Part 1

Worked solution

Instructor guide / Traceability and test interpretation

1. Match each vial

Vial	Finding	Documented basis
A	Match D2 to DEMO-TP-041.	D1 and D2 agree on TP04-5 and the supplier lot. R-241 is the receiving stock ID.
B	Match D3 to DEMO-TP-042.	D1 and D3 agree on TP04-5 and the supplier lot. R-242 is the receiving stock ID.
C	Hold the match open.	D1 has an unreadable lot field. R-243 is an internal stock ID. A shared catalog number and shipment leave both lots possible.

2. Compare the reported results

Attribute	Criterion	A / D2	B / D3
Intact mass	1124.10–1125.10 Da	1124.71 Da / meets	1124.55 Da / meets
Main peak area	≥ 98.0 area %	98.6 area % / meets	99.2 area % / meets
Peptide content	4.50–5.50 mg/vial	4.92 mg/vial / meets	4.32 mg/vial / below

The content shortfall is 4.50 − 4.32 = 0.18 mg/vial. The main-peak percentage uses total integrated detector area as its denominator. The calibrated assay estimates mg per vial. The two values can differ independently in this example.

The mass results meet the exercise's intact-mass criterion. Agreement with a mass window supplies evidence at the level measured. The amino-acid sequence and the identity of individual receiving vials require additional evidence.

Part 2

Decision and teaching notes

Instructor guide / External evidence and assessment

3. Evaluate the external report

D4 names laboratory sample DEMO-EXT-714 and submitter reference TR-714. It lacks the vial stock ID and supplier lot. The forwarding note is a hypothesis. Request the original sample submission or custody record and any vial-label image that maps DEMO-EXT-714 or TR-714 to receiving stock ID R-242 and supplier lot DEMO-TP-042.

Even if that mapping were established, D4 has no content measurement in mg/vial. Its area percentage therefore cannot resolve the content result outside its criterion in D3. D4 also supplies no acceptance criteria of its own.

4. Example decision note

Vial	Status	Example record entry
A	Documented for the exercise	D1 matches D2 (lot DEMO-TP-041). All three reported results meet their criteria.
B	Hold for a result	D1 matches D3. Record 4.32 mg/vial against 4.50–5.50 mg/vial and request the issuer's investigation or relevant assay record.
C	Hold for traceability	D1 shows an unreadable lot. Request a legible original label or a shipment record that explicitly maps R-243 to a supplier lot.

D2 and D3 describe the respective issuer-selected samples and D4 describes the externally received sample. The teaching decision follows documented links and scope.

Facilitation and scoring

Allow 10 minutes for matching, 10 for the result table and 15–25 for the external report and debrief. Award up to 12 points: vial matching (3), result comparisons and shortfall (3), external linkage and scope (3), documented decisions (3). Accept equivalent follow-up requests that could actually establish the missing link.

Source context

ICH Q7 §11.4 describes certificates of analysis for active pharmaceutical ingredients. It informed the example's document fields. The fictional thresholds and classroom decisions are specific to this exercise.

FDA / ICH Q7 guidance, section 11.4