Dissolution by mass

One vial dissolved whole by mass: the three weighings with their times, the venting, the medium, the clarity record and the aliquots drawn from the stock, in the order of the work.

Not yet approved
No approval of this revision is on file. This form is a controlled record once approved; until then it is the proposed layout of the bench record its procedure names.

Worksheet	
Number	WS-03
Revision	1, first issue
Governs	SOP-06 Mass per vial by external standard, revision 1
Status	Not yet approved
Effective	Not yet in effect; takes effect when approved
Applies to	Every vial dissolved for Mass per vial, Purity by RP-HPLC–UV, Identity by LC–MS or Bacterial endotoxin
Supersedes	Nothing; first issue
Fingerprint	0161 ae01 526e 1ed6

Laboratory	
Name	Cupel Laboratories
Address	2599 Speakman Dr Mississauga, ON L5K 1B1
Country	Canada
Not on file	Not yet published: legal entity, postal address, telephone and country
Web	cupel.ca
Email	help@cupel.ca

1 Header

Accession, or the set id before logging

Analyte, as labelled

Analyst (the “Working as” name)

Date of the work (UTC)

Reviewer: line-by-line check (initials, date)

Attached to the set as (caption “WS-03 page p”)

2 How this form is used

- This worksheet is the original record of every value measured away from the backend. It is filled in ink at the moment of measurement; each line carries the time of the measurement and the analyst’s initials.
- A correction is a single line through the value, the new value, initials, the date and the reason; nothing is overwritten or erased.
- The completed form is photographed or scanned the same day and attached to the set at /photo/<id>/<name> with the caption “WS-03 page p”, each file hashed into the set’s trail as a “photo” entry; the values are typed into the form from it, and the reviewer checks the typed set against these pages line by line before signing.
- Lines marked “model only” feed a key the backend’s form does not yet expose: the value is typed into the section’s notes until it does. Lines marked “worksheet only” stay on this paper and in the notes.
- A failed criterion stops the work at that line: the time and what was done are written here, and the event goes to the set the same day as a note, a stop or a deviation (SOP-08).

3 Record

Vial: P1

One block per vial dissolved whole by mass; a test code with one vial (PUR, IDP, ID, LAL) uses the first block for that vial.

#	Field, and the result-set key it feeds	Unit, decimals	Criterion	Value	Time (UTC), initials
1	Vial number (WS-01); format; brimful capacity (SOP-09's format table); route: in-vial or tube qnt.sample.preparations[].label qnt.sample.preparations[].container	text			
2	Time out of storage; stood sealed in the balance room worksheet only	hh:mm UTC	for at least 2 h before any weighing (SOP-05)		
3	Vented: method (stopper lifted / needle / none); time qnt.sample.preparations[].vented qnt.sample.preparations[].vent_method	text	lift the stopper for about a minute under the hood, reseat, equilibrate 10 min, then weigh (SOP-06)		
4	W0, the vented sealed vial qnt.sample.preparations[].w0_mg qnt.sample.preparations[].w0_utc	mg, 2 decimals			
5	Decrimped in one piece; powder on the stopper (rinsed into the vial) worksheet only Powder on the stopper flags the gross fill.	Y / N		Y / N	
6	Wc, the closure, dry qnt.sample.preparations[].wc_mg qnt.sample.preparations[].wc_utc	mg, 2 decimals	within 2 min of decapping (SOP-06)		

Vial: P2

#	Field, and the result-set key it feeds	Unit, decimals	Criterion	Value	Time (UTC), initials
7	Vial number (WS-01); format; brimful capacity (SOP-09's format table); route: in-vial or tube qnt.sample.preparations[].label qnt.sample.preparations[].container	text			
8	Time out of storage; stood sealed in the balance room worksheet only	hh:mm UTC	for at least 2 h before any weighing (SOP-05)		
9	Vented: method (stopper lifted / needle / none); time qnt.sample.preparations[].vented qnt.sample.preparations[].vent_method	text	lift the stopper for about a minute under the hood, reseat, equilibrate 10 min, then weigh (SOP-06)		
10	W0, the vented sealed vial qnt.sample.preparations[].w0_mg qnt.sample.preparations[].w0_utc	mg, 2 decimals			
11	Decrimped in one piece; powder on the stopper (rinsed into the vial) worksheet only Powder on the stopper flags the gross fill.	Y / N		Y / N	
12	Wc, the closure, dry qnt.sample.preparations[].wc_mg qnt.sample.preparations[].wc_utc	mg, 2 decimals	within 2 min of decapping (SOP-06)		

Record, continued

Vial: P3

#	Field, and the result-set key it feeds	Unit, decimals	Criterion	Value	Time (UTC), initials
13	Vial number (WS-01); format; brimful capacity (SOP-09's format table); route: in-vial or tube qnt.sample.preparations[].label qnt.sample.preparations[].container	text			
14	Time out of storage; stood sealed in the balance room worksheet only	hh:mm UTC	for at least 2 h before any weighing (SOP-05)		
15	Vented: method (stopper lifted / needle / none); time qnt.sample.preparations[].vented qnt.sample.preparations[].vent_method	text	lift the stopper for about a minute under the hood, reseat, equilibrate 10 min, then weigh (SOP-06)		
16	W0, the vented sealed vial qnt.sample.preparations[].w0_mg qnt.sample.preparations[].w0_utc	mg, 2 decimals			
17	Decrimped in one piece; powder on the stopper (rinsed into the vial) worksheet only Powder on the stopper flags the gross fill.	Y / N		Y / N	
18	Wc, the closure, dry qnt.sample.preparations[].wc_mg qnt.sample.preparations[].wc_utc	mg, 2 decimals	within 2 min of decapping (SOP-06)		

Medium and dissolution

#	Field, and the result-set key it feeds	Unit, decimals	Criterion	Value	Time (UTC), initials
19	Medium: name, lot, certificate, expiry checked qnt.medium.name qnt.medium.lot qnt.medium.certificate_ref qnt.medium.expiry_utc qnt.sample.preparations[].medium	hh:mm UTC	dissolved by mass, to 2.0 mg/mL nominal in LAL reagent water (10 mM Tris of LAL grade for semaglutide, tirzepatide and retatrutide)		
20	pH of the Tris medium at preparation (10 mM Tris, pH 7.8, LAL grade) worksheet only	pH, 2 decimals	10 mM Tris, pH 7.8, LAL grade; the buffer drifts about 0.03 pH per °C (SOP-04)		
21	Medium temperature qnt.sample.preparations[].temperature_c	°C, 1 decimal	temperature at preparation to 0.5 °C (SOP-06)		
22	Target medium mass m_w = V × rho_w(T); found m_w qnt.sample.preparations[].medium_mass_g	g, 4 decimals	rho_w: 15 °C 0.9991 g/mL; 20 °C 0.9982 g/mL; 25 °C 0.99705 g/mL; 30 °C 0.99565 g/mL		
23	Tube route: tube lot and certificate; first portion; rinses 1–3 (masses) worksheet only	text	0.8–1.0 mL of medium in the vial (SOP-06)		
24	Mixing: method; start and end; sonication (s, °C) worksheet only	text	inversion or rolling for 10 min at 20–25 °C (SOP-06)		

Record, continued

#	Field, and the result-set key it feeds	Unit, decimals	Criterion	Value	Time (UTC), initials
25	Clarity against black and white; colour qnt.sample.preparations[].clarity sample.reconstitution_observation	text			
26	Time to dissolve; time of the clarity record (the hold clock starts) qnt.sample.preparations[].time_to_dissolve_min qnt.sample.preparations[].dissolved_utc	min			

Aliquots, in order, from the first preparation

#	Field, and the result-set key it feeds	Unit, decimals	Criterion	Value	Time (UTC), initials
27	Endotoxin aliquot 1 + 39 (P1): time lal.sample.preparation_source lal.sample.aliquot_utc	hh:mm UTC	within 15 min of the clarity record (SOP-04)		
28	Purity solution 1 + 1 in mobile phase A (P1): time hplc.sample.source hplc.sample.prepared_utc	hh:mm UTC	1 mg/mL nominal		
29	Content solution 1 + 9 by mass (each vial): D_m = (m_s + m_d) / m_s qnt.sample.preparations[].dilution_factor	ratio, from the two masses	the Tris stock added to the pre-weighed mobile phase A with immediate mixing, never the reverse		
30	Identity solution the purity solution 1 + 9 in mobile phase A (P1): time worksheet only	hh:mm UTC			
31	Stock to 2–8 °C: time; discard time worksheet only	hh:mm UTC	the stock 24 h at 2–8 °C (SOP-02)		

After the analysis

#	Field, and the result-set key it feeds	Unit, decimals	Criterion	Value	Time (UTC), initials
32	W2, the bare glass: rinsed, dried, equilibrated; weighed qnt.sample.preparations[].w2_mg qnt.sample.preparations[].w2_utc	mg, 2 decimals	dried 1 h at 105 °C and equilibrated open in the balance room for at least 2 h (SOP-06)		
33	G = W0 – Wc – W2, by the analyst for the sanity check only qnt.sample.preparations[].gross_fill_mg The model derives G; typed only when the three weighings are not recorded.	mg, 2 decimals			

Every solution container is labelled with the accession, the solution name (STOCK, PUR, ID, CONT, LAL 1:40), the concentration, the date and time made, the analyst and the expiry.

4 Completion

Completed by (signature) and time (UTC)

Reviewed line by line by (initials) on (date)

5 Revision history

Revision	Change	Approval
1	First issue.	Not yet approved

The fingerprint in the control block is the SHA-256 of this document's text as composed, first 16 hex digits. A change in any controlled source changes it; a copy whose fingerprint differs from the approved one is not the approved text, and a change is approved as a new revision.

Cupel holds no ISO/IEC 17025 accreditation; results are not accredited results.

This document is published so that a chemist can judge how a result was produced and what it can and cannot show; it is not an accredited procedure and claims no conformity with any standard it cites.

The current revision of every laboratory document is the one published at cupel.ca/methods. A printed copy is uncontrolled: compare its fingerprint with the published one.

Current revisions

End of document