Mass per vial: the standard and the levels

The reference standard's weighing and dilution, the calibration levels and the content solutions by mass, the sequence and its areas; the standard block the purity run shares.

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-05
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	Test codes QNT, FULL; the suitability standard of PUR and IDP
Supersedes	Nothing; first issue
Fingerprint	42b9 7b57 bf03 f828

Laboratory	
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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-05 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-05 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

The reference standard

#	Field, and the result-set key it feeds	Unit, decimals	Criterion	Value	Time (UTC), initials
1	Name; supplier; catalogue; lot qnt.standard.name qnt.standard.supplier qnt.standard.catalogue qnt.standard.lot	text			
2	Assigned content; basis; how assigned; uncertainty and its source qnt.standard.content_pct qnt.standard.content_basis qnt.standard.content_source qnt.standard.content_u_rel_pct qnt.standard.content_u_source	%, 1 decimal	default u 3% relative when the certificate states none		
3	Certificate reference; assigned by; expiry checked; storage; date first opened; openings qnt.standard.certificate_ref qnt.standard.assigned_by qnt.standard.expiry_utc qnt.standard.storage	hh:mm UTC			
4	Container out of the freezer; opened worksheet only	hh:mm UTC	stand sealed at room temperature for at least 30 min (SOP-06)		
5	Balance id; tare container; mass of standard by difference; time open qnt.balance.id	mg, as displayed	weigh at least 10 mg by difference; within 30 s of opening		
6	Medium (as WS-03); medium mass; stock concentration worksheet only	g; mg/mL, as displayed	stock 2 mg/mL nominal		

Calibration levels by mass, the stock into the acid

#	Field, and the result-set key it feeds	Unit, decimals	Criterion	Value	Time (UTC), initials
7	L1–Ln: m_stock, m_MPA, D_m, nominal concentration; vial type; prepared qnt.standard.levels[].conc_mg_ml qnt.standard.levels[].prepared_utc	mg/mL, 2 decimals	the stock added to the acid: 1 + 4, 3 + 17, 1 + 9, 1 + 19 and 1 + 39 of the stock give 0.4, 0.3, 0.2, 0.1, 0.05 mg/mL (SOP-06)		
8	Content solutions P1–P3: m_stock, m_MPA, D_m, vial type, time; mixing order ticked qnt.sample.preparations[].dilution_factor	g; ratio, D_m from the two masses	the Tris stock added to the pre-weighed mobile phase A with immediate mixing, never the reverse		

Sequence and areas

#	Field, and the result-set key it feeds	Unit, decimals	Criterion	Value	Time (UTC), initials
9	Instrument id; software; column id or lot qnt.instrument.id qnt.instrument.software qnt.column.serial_or_lot	text			

Record, continued

#	Field, and the result-set key it feeds	Unit, decimals	Criterion	Value	Time (UTC), initials
10	Sequence names (_L1 to _Ln, _P1 to _P3, _RINSE for the lipidated); data file; acquired qnt.data_file qnt.acquired_utc	hh:mm UTC			
11	Areas L1–Ln qnt.standard.levels[].area	mAU*s, 1 decimal			
12	Areas P1–P3 qnt.sample.preparations[].area qnt.sample.areas[]	mAU*s, 1 decimal			
13	Fourth-rinse injection (Semaglutide, tirzepatide and retatrutide): peptide found as % of the content worksheet only	%, as displayed	peptide found at most 0.2% of the content (SOP-06)		
14	r^2; every P area between L1 and the top level (as the model reads it after entry); action on a failure worksheet only	text	r^2 at least 0.999; A level is never removed (SOP-06)		
15	Vials consumed qnt.vials_consumed	count			
16	Deviations (text) audit trail: deviation entry	text			

Every solution container is labelled with the accession, the solution name (STD stock, L1 to Ln, CONT P1 to Pn), 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

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Current revisions

End of document