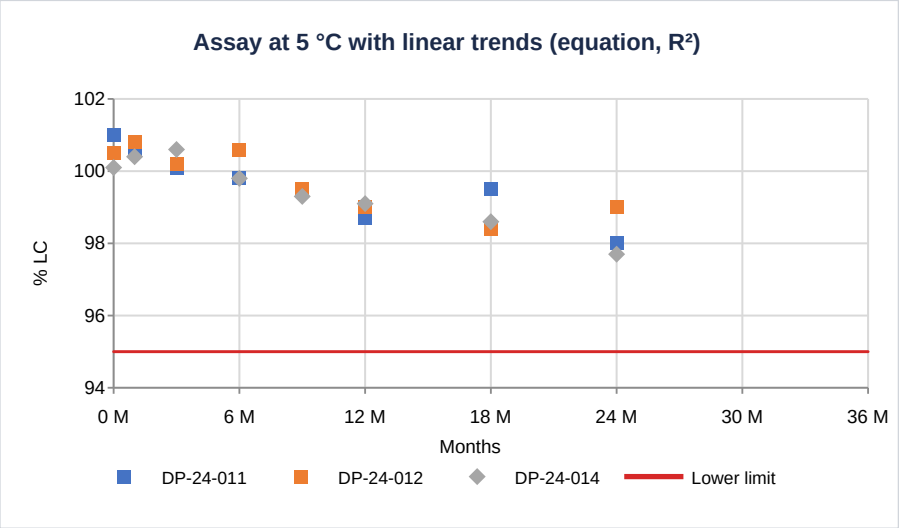
Month	Pooled fit	Pooled lower bound	Margin to 95.0 %	Assessment (pooled)	Lower bound DP-24-011	Lower bound DP-24-012	Lower bound DP-24-014	LSL
0	100,55	**100,33**	+5,33	Lower bound >= LSL	100,10	100,08	100,19	95,0
1	100,44	**100,24**	+5,24	Lower bound >= LSL	100,03	100,02	100,10	95,0
2	100,34	**100,15**	+5,15	Lower bound >= LSL	99,95	99,95	100,00	95,0
3	100,24	**100,06**	+5,06	Lower bound >= LSL	99,88	99,89	99,91	95,0
4	100,14	**99,97**	+4,97	Lower bound >= LSL	99,80	99,82	99,81	95,0
5	100,04	**99,88**	+4,88	Lower bound >= LSL	99,71	99,75	99,71	95,0
6	99,93	**99,78**	+4,78	Lower bound >= LSL	99,63	99,68	99,61	95,0
7	99,83	**99,69**	+4,69	Lower bound >= LSL	99,54	99,60	99,50	95,0
8	99,73	**99,59**	+4,59	Lower bound >= LSL	99,44	99,52	99,39	95,0
9	99,63	**99,49**	+4,49	Lower bound >= LSL	99,34	99,43	99,28	95,0
10	99,53	**99,39**	+4,39	Lower bound >= LSL	99,24	99,34	99,17	95,0
11	99,43	**99,28**	+4,28	Lower bound >= LSL	99,13	99,24	99,06	95,0
12	99,32	**99,17**	+4,17	Lower bound >= LSL	99,02	99,13	98,94	95,0
13	99,22	**99,06**	+4,06	Lower bound >= LSL	98,90	99,03	98,82	95,0
14	99,12	**98,95**	+3,95	Lower bound >= LSL	98,77	98,92	98,70	95,0
15	99,02	**98,84**	+3,84	Lower bound >= LSL	98,65	98,80	98,57	95,0
16	98,92	**98,73**	+3,73	Lower bound >= LSL	98,52	98,68	98,44	95,0
17	98,81	**98,62**	+3,62	Lower bound >= LSL	98,39	98,56	98,32	95,0
18	98,71	**98,50**	+3,50	Lower bound >= LSL	98,26	98,44	98,19	95,0
19	98,61	**98,39**	+3,39	Lower bound >= LSL	98,13	98,32	98,06	95,0
20	98,51	**98,27**	+3,27	Lower bound >= LSL	97,99	98,20	97,93	95,0
21	98,41	**98,15**	+3,15	Lower bound >= LSL	97,86	98,07	97,80	95,0
22	98,31	**98,04**	+3,04	Lower bound >= LSL	97,72	97,94	97,67	95,0
23	98,20	**97,92**	+2,92	Lower bound >= LSL	97,58	97,82	97,54	95,0
24	98,10	**97,80**	+2,80	Lower bound >= LSL	97,44	97,69	97,41	95,0
25	98,00	**97,68**	+2,68	Lower bound >= LSL	97,31	97,56	97,28	95,0
26	97,90	**97,57**	+2,57	Lower bound >= LSL	97,17	97,43	97,14	95,0
27	97,80	**97,45**	+2,45	Lower bound >= LSL	97,03	97,30	97,01	95,0
28	97,69	**97,33**	+2,33	Lower bound >= LSL	96,89	97,17	96,88	95,0
29	97,59	**97,21**	+2,21	Lower bound >= LSL	96,75	97,04	96,75	95,0
30	97,49	**97,09**	+2,09	Lower bound >= LSL	96,61	96,91	96,61	95,0
31	97,39	**96,97**	+1,97	Lower bound >= LSL	96,47	96,78	96,48	95,0
32	97,29	**96,86**	+1,86	Lower bound >= LSL	96,33	96,65	96,35	95,0
33	97,19	**96,74**	+1,74	Lower bound >= LSL	96,19	96,52	96,22	95,0
34	97,08	**96,62**	+1,62	Lower bound >= LSL	96,05	96,39	96,08	95,0
35	96,98	**96,50**	+1,50	Lower bound >= LSL	95,91	96,26	95,95	95,0
36	96,88	**96,38**	+1,38	Lower bound >= LSL	95,76	96,13	95,82	95,0
37	96,78	**96,26**	+1,26	Lower bound >= LSL	95,62	96,00	95,68	95,0
38	96,68	**96,14**	+1,14	Lower bound >= LSL	95,48	95,87	95,55	95,0
39	96,57	**96,02**	+1,02	Lower bound >= LSL	95,34	95,73	95,42	95,0
40	96,47	**95,90**	+0,90	Lower bound >= LSL	95,20	95,60	95,28	95,0
41	96,37	**95,79**	+0,79	Lower bound >= LSL	95,06	95,47	95,15	95,0
42	96,27	**95,67**	+0,67	Lower bound >= LSL	94,91	95,34	95,02	95,0
43	96,17	**95,55**	+0,55	Lower bound >= LSL	94,77	95,21	94,88	95,0
44	96,06	**95,43**	+0,43	Lower bound >= LSL	94,63	95,07	94,75	95,0
45	95,96	**95,31**	+0,31	Lower bound >= LSL	94,49	94,94	94,61	95,0
46	95,86	**95,19**	+0,19	Lower bound >= LSL	94,35	94,81	94,48	95,0
47	95,76	**95,07**	+0,07	Lower bound >= LSL	94,21	94,68	94,35	95,0
48	95,66	**94,95**	-0,05	Lower bound below LSL	94,06	94,55	94,21	95,0
49	95,56	**94,83**	-0,17	Lower bound below LSL	93,92	94,41	94,08	95,0
50	95,45	**94,71**	-0,29	Lower bound below LSL	93,78	94,28	93,95	95,0
51	95,35	**94,59**	-0,41	Lower bound below LSL	93,64	94,15	93,81	95,0
52	95,25	**94,47**	-0,53	Lower bound below LSL	93,49	94,02	93,68	95,0
53	95,15	**94,35**	-0,65	Lower bound below LSL	93,35	93,89	93,54	95,0
54	95,05	**94,23**	-0,77	Lower bound below LSL	93,21	93,75	93,41	95,0

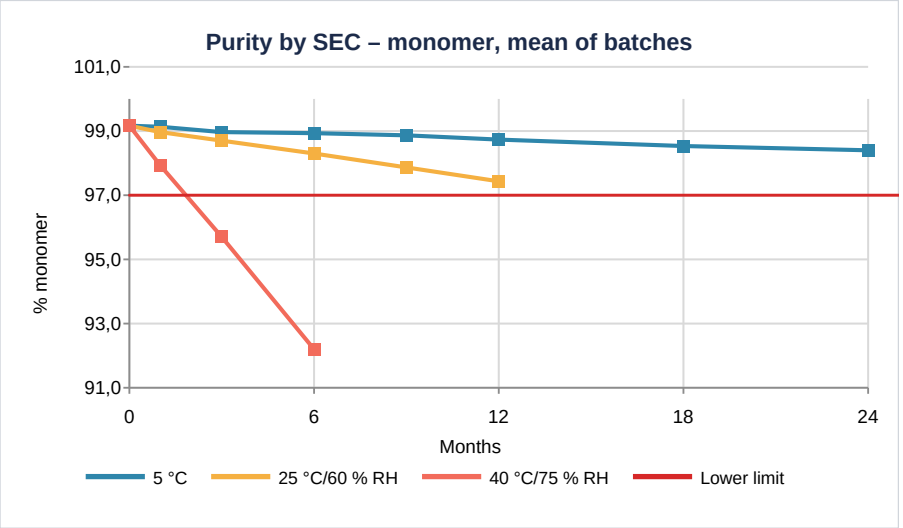
Rows for months 25–54 are grouped (outline level 1). The lower bound decreases monotonically over the whole range, so the shelf-life estimate equals the number of months with a bound at or above the limit (COUNTIF) minus one.

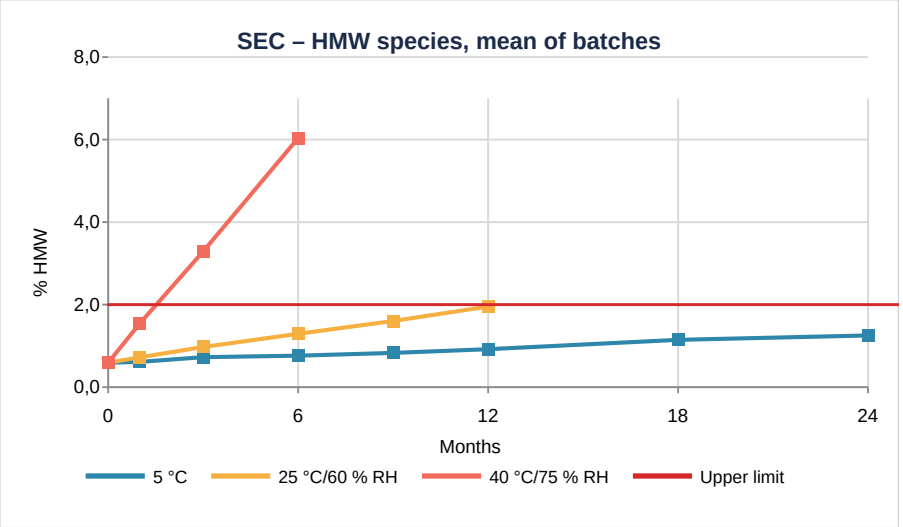
Stability trend charts

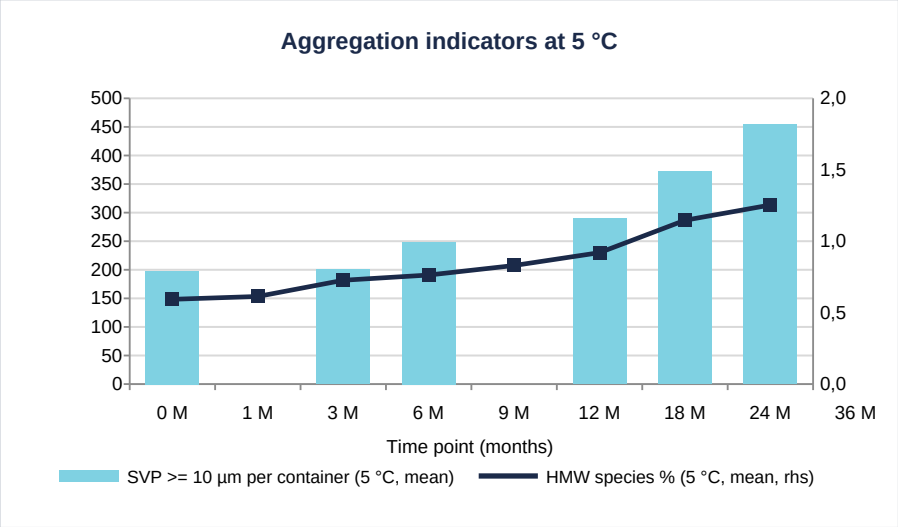
◄ Summary

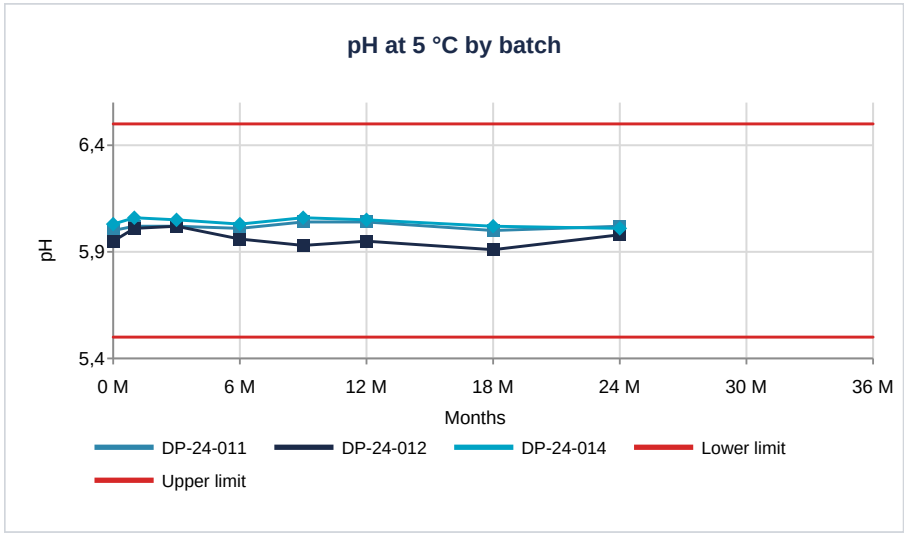
Batch results and batch means by storage condition; dashed red lines are acceptance criteria. Gaps = attribute not tested at that time point.

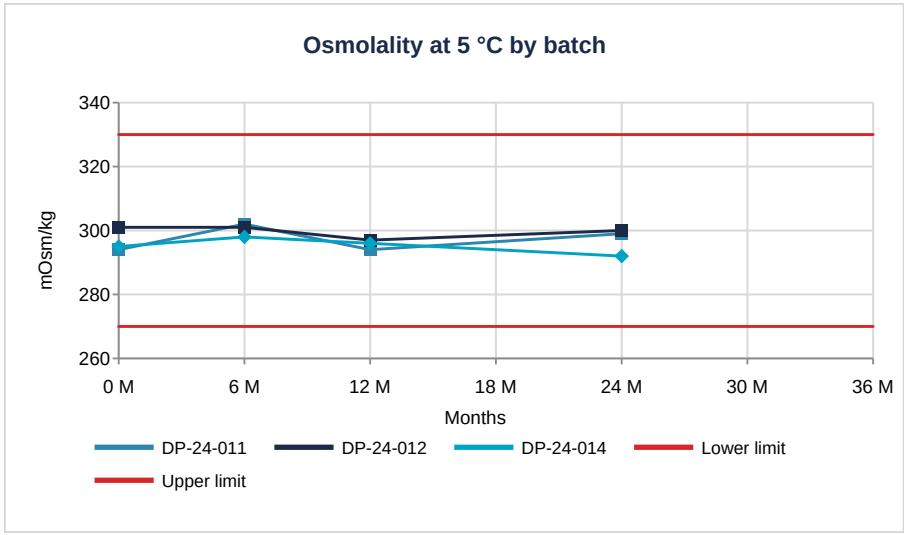


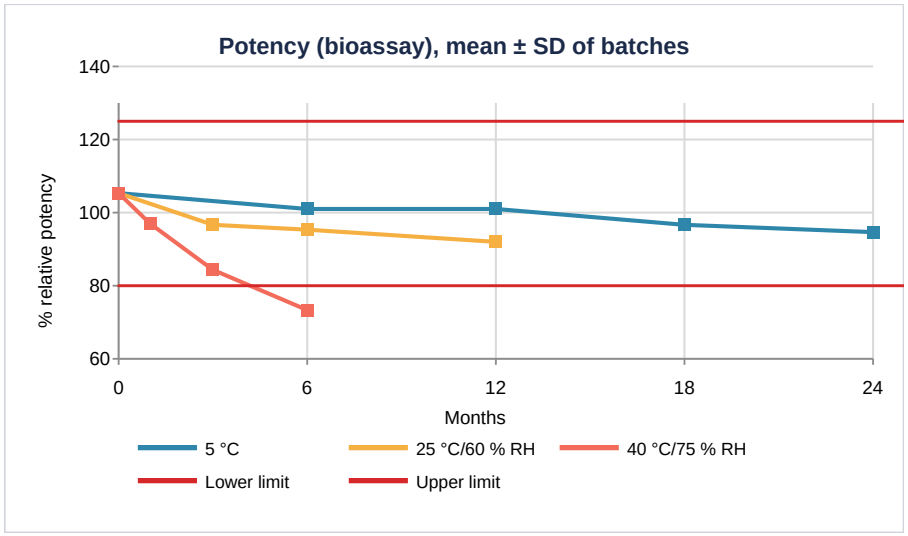


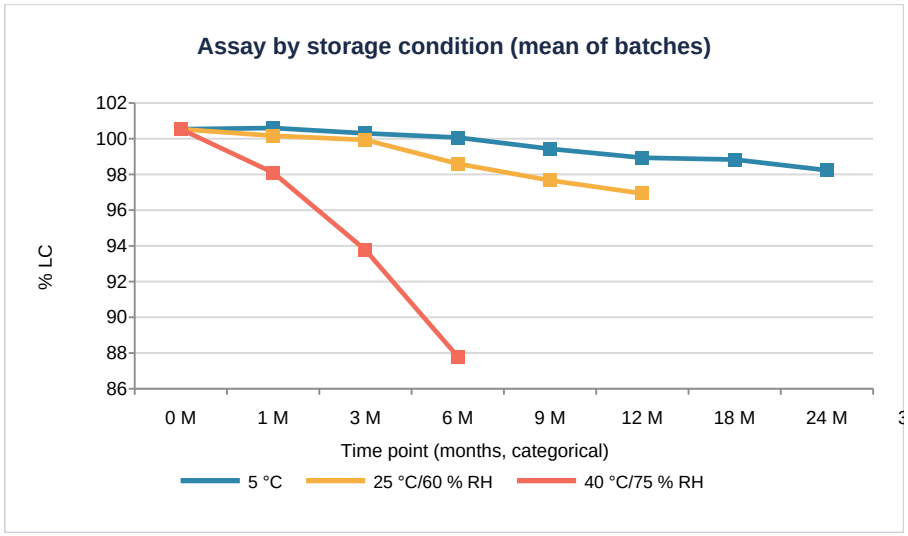





pH at 5 °C by batch
pH
6,4
5,9
5,4
0 M
6 M
12 M
18 M
24 M
30 M
36 M
Months
DP-24-011
DP-24-012
DP-24-014
Lower limit
Upper limit


Osmolality at 5 °C by batch
mOsm/kg
340
320
300
280
260
0 M
6 M
12 M
18 M
24 M
30 M
36 M
Months
DP-24-011
DP-24-012
DP-24-014
Lower limit
Upper limit


Potency (bioassay), mean ± SD of batches
% relative potency
140
120
100
80
60
0
6
12
18
24
Months
5 °C
25 °C/60 % RH
40 °C/75 % RH
Lower limit
Upper limit


Assay by storage condition (mean of batches)
% LC
102
100
98
96
94
92
90
88
86
0 M
1 M
3 M
6 M
9 M
12 M
18 M
24 M
Time point (months, categorical)
5 °C
25 °C/60 % RH
40 °C/75 % RH

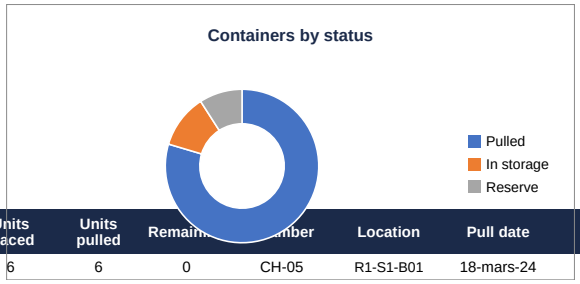
Sample inventory

◄ Summary

Containers placed, pulled and remaining per study arm, time point and test set · filter with the drop-down arrows in the header row

Inventory status at data cut-off

Status	Sample sets	Containers	Share
Pulled	144	738	79,6%
In storage	18	105	11,3%
Reserve	21	84	9,1%
Total	**183**	**927**	**100,0%**



Containers are 6R glass vials (4.0 mL fill). Sample IDs follow the pattern S<batch>-<arm><orientation>-<months>-<test set>-<n>; arm codes: I initial, L long term 5 °C, A accelerated, S stress, P photostability; orientation: U upright, I inverted, H horizontal. Study arm, orientation, months and test set are taken from the pull schedule on the Protocol sheet (INDEX/MATCH on the batch | arm | months key).

Sample ID	Batch	Study arm	Orientation	Months	Test set	Units placed	Units pulled	Remaining	Chamber	Location	Pull date	Status
S011-IU-00-PC1	DP-24-011	Initial	Upright	0	Physicochemical	6	6	0	CH-05	R1-S1-B01	18-mars-24	Pulled
S011-IU-00-BA1	DP-24-011	Initial	Upright	0	Bioassay	3	3	0	CH-05	R1-S2-B02	18-mars-24	Pulled
S011-IU-00-PA1	DP-24-011	Initial	Upright	0	Particles	5	5	0	CH-05	R1-S3-B03	18-mars-24	Pulled
S011-LU-01-PC1	DP-24-011	5 °C	Upright	1	Physicochemical	6	6	0	CH-05	R1-S4-B04	18-avr-24	Pulled
S011-LU-03-PC1	DP-24-011	5 °C	Upright	3	Physicochemical	6	6	0	CH-05	R1-S5-B05	18-juin-24	Pulled
S011-LU-03-PA1	DP-24-011	5 °C	Upright	3	Particles	5	5	0	CH-05	R1-S1-B06	18-juin-24	Pulled
S011-LU-06-PC1	DP-24-011	5 °C	Upright	6	Physicochemical	6	6	0	CH-05	R1-S2-B07	18-sept-24	Pulled
S011-LU-06-BA1	DP-24-011	5 °C	Upright	6	Bioassay	3	3	0	CH-05	R1-S3-B08	18-sept-24	Pulled
S011-LU-06-PA1	DP-24-011	5 °C	Upright	6	Particles	5	5	0	CH-05	R1-S4-B09	18-sept-24	Pulled
S011-LI-06-PC1	DP-24-011	5 °C	Inverted	6	Physicochemical	6	6	0	CH-05	R1-S5-B10	18-sept-24	Pulled
S011-LI-06-PA1	DP-24-011	5 °C	Inverted	6	Particles	5	5	0	CH-05	R1-S1-B11	18-sept-24	Pulled
S011-LU-09-PC1	DP-24-011	5 °C	Upright	9	Physicochemical	6	6	0	CH-05	R1-S2-B12	18-déc-24	Pulled
S011-LU-12-PC1	DP-24-011	5 °C	Upright	12	Physicochemical	6	6	0	CH-05	R1-S3-B13	18-mars-25	Pulled
S011-LU-12-BA1	DP-24-011	5 °C	Upright	12	Bioassay	3	3	0	CH-05	R1-S4-B14	18-mars-25	Pulled
S011-LU-12-PA1	DP-24-011	5 °C	Upright	12	Particles	5	5	0	CH-05	R1-S5-B15	18-mars-25	Pulled
S011-LU-12-CC1	DP-24-011	5 °C	Upright	12	CCI	10	10	0	CH-05	R1-S1-B16	18-mars-25	Pulled
S011-LI-12-PC1	DP-24-011	5 °C	Inverted	12	Physicochemical	6	6	0	CH-05	R1-S2-B17	18-mars-25	Pulled
S011-LI-12-PA1	DP-24-011	5 °C	Inverted	12	Particles	5	5	0	CH-05	R1-S3-B18	18-mars-25	Pulled
S011-LU-18-PC1	DP-24-011	5 °C	Upright	18	Physicochemical	6	6	0	CH-05	R1-S4-B19	18-sept-25	Pulled
S011-LU-18-BA1	DP-24-011	5 °C	Upright	18	Bioassay	3	3	0	CH-05	R1-S5-B20	18-sept-25	Pulled
S011-LU-18-PA1	DP-24-011	5 °C	Upright	18	Particles	5	5	0	CH-05	R1-S1-B21	18-sept-25	Pulled
S011-LU-24-PC1	DP-24-011	5 °C	Upright	24	Physicochemical	6	6	0	CH-05	R1-S2-B22	18-mars-26	Pulled
S011-LU-24-BA1	DP-24-011	5 °C	Upright	24	Bioassay	3	3	0	CH-05	R1-S3-B23	18-mars-26	Pulled
S011-LU-24-PA1	DP-24-011	5 °C	Upright	24	Particles	5	5	0	CH-05	R1-S4-B24	18-mars-26	Pulled
S011-LU-24-CC1	DP-24-011	5 °C	Upright	24	CCI	10	10	0	CH-05	R1-S5-B01	18-mars-26	Pulled
S011-LI-24-PC1	DP-24-011	5 °C	Inverted	24	Physicochemical	6	6	0	CH-05	R1-S1-B02	18-mars-26	Pulled
S011-LI-24-PA1	DP-24-011	5 °C	Inverted	24	Particles	5	5	0	CH-05	R1-S2-B03	18-mars-26	Pulled
S011-LU-36-PC1	DP-24-011	5 °C	Upright	36	Physicochemical	6	0	6	CH-05	R1-S3-B04	18-mars-27	In storage
S011-LU-36-BA1	DP-24-011	5 °C	Upright	36	Bioassay	3	0	3	CH-05	R1-S4-B05	18-mars-27	In storage
S011-LU-36-PA1	DP-24-011	5 °C	Upright	36	Particles	5	0	5	CH-05	R1-S5-B06	18-mars-27	In storage
S011-LU-36-CC1	DP-24-011	5 °C	Upright	36	CCI	10	0	10	CH-05	R1-S1-B07	18-mars-27	In storage
S011-LI-36-PC1	DP-24-011	5 °C	Inverted	36	Physicochemical	6	0	6	CH-05	R1-S2-B08	18-mars-27	In storage
S011-LI-36-PA1	DP-24-011	5 °C	Inverted	36	Particles	5	0	5	CH-05	R1-S3-B09	18-mars-27	In storage
S011-AU-01-PC1	DP-24-011	25 °C	Upright	1	Physicochemical	6	6	0	CH-12	R1-S4-B10	18-avr-24	Pulled
S011-AU-03-PC1	DP-24-011	25 °C	Upright	3	Physicochemical	6	6	0	CH-12	R1-S5-B11	18-juin-24	Pulled
S011-AU-03-BA1	DP-24-011	25 °C	Upright	3	Bioassay	3	3	0	CH-12	R1-S1-B12	18-juin-24	Pulled
S011-AU-03-PA1	DP-24-011	25 °C	Upright	3	Particles	5	5	0	CH-12	R1-S2-B13	18-juin-24	Pulled
S011-AU-06-PC1	DP-24-011	25 °C	Upright	6	Physicochemical	6	6	0	CH-12	R1-S3-B14	18-sept-24	Pulled
S011-AU-06-BA1	DP-24-011	25 °C	Upright	6	Bioassay	3	3	0	CH-12	R1-S4-B15	18-sept-24	Pulled
S011-AU-06-PA1	DP-24-011	25 °C	Upright	6	Particles	5	5	0	CH-12	R1-S5-B16	18-sept-24	Pulled
S011-AU-09-PC1	DP-24-011	25 °C	Upright	9	Physicochemical	6	6	0	CH-12	R1-S1-B17	18-déc-24	Pulled
S011-AU-12-PC1	DP-24-011	25 °C	Upright	12	Physicochemical	6	6	0	CH-12	R1-S2-B18	18-mars-25	Pulled
S011-AU-12-BA1	DP-24-011	25 °C	Upright	12	Bioassay	3	3	0	CH-12	R1-S3-B19	18-mars-25	Pulled
S011-AU-12-PA1	DP-24-011	25 °C	Upright	12	Particles	5	5	0	CH-12	R1-S4-B20	18-mars-25	Pulled
S011-SU-01-PC1	DP-24-011	40 °C	Upright	1	Physicochemical	6	6	0	CH-14	R1-S5-B21	18-avr-24	Pulled
S011-SU-01-BA1	DP-24-011	40 °C	Upright	1	Bioassay	3	3	0	CH-14	R1-S1-B22	18-avr-24	Pulled
S011-SU-01-PA1	DP-24-011	40 °C	Upright	1	Particles	5	5	0	CH-14	R1-S2-B23	18-avr-24	Pulled
S011-SU-03-PC1	DP-24-011	40 °C	Upright	3	Physicochemical	6	6	0	CH-14	R1-S3-B24	18-juin-24	Pulled
S011-SU-03-BA1	DP-24-011	40 °C	Upright	3	Bioassay	3	3	0	CH-14	R1-S4-B01	18-juin-24	Pulled
S011-SU-03-PA1	DP-24-011	40 °C	Upright	3	Particles	5	5	0	CH-14	R1-S5-B02	18-juin-24	Pulled
S011-SU-06-PC1	DP-24-011	40 °C	Upright	6	Physicochemical	6	6	0	CH-14	R1-S1-B03	18-sept-24	Pulled
S011-SU-06-BA1	DP-24-011	40 °C	Upright	6	Bioassay	3	3	0	CH-14	R1-S2-B04	18-sept-24	Pulled
S011-SU-06-PA1	DP-24-011	40 °C	Upright	6	Particles	5	5	0	CH-14	R1-S3-B05	18-sept-24	Pulled
S011-LU-RS-RV1	DP-24-011	5 °C	Upright		Reserve	4	0	4	CH-05	R1-S4-B06		Reserve
S011-LU-RS-RV2	DP-24-011	5 °C	Upright		Reserve	4	0	4	CH-05	R1-S5-B07		Reserve
S011-LU-RS-RV3	DP-24-011	5 °C	Upright		Reserve	4	0	4	CH-05	R1-S1-B08		Reserve
S011-LU-RS-RV4	DP-24-011	5 °C	Upright		Reserve	4	0	4	CH-05	R1-S2-B09		Reserve
S011-AU-RS-RV1	DP-24-011	25 °C	Upright		Reserve	4	0	4	CH-12	R1-S3-B10		Reserve
S011-SU-RS-RV1	DP-24-011	40 °C	Upright		Reserve	4	0	4	CH-14	R1-S4-B11		Reserve
S011-PH-00-PH1	DP-24-011	Q1B light	Horizontal	0	Photostability	4	4	0	LC-02	R1-S5-B12	29-avr-24	Pulled
S011-PH-00-RV1	DP-24-011	Q1B light	Horizontal	0	Reserve	4	0	4	LC-02	R1-S1-B13	29-avr-24	Reserve
S012-IU-00-PC1	DP-24-012	Initial	Upright	0	Physicochemical	6	6	0	CH-05	R2-S2-B14	25-mars-24	Pulled
S012-IU-00-BA1	DP-24-012	Initial	Upright	0	Bioassay	3	3	0	CH-05	R2-S3-B15	25-mars-24	Pulled

Sample ID	Batch	Study arm	Orientation	Months	Test set	Units placed	Units pulled	Remaining	Chamber	Location	Pull date	Status
S012-IU-00-PA1	DP-24-012	Initial	Upright	0	Particles	5	5	0	CH-05	R2-S4-B16	25-mars-24	Pulled
S012-LU-01-PC1	DP-24-012	5 °C	Upright	1	Physicochemical	6	6	0	CH-05	R2-S5-B17	25-avr-24	Pulled
S012-LU-03-PC1	DP-24-012	5 °C	Upright	3	Physicochemical	6	6	0	CH-05	R2-S1-B18	25-juin-24	Pulled
S012-LU-03-PA1	DP-24-012	5 °C	Upright	3	Particles	5	5	0	CH-05	R2-S2-B19	25-juin-24	Pulled
S012-LU-06-PC1	DP-24-012	5 °C	Upright	6	Physicochemical	6	6	0	CH-05	R2-S3-B20	25-sept-24	Pulled
S012-LU-06-BA1	DP-24-012	5 °C	Upright	6	Bioassay	3	3	0	CH-05	R2-S4-B21	25-sept-24	Pulled
S012-LU-06-PA1	DP-24-012	5 °C	Upright	6	Particles	5	5	0	CH-05	R2-S5-B22	25-sept-24	Pulled
S012-LI-06-PC1	DP-24-012	5 °C	Inverted	6	Physicochemical	6	6	0	CH-05	R2-S1-B23	25-sept-24	Pulled
S012-LI-06-PA1	DP-24-012	5 °C	Inverted	6	Particles	5	5	0	CH-05	R2-S2-B24	25-sept-24	Pulled
S012-LU-09-PC1	DP-24-012	5 °C	Upright	9	Physicochemical	6	6	0	CH-05	R2-S3-B01	25-déc-24	Pulled
S012-LU-12-PC1	DP-24-012	5 °C	Upright	12	Physicochemical	6	6	0	CH-05	R2-S4-B02	25-mars-25	Pulled
S012-LU-12-BA1	DP-24-012	5 °C	Upright	12	Bioassay	3	3	0	CH-05	R2-S5-B03	25-mars-25	Pulled
S012-LU-12-PA1	DP-24-012	5 °C	Upright	12	Particles	5	5	0	CH-05	R2-S1-B04	25-mars-25	Pulled
S012-LU-12-CC1	DP-24-012	5 °C	Upright	12	CCI	10	10	0	CH-05	R2-S2-B05	25-mars-25	Pulled
S012-LI-12-PC1	DP-24-012	5 °C	Inverted	12	Physicochemical	6	6	0	CH-05	R2-S3-B06	25-mars-25	Pulled
S012-LI-12-PA1	DP-24-012	5 °C	Inverted	12	Particles	5	5	0	CH-05	R2-S4-B07	25-mars-25	Pulled
S012-LU-18-PC1	DP-24-012	5 °C	Upright	18	Physicochemical	6	6	0	CH-05	R2-S5-B08	25-sept-25	Pulled
S012-LU-18-BA1	DP-24-012	5 °C	Upright	18	Bioassay	3	3	0	CH-05	R2-S1-B09	25-sept-25	Pulled
S012-LU-18-PA1	DP-24-012	5 °C	Upright	18	Particles	5	5	0	CH-05	R2-S2-B10	25-sept-25	Pulled
S012-LU-24-PC1	DP-24-012	5 °C	Upright	24	Physicochemical	6	6	0	CH-05	R2-S3-B11	25-mars-26	Pulled
S012-LU-24-BA1	DP-24-012	5 °C	Upright	24	Bioassay	3	3	0	CH-05	R2-S4-B12	25-mars-26	Pulled
S012-LU-24-PA1	DP-24-012	5 °C	Upright	24	Particles	5	5	0	CH-05	R2-S5-B13	25-mars-26	Pulled
S012-LU-24-CC1	DP-24-012	5 °C	Upright	24	CCI	10	10	0	CH-05	R2-S1-B14	25-mars-26	Pulled
S012-LI-24-PC1	DP-24-012	5 °C	Inverted	24	Physicochemical	6	6	0	CH-05	R2-S2-B15	25-mars-26	Pulled
S012-LI-24-PA1	DP-24-012	5 °C	Inverted	24	Particles	5	5	0	CH-05	R2-S3-B16	25-mars-26	Pulled
S012-LU-36-PC1	DP-24-012	5 °C	Upright	36	Physicochemical	6	0	6	CH-05	R2-S4-B17	25-mars-27	In storage
S012-LU-36-BA1	DP-24-012	5 °C	Upright	36	Bioassay	3	0	3	CH-05	R2-S5-B18	25-mars-27	In storage
S012-LU-36-PA1	DP-24-012	5 °C	Upright	36	Particles	5	0	5	CH-05	R2-S1-B19	25-mars-27	In storage
S012-LU-36-CC1	DP-24-012	5 °C	Upright	36	CCI	10	0	10	CH-05	R2-S2-B20	25-mars-27	In storage
S012-LI-36-PC1	DP-24-012	5 °C	Inverted	36	Physicochemical	6	0	6	CH-05	R2-S3-B21	25-mars-27	In storage
S012-LI-36-PA1	DP-24-012	5 °C	Inverted	36	Particles	5	0	5	CH-05	R2-S4-B22	25-mars-27	In storage
S012-AU-01-PC1	DP-24-012	25 °C	Upright	1	Physicochemical	6	6	0	CH-12	R2-S5-B23	25-avr-24	Pulled
S012-AU-03-PC1	DP-24-012	25 °C	Upright	3	Physicochemical	6	6	0	CH-12	R2-S1-B24	25-juin-24	Pulled
S012-AU-03-BA1	DP-24-012	25 °C	Upright	3	Bioassay	3	3	0	CH-12	R2-S2-B01	25-juin-24	Pulled
S012-AU-03-PA1	DP-24-012	25 °C	Upright	3	Particles	5	5	0	CH-12	R2-S3-B02	25-juin-24	Pulled
S012-AU-06-PC1	DP-24-012	25 °C	Upright	6	Physicochemical	6	6	0	CH-12	R2-S4-B03	25-sept-24	Pulled
S012-AU-06-BA1	DP-24-012	25 °C	Upright	6	Bioassay	3	3	0	CH-12	R2-S5-B04	25-sept-24	Pulled
S012-AU-06-PA1	DP-24-012	25 °C	Upright	6	Particles	5	5	0	CH-12	R2-S1-B05	25-sept-24	Pulled
S012-AU-09-PC1	DP-24-012	25 °C	Upright	9	Physicochemical	6	6	0	CH-12	R2-S2-B06	25-déc-24	Pulled
S012-AU-12-PC1	DP-24-012	25 °C	Upright	12	Physicochemical	6	6	0	CH-12	R2-S3-B07	25-mars-25	Pulled
S012-AU-12-BA1	DP-24-012	25 °C	Upright	12	Bioassay	3	3	0	CH-12	R2-S4-B08	25-mars-25	Pulled
S012-AU-12-PA1	DP-24-012	25 °C	Upright	12	Particles	5	5	0	CH-12	R2-S5-B09	25-mars-25	Pulled
S012-SU-01-PC1	DP-24-012	40 °C	Upright	1	Physicochemical	6	6	0	CH-14	R2-S1-B10	25-avr-24	Pulled
S012-SU-01-BA1	DP-24-012	40 °C	Upright	1	Bioassay	3	3	0	CH-14	R2-S2-B11	25-avr-24	Pulled
S012-SU-01-PA1	DP-24-012	40 °C	Upright	1	Particles	5	5	0	CH-14	R2-S3-B12	25-avr-24	Pulled
S012-SU-03-PC1	DP-24-012	40 °C	Upright	3	Physicochemical	6	6	0	CH-14	R2-S4-B13	25-juin-24	Pulled
S012-SU-03-BA1	DP-24-012	40 °C	Upright	3	Bioassay	3	3	0	CH-14	R2-S5-B14	25-juin-24	Pulled
S012-SU-03-PA1	DP-24-012	40 °C	Upright	3	Particles	5	5	0	CH-14	R2-S1-B15	25-juin-24	Pulled
S012-SU-06-PC1	DP-24-012	40 °C	Upright	6	Physicochemical	6	6	0	CH-14	R2-S2-B16	25-sept-24	Pulled
S012-SU-06-BA1	DP-24-012	40 °C	Upright	6	Bioassay	3	3	0	CH-14	R2-S3-B17	25-sept-24	Pulled
S012-SU-06-PA1	DP-24-012	40 °C	Upright	6	Particles	5	5	0	CH-14	R2-S4-B18	25-sept-24	Pulled
S012-LU-RS-RV1	DP-24-012	5 °C	Upright		Reserve	4	0	4	CH-05	R2-S5-B19		Reserve
S012-LU-RS-RV2	DP-24-012	5 °C	Upright		Reserve	4	0	4	CH-05	R2-S1-B20		Reserve
S012-LU-RS-RV3	DP-24-012	5 °C	Upright		Reserve	4	0	4	CH-05	R2-S2-B21		Reserve
S012-LU-RS-RV4	DP-24-012	5 °C	Upright		Reserve	4	0	4	CH-05	R2-S3-B22		Reserve
S012-AU-RS-RV1	DP-24-012	25 °C	Upright		Reserve	4	0	4	CH-12	R2-S4-B23		Reserve
S012-SU-RS-RV1	DP-24-012	40 °C	Upright		Reserve	4	0	4	CH-14	R2-S5-B24		Reserve
S012-PH-00-PH1	DP-24-012	Q1B light	Horizontal	0	Photostability	4	4	0	LC-02	R2-S1-B01	29-avr-24	Pulled
S012-PH-00-RV1	DP-24-012	Q1B light	Horizontal	0	Reserve	4	0	4	LC-02	R2-S2-B02	29-avr-24	Reserve
S014-IU-00-PC1	DP-24-014	Initial	Upright	0	Physicochemical	6	6	0	CH-05	R3-S3-B03	22-avr-24	Pulled
S014-IU-00-BA1	DP-24-014	Initial	Upright	0	Bioassay	3	3	0	CH-05	R3-S4-B04	22-avr-24	Pulled
S014-IU-00-PA1	DP-24-014	Initial	Upright	0	Particles	5	5	0	CH-05	R3-S5-B05	22-avr-24	Pulled
S014-LU-01-PC1	DP-24-014	5 °C	Upright	1	Physicochemical	6	6	0	CH-05	R3-S1-B06	22-mai-24	Pulled
S014-LU-03-PC1	DP-24-014	5 °C	Upright	3	Physicochemical	6	6	0	CH-05	R3-S2-B07	22-juil-24	Pulled
S014-LU-03-PA1	DP-24-014	5 °C	Upright	3	Particles	5	5	0	CH-05	R3-S3-B08	22-juil-24	Pulled
S014-LU-06-PC1	DP-24-014	5 °C	Upright	6	Physicochemical	6	6	0	CH-05	R3-S4-B09	22-oct-24	Pulled
S014-LU-06-BA1	DP-24-014	5 °C	Upright	6	Bioassay	3	3	0	CH-05	R3-S5-B10	22-oct-24	Pulled
S014-LU-06-PA1	DP-24-014	5 °C	Upright	6	Particles	5	5	0	CH-05	R3-S1-B11	22-oct-24	Pulled
S014-LI-06-PC1	DP-24-014	5 °C	Inverted	6	Physicochemical	6	6	0	CH-05	R3-S2-B12	22-oct-24	Pulled
S014-LI-06-PA1	DP-24-014	5 °C	Inverted	6	Particles	5	5	0	CH-05	R3-S3-B13	22-oct-24	Pulled
S014-LU-09-PC1	DP-24-014	5 °C	Upright	9	Physicochemical	6	6	0	CH-05	R3-S4-B14	22-janv-25	Pulled
S014-LU-12-PC1	DP-24-014	5 °C	Upright	12	Physicochemical	6	6	0	CH-05	R3-S5-B15	22-avr-25	Pulled
S014-LU-12-BA1	DP-24-014	5 °C	Upright	12	Bioassay	3	3	0	CH-05	R3-S1-B16	22-avr-25	Pulled
S014-LU-12-PA1	DP-24-014	5 °C	Upright	12	Particles	5	5	0	CH-05	R3-S2-B17	22-avr-25	Pulled
S014-LU-12-CC1	DP-24-014	5 °C	Upright	12	CCI	10	10	0	CH-05	R3-S3-B18	22-avr-25	Pulled

Sample ID	Batch	Study arm	Orientation	Months	Test set	Units placed	Units pulled	Remaining	Chamber	Location	Pull date	Status
S014-LI-12-PC1	DP-24-014	5 °C	Inverted	12	Physicochemical	6	6	0	CH-05	R3-S4-B19	22-avr-25	Pulled
S014-LI-12-PA1	DP-24-014	5 °C	Inverted	12	Particles	5	5	0	CH-05	R3-S5-B20	22-avr-25	Pulled
S014-LU-18-PC1	DP-24-014	5 °C	Upright	18	Physicochemical	6	6	0	CH-05	R3-S1-B21	22-oct-25	Pulled
S014-LU-18-BA1	DP-24-014	5 °C	Upright	18	Bioassay	3	3	0	CH-05	R3-S2-B22	22-oct-25	Pulled
S014-LU-18-PA1	DP-24-014	5 °C	Upright	18	Particles	5	5	0	CH-05	R3-S3-B23	22-oct-25	Pulled
S014-LU-24-PC1	DP-24-014	5 °C	Upright	24	Physicochemical	6	6	0	CH-05	R3-S4-B24	22-avr-26	Pulled
S014-LU-24-BA1	DP-24-014	5 °C	Upright	24	Bioassay	3	3	0	CH-05	R3-S5-B01	22-avr-26	Pulled
S014-LU-24-PA1	DP-24-014	5 °C	Upright	24	Particles	5	5	0	CH-05	R3-S1-B02	22-avr-26	Pulled
S014-LU-24-CC1	DP-24-014	5 °C	Upright	24	CCI	10	10	0	CH-05	R3-S2-B03	22-avr-26	Pulled
S014-LI-24-PC1	DP-24-014	5 °C	Inverted	24	Physicochemical	6	6	0	CH-05	R3-S3-B04	22-avr-26	Pulled
S014-LI-24-PA1	DP-24-014	5 °C	Inverted	24	Particles	5	5	0	CH-05	R3-S4-B05	22-avr-26	Pulled
S014-LU-36-PC1	DP-24-014	5 °C	Upright	36	Physicochemical	6	0	6	CH-05	R3-S5-B06	22-avr-27	In storage
S014-LU-36-BA1	DP-24-014	5 °C	Upright	36	Bioassay	3	0	3	CH-05	R3-S1-B07	22-avr-27	In storage
S014-LU-36-PA1	DP-24-014	5 °C	Upright	36	Particles	5	0	5	CH-05	R3-S2-B08	22-avr-27	In storage
S014-LU-36-CC1	DP-24-014	5 °C	Upright	36	CCI	10	0	10	CH-05	R3-S3-B09	22-avr-27	In storage
S014-LI-36-PC1	DP-24-014	5 °C	Inverted	36	Physicochemical	6	0	6	CH-05	R3-S4-B10	22-avr-27	In storage
S014-LI-36-PA1	DP-24-014	5 °C	Inverted	36	Particles	5	0	5	CH-05	R3-S5-B11	22-avr-27	In storage
S014-AU-01-PC1	DP-24-014	25 °C	Upright	1	Physicochemical	6	6	0	CH-12	R3-S1-B12	22-mai-24	Pulled
S014-AU-03-PC1	DP-24-014	25 °C	Upright	3	Physicochemical	6	6	0	CH-12	R3-S2-B13	22-juil-24	Pulled
S014-AU-03-BA1	DP-24-014	25 °C	Upright	3	Bioassay	3	3	0	CH-12	R3-S3-B14	22-juil-24	Pulled
S014-AU-03-PA1	DP-24-014	25 °C	Upright	3	Particles	5	5	0	CH-12	R3-S4-B15	22-juil-24	Pulled
S014-AU-06-PC1	DP-24-014	25 °C	Upright	6	Physicochemical	6	6	0	CH-12	R3-S5-B16	22-oct-24	Pulled
S014-AU-06-BA1	DP-24-014	25 °C	Upright	6	Bioassay	3	3	0	CH-12	R3-S1-B17	22-oct-24	Pulled
S014-AU-06-PA1	DP-24-014	25 °C	Upright	6	Particles	5	5	0	CH-12	R3-S2-B18	22-oct-24	Pulled
S014-AU-09-PC1	DP-24-014	25 °C	Upright	9	Physicochemical	6	6	0	CH-12	R3-S3-B19	22-janv-25	Pulled
S014-AU-12-PC1	DP-24-014	25 °C	Upright	12	Physicochemical	6	6	0	CH-12	R3-S4-B20	22-avr-25	Pulled
S014-AU-12-BA1	DP-24-014	25 °C	Upright	12	Bioassay	3	3	0	CH-12	R3-S5-B21	22-avr-25	Pulled
S014-AU-12-PA1	DP-24-014	25 °C	Upright	12	Particles	5	5	0	CH-12	R3-S1-B22	22-avr-25	Pulled
S014-SU-01-PC1	DP-24-014	40 °C	Upright	1	Physicochemical	6	6	0	CH-14	R3-S2-B23	22-mai-24	Pulled
S014-SU-01-BA1	DP-24-014	40 °C	Upright	1	Bioassay	3	3	0	CH-14	R3-S3-B24	22-mai-24	Pulled
S014-SU-01-PA1	DP-24-014	40 °C	Upright	1	Particles	5	5	0	CH-14	R3-S4-B01	22-mai-24	Pulled
S014-SU-03-PC1	DP-24-014	40 °C	Upright	3	Physicochemical	6	6	0	CH-14	R3-S5-B02	22-juil-24	Pulled
S014-SU-03-BA1	DP-24-014	40 °C	Upright	3	Bioassay	3	3	0	CH-14	R3-S1-B03	22-juil-24	Pulled
S014-SU-03-PA1	DP-24-014	40 °C	Upright	3	Particles	5	5	0	CH-14	R3-S2-B04	22-juil-24	Pulled
S014-SU-06-PC1	DP-24-014	40 °C	Upright	6	Physicochemical	6	6	0	CH-14	R3-S3-B05	22-oct-24	Pulled
S014-SU-06-BA1	DP-24-014	40 °C	Upright	6	Bioassay	3	3	0	CH-14	R3-S4-B06	22-oct-24	Pulled
S014-SU-06-PA1	DP-24-014	40 °C	Upright	6	Particles	5	5	0	CH-14	R3-S5-B07	22-oct-24	Pulled
S014-LU-RS-RV1	DP-24-014	5 °C	Upright		Reserve	4	0	4	CH-05	R3-S1-B08		Reserve
S014-LU-RS-RV2	DP-24-014	5 °C	Upright		Reserve	4	0	4	CH-05	R3-S2-B09		Reserve
S014-LU-RS-RV3	DP-24-014	5 °C	Upright		Reserve	4	0	4	CH-05	R3-S3-B10		Reserve
S014-LU-RS-RV4	DP-24-014	5 °C	Upright		Reserve	4	0	4	CH-05	R3-S4-B11		Reserve
S014-AU-RS-RV1	DP-24-014	25 °C	Upright		Reserve	4	0	4	CH-12	R3-S5-B12		Reserve
S014-SU-RS-RV1	DP-24-014	40 °C	Upright		Reserve	4	0	4	CH-14	R3-S1-B13		Reserve
S014-PH-00-PH1	DP-24-014	Q1B light	Horizontal	0	Photostability	4	4	0	LC-02	R3-S2-B14	27-mai-24	Pulled
S014-PH-00-RV1	DP-24-014	Q1B light	Horizontal	0	Reserve	4	0	4	LC-02	R3-S3-B15	27-mai-24	Reserve
Total						927	738	189			Sets:	183

Review and approval

◄ Summary

Interim stability report STR-0217-DP-24M, version 1.0 · electronic signatures in the document management system take precedence over this record

1. Review checklist

No.	Item	Result	Reviewer	Remark
1	All results transcribed from LIMS have been verified (100 % check)	Yes	M. Zehnder	
2	Time points pulled within the protocol windows	Yes	M. Zehnder	One pull at +3 d (window ±7 d).
3	Chamber excursions assessed and documented	Yes	L. Imboden	DEV-25-0311, no impact.
4	OOS results investigated and closed	Yes	S. Furrer	INV-26-0118 closed 03-Jun-2026.
5	OOT evaluation performed for long-term and accelerated arms	Yes	L. Imboden	Accelerated assay OOT is expected.
6	Statistical evaluation according to ICH Q1E	Yes	M. Zehnder	Pooled model, p > 0.25.
7	Shelf-life proposal within the extrapolation limits of Q1E	Yes	L. Imboden	
8	Photostability (ICH Q1B) results included	N/A	L. Imboden	Reported separately in STR-0217-DP-PH.
9	Reference standard and system suitability within limits	Yes	M. Zehnder	
10	Report reviewed against protocol STP-0217-DP-003 v2.0	Yes	S. Furrer	
11	Commitments to regulatory authorities identified	No	S. Furrer	To be completed before submission.
	Open items	1		

2. Reviewer comments

No.	Comment	Section	Raised by	Response	Date	Status
1	Clarify whether the 25 °C OOS (HMW, 12 M) affects the proposed storage statement.	Results 25 °C	S. Furrer (QA)	No impact: accelerated arm; statement remains "Store at 2–8 °C".	04-juin-2026	Closed
2	Add residual analysis to the regression sheet.	Regression	Dr. P. Kälin (Statistics)	Residuals vs pooled fit added with data bars.	05-juin-2026	Closed
3	Confirm sample reserve is sufficient for a 48-month extension.	Sample inventory	L. Imboden	Four reserve sets per batch at 5 °C remain.	08-juin-2026	Closed
4	Include potency SD in the trend chart.	Charts	M. Zehnder	Error bars (± SD) added.	09-juin-2026	Closed

3. Approval signatures

	Role	Name	Function	Signature	Date	Meaning of signature
1	**Author**	Marco Zehnder	QC Stability Scientist		10-juin-2026	Prepared; data verified
2	**Reviewer**	Dr. Lea Imboden	Head of QC Stability		11-juin-2026	Technically reviewed
3	**Approver**	Sandra Furrer	QA Manager, Product Quality			Approved for release
4	**Approver**	Dr. Thomas Abgottspon	Qualified Person			Approved for regulatory use

4. Revision history

Ver.	Description	Date	Author	Change control
0.1	Draft with 18-month data	20-nov-2025	M. Zehnder	–
0.2	24-month data added; regression updated	29-mai-2026	M. Zehnder	–
1.0	Reviewer comments incorporated; issued for approval	12-juin-2026	M. Zehnder	CC-26-0457