



TEKMERIS
GLOBAL

THE TEKMERIS
STANDARD

INDEPENDENT VERIFICATION • PRODUCTS AND FACILITIES

The 65-Point Verification Standard.

The protocol TEKMERIS applies on the client's behalf, in full, on every engagement. Three phases in a fixed order: the counterparty is checked before money moves, the site is seen before its production is trusted, and, where the seal is sought, the units are sealed at the line and the sample is tested blind. Every check, in one document.

65

CHECKPOINTS

3

PHASES, FIXED ORDER

7

ANNEXES, ONE SPINE

1

SIGNATURE ON EVERY
REPORT

This is the checklist behind every TEKMERIS engagement: counterparty and documents, the facility and its process, selection and sealing at the line, the blind laboratory panel, and the records that close the file. One spine, applied across every annex. Read it to see exactly what *verified* means before a seal is ever scanned.

TEKMERIS does not verify dates. It verifies runs.

A production date is not proof. A verified production run is.

Most units on the market carry two data points: a manufacture date and an expiry date. No batch number, no lot record, no sampling chain. A unit labelled with a date could have been filled last year, last month or yesterday, and no document can prove which.

Goods arrive with a laboratory report. It says a sample was tested and that it passed. In this trade the document is called a certificate of analysis, or COA. It is issued by the party selling the goods, on a sample that party chose, and it verifies paper against paper: a number matches a number, not a unit. Nothing in a paper trail can show that the unit in a buyer's hand was filled in the run those results describe.

The 65-Point Verification Standard is the answer to that gap, made explicit. It is the full checklist TEKMERIS applies on every engagement, organised into the three phases a run has to clear, from the counterparty's registration to the signed, hashed report and the registry record. The standard never changes; only the laboratory panel does, by annex (page 3). This document explains what is checked and why; it is not itself a verification report. Every engagement produces a signed, hashed report specific to that run or facility, and a registry record the holder of a seal or a badge can check.

PHASE 1 · COUNTERPARTY

Before money moves

The party on the contract is matched against the public register and against the holder of the production licence. A trading company or a sales office has no line to witness; that is reported in writing before anything else is spent. Section A.

PHASE 2 · SITE

Before production is trusted

TEKMERIS attends the site and records what was observed on a stated date: the line, clean-room practice, the records as presented. The facility as it operates, not as it photographs. Sections B and C.

PHASE 3 · BLIND SAMPLE

The result the seal waits for

Units selected at the line by TEKMERIS, blind-coded, shipped by the factory to an ISO/IEC 17025-accredited laboratory, and tested against the client's specification. Sections D and E.

THREE WORDS, FIXED MEANINGS

Every fact in a TEKMERIS report carries one of three labels. **Observed** — the observer saw it, on the stated date. **Presented** — the factory produced the record; recorded as given, not observed being made. **Registry-confirmed** — checked against a public register on the stated date. No sentence blurs them. The same labels are shown against the checkpoints in this document.

INDEPENDENCE · STATED ONCE

TEKMERIS is engaged and paid by the commissioning party. Fees are fixed in advance and are not contingent on the outcome. TEKMERIS does not manufacture, buy, sell, import, export or distribute any product; does not select, introduce or recommend a supplier; takes no fee from any factory; and performs no analysis of any kind.

One spine. Seven annexes.

The standard never changes; the panel does. Sections A, B, C and E are identical across every annex; Section D swaps in the annex panel (page 8). Products end in the seal; facilities end in the badge.

ANNEX	SCOPE	WHAT THE PANEL OR THE ATTENDANCE COVERS	ENDS IN
P	Peptides, APIs & Compounds	Witnessed production and blind testing: identity, purity with the full peak table, net content, endotoxin, sterility where claimed.	The seal
N	Nutraceuticals, Supplements & Traditional Medicine	Identity, assay and contaminants. Label claim against bottle content: proprietary blends, undeclared fillers, botanical identity.	The seal
C	Cosmetics & Topicals	Identity, contaminants and stability. Heavy metals, preservatives and active stability at the emulsion level.	The seal
F	Olive Oil, Premium Foods & Beverages	Authenticity forensics. Origin and purity shown by profile and marker, not by label.	The seal
D	Medical Devices, Equipment & Supplies	Device safety and traceability. Registration and class at source; the standards the regulator's own checklist names; pressure, oxygen-depletion and electrical safety controls where the device requires them.	The seal
H	Hospitals & Healthcare Facilities	Clinical infrastructure, sterilization discipline and emergency readiness, as observed on a stated date.	The badge
W	Longevity Clinics, Med-Spas & Wellness	Equipment calibration, hygiene and protocol compliance, as observed on a stated date.	The badge

Three engagements

ENGAGEMENT	WHO COMMISSIONS	WHAT TEKMERIS DOES	WHAT THE CLIENT RECEIVES
01 · Access check	The buyer	Matches the counterparty to the register and the licence holder; asks whether an observer will be admitted at the run.	A written answer. Either answer is a result.
02 · Batch verification	The buyer, or a producer for its own runs	Phases 1 and 2 on the specific run; phase 3 where the seal is sought.	The report; the seals applied at the line; the registry record of the result.
03 · Facility verification	The operator, or a network verifying its sites	Attends openly on a stated date, records what was observed, confirms registration.	The report; the badge, dated, lapsing on cycle.

Each engagement is a separate fixed fee, agreed in advance; the quote states the panel, the timing and the fee before the client commits.

A Counterparty & Documents

POINTS 1–15

Before a dollar moves. A trading company or a sales office has no line to witness; a re-labelled origin fails here, at the cheapest point in the process.

01	Unified Social Credit Code (统一社会信用代码 tǒngyī shèhuì xìnyòng dàimǎ, 18 digits) on the contract matches the public register exactly	REGISTRY-CONFIRMED
02	Business-licence scope includes production (生产 shēngchǎn) for the product class, not only sales (销售 xiāoshòu)	REGISTRY-CONFIRMED
2a	Scope covers production of the class being purchased, not a neighbouring class	REGISTRY-CONFIRMED
2b	GMP-certificate holder is the contract counterparty; no undisclosed intermediary between them	REGISTRY-CONFIRMED
03	Licence holder = site name = GMP-certificate holder	REGISTRY-CONFIRMED
04	Drug Manufacturing Licence (药品生产许可证 yàopǐn shēngchǎn xǔkězhèng) current where the class requires it	REGISTRY-CONFIRMED
05	GMP certificate checked against the issuing body's public record; a consultancy-issued paper is recorded as presented, not as a certificate	REGISTRY-CONFIRMED
06	ISO 9001, and ISO/IEC 17025 for any in-house laboratory, current and in scope	REGISTRY-CONFIRMED
07	Enterprise credit extract (国家企业信用信息公示系统 GSXT): no abnormal-operation listing, no serious-violation listing	REGISTRY-CONFIRMED
08	NMPA or provincial registry listing where the class requires it	REGISTRY-CONFIRMED
09	Registered and paid-in capital consistent with the claimed scale of operation	REGISTRY-CONFIRMED
10	Licensed address is the address to be attended	REGISTRY-CONFIRMED
11	Export licence or registration for the product where export is claimed	REGISTRY-CONFIRMED
12	No enforcement, penalty or litigation flag on the register extract	REGISTRY-CONFIRMED
13	Intermediary-disclosure warranty signed by the counterparty	PRESENTED
14	If an intermediary: the licence holder is identified and access to its line is secured, or the engagement is declined in writing	REGISTRY-CONFIRMED
15	Sanctions and denied-party screen on the entity and its principals	REGISTRY-CONFIRMED

ELIGIBILITY FLOOR

TEKMERIS attends production only at sites holding the licence the law requires for that product category. Where the site does not, the engagement stops at Phase 1 and the client receives that answer in writing. TEKMERIS confirms registration against the public register; it does not verify licensing the way a regulator would.

B Facility & Process

POINTS 16–32

TEKMERIS attends openly, on a stated date, and records the facility as it operates, not as it photographs for a sales deck. Anything the observer could not see is stated in the report, with its start and end time.

16	Stamped access confirmation (公章 gōngzhāng, company chop) naming the observer and the attendance date	PRESENTED
17	Opening meeting held; scope stated; no consulting offered or given	OBSERVED
18	Production areas match the licence scope; no undisclosed off-site subcontracting of the run	OBSERVED
19	Equipment register present; major asset identifiers match on the floor	OBSERVED
20	Clean-room classification certificate; differential-pressure and HEPA logs current	PRESENTED
21	Water-for-injection or purified-water system validated; monitoring current	PRESENTED
22	HVAC qualification records available	PRESENTED
23	Line clearance for the witnessed run, as it happens	OBSERVED
24	Batch record for the run complete and contemporaneous; recorded as given	PRESENTED
25	Weighing and dispensing with a second-person check, or witnessed by the observer	OBSERVED
26	In-process controls documented in the batch record	PRESENTED
27	Deviation and CAPA log present and in use	PRESENTED
28	Change-control system operative	PRESENTED
29	Raw-material supplier qualification (resins, solvents, excipients, botanicals)	PRESENTED
30	Stability programme exists for the class	PRESENTED
31	Environmental and pest monitoring where the class requires it (Annexes N, C, F)	PRESENTED
32	Segregation and cross-contamination controls, as observed on the day	OBSERVED

For facility verification (Annexes H and W) this section carries the annex's own observation list, and the engagement ends at Section E with the badge. No units are drawn and no laboratory panel is run.

C Selection, Sealing & Custody

POINTS 33–44

The factory never chooses the sample, and the laboratory never learns whose sample it holds. A supplier can prepare a sample. No one can prepare a run.

33	Sampling plan agreed before the visit: TEKMERIS Default Sampling Plan v1.0 (S1 first 5%, S2 ≈50%, S3 final 5%, R1–R2 retained), or the recorded deviation	PRESENTED
34	Units selected by the TEKMERIS observer at the line, from the witnessed run. No unit is handed to the observer; warehouse stock is never a sample	OBSERVED
35	Blind codes applied at the line; the code key is held by TEKMERIS only	OBSERVED
36	Seal applied at the line, on the day of the run, over tamper-evident tape, in front of the factory's staff	OBSERVED
37	Every serial applied is recorded that day and enters the registry as PENDING; issued = applied + voided + outstanding	REGISTRY-CONFIRMED
38	Custody form TKM-CF signed at the line by the observer and by the factory's signatory, with time and location data	OBSERVED
39	The factory ships the sealed sample under the client's written instruction. TEKMERIS never takes custody	OBSERVED
40	Temperature logger placed in the consignment where the client's instruction requires it; transit belongs to the client and its carrier	OBSERVED
41	Quantity sufficient for the full panel plus retained units	OBSERVED
42	Retained units sealed and held per protocol, not tested	OBSERVED
43	Transport packaging tamper-evident and carrying no name, batch number or client reference; the laboratory receives a code-only manifest	OBSERVED
44	Laboratory confirms receipt with packaging intact. Packaging not intact is a determinative exception: the sample is not tested	REGISTRY-CONFIRMED

WHAT THE SEAL IS

The seal is a record of custody, not a promise of a result. It ties the pack to the run that was witnessed, on the day it was witnessed. It reads PENDING until the laboratory result is recorded, then VERIFIED or WITHDRAWN for every seal on that run. Break the seal and it shows.

Sections A to C decide whether a run can be verified at all. A determinative exception in any of them makes the run NOT VERIFIED regardless of the laboratory result (Section E, point 59).

D Laboratory

POINTS 45–56

An independent, accredited laboratory tests coded samples with no knowledge of the supplier or the claim. TEKMERIS performs no analysis of any kind; the laboratory's result is the laboratory's, bound to the run and never restated.

45	Laboratory accredited to ISO/IEC 17025 for every method in the panel	REGISTRY-CONFIRMED
46	Laboratory independent of the supplier; chosen by the client, or arranged by TEKMERIS on the client's instruction	REGISTRY-CONFIRMED
47	Panel specified per annex (page 8) against the specification the client has set	PRESENTED
47a	Diluent supplied inside the sealed pack is tested as part of the run (benzyl alcohol content, sterility, endotoxin), or excluded on the face of the report	
48	Identity: high-resolution mass spectrometry or MS/MS against reference	
48a	Unlabelled-substance screen where the primary container carries no product identity	
49	Purity and assay: HPLC with the full peak table, never a single figure	
49a	Net peptide content reported by mass; a purity percentage is not a content claim	
49b	Counter-ion and TFA content quantified where RP-HPLC purification is claimed; stated mass corrected to net peptide	
50	Endotoxin (LAL, USP <85>) where an injectable grade is claimed	
51	Heavy metals by ICP-MS against ICH Q3D or the class limit	
52	Residual solvents by GC against ICH Q3C where synthesis is claimed	
53	Microbial limits per USP or the class standard where applicable	
53a	Sterility (USP <71>) where a sterile or aseptically filled claim is made; microbial limits do not evidence sterility	
54	Authenticity markers for oils, foods and beverages: fatty-acid profile, sterols, UV K-values, origin markers	
55	Label-claim and net-content verification for Annexes N, C and F; Annex P content at 49a	
56	Results reported against the code only, and reproduced in the report exactly as issued: units, decimals, qualifiers	REGISTRY-CONFIRMED

Point 47 — the panel by annex.

Same three phases. Different laboratory panel. The client's specification sets the limits; the annex sets the methods.

ANNEX P	Identity (HRMS / MS-MS) · Purity (HPLC, full peak table) · Net peptide content, salt-corrected · Counter-ion / TFA · Endotoxin (LAL, USP <85>) · Sterility (USP <71>) where claimed · Heavy metals (ICP-MS) · Residual solvents (GC) · Diluent panel where supplied
ANNEX N	Active assay (HPLC / UV) · Identity markers, including botanical identity · Heavy metals (ICP-MS, USP <2232>) · Microbial limits (USP <2023>) · Net-content verification · Undeclared pharmaceutical screen where the category warrants it
ANNEX C	Active identity · Contaminant screening · Heavy metals · Microbial limits · Preservative content · Stability (accelerated and real-time)
ANNEX F	Fatty-acid profile · Sterol composition · UV K-values (K232 / K270) · Origin markers · Adulterant screen (seed oils) · Beverage identity and authenticity markers
ANNEX D	NMPA registration and class at source · CE MDR / FDA claims checked with the issuing body · ISO 13485 scope · ISO 14971 risk file · IEC 60601 electrical safety · pressure-vessel and oxygen-depletion controls · calibration · sterilization validation · biocompatibility · lot sterility · serial, component, firmware and maintenance traceability as the regulator's checklist names it
ANNEXES H · W	No laboratory panel. The engagement ends at Section E with the badge: attendance on a stated date, registration confirmed, lapsing on cycle.

Why blind matters

The laboratory never learns who the supplier is, what the seller claimed, or which annex applies until the code is reconciled to the run after testing is complete. The factory may know the laboratory; it cannot tell the laboratory which sample is its. Whoever selects the sample controls what a certificate can say; on a TEKMERIS engagement, that is the observer at the line and no one else.

Silence during the engagement

Nothing is released while an engagement is under way: no interim findings, no locations, no logistics. The result is the report, and the report only.

THE FACTORY'S IDENTITY

The factory's identity is recorded in the run file and disclosed only to the buyer, or under lawful order of a court or regulator with jurisdiction. The public registry shows a batch number and a seal.

E Records, Determination & Release

POINTS 57–65

Every finding is reconciled, reviewed and signed before a report is released, and every determinative exception is screened, every time. Nothing is released, to anyone, before the Managing Director has signed.

57	Workpapers complete: photographs with date, time and location data; forms; logs; the custody form	OBSERVED
58	Exceptions log: every exception marked determinative or non-determinative, with time, evidence and the factory's response as presented	OBSERVED
59	Determinative by rule, screened on every run: observer out of sight of the line between first unit and sealing · any unit handed to the observer rather than selected · packaging not intact at receipt · counterparty not the licence holder and the chain not established · coding or sealing refused in sight · request for payment to a personal account · certificate dated before the run · batch or label mismatch	OBSERVED
60	Determination drafted: RUN VERIFIED or RUN NOT VERIFIED. Two values. No conditional	
61	Managing Director review of every line, every annex and every registry entry; corrections looped to the observer	
62	Managing Director signature applied; SHA-256 hash generated at release and recorded	
63	Seal manifest reconciled: issued = applied + voided + outstanding, with none outstanding	REGISTRY-CONFIRMED
64	Result recorded in the registry by the Managing Director. Every applied seal on the run moves from PENDING to VERIFIED, or to WITHDRAWN	REGISTRY-CONFIRMED
65	Report released to the client; retained by TEKMERIS for five years. For a facility: the badge issued, dated, lapsing on cycle	

WHAT A DETERMINATION MEANS

That the events in the report happened as recorded, on the date recorded, in the presence of a party with no interest in the outcome, and that the laboratory result belongs to this run and no other. It is not a statement that the product is safe, effective, lawful or fit for any purpose. It is not a certification, an accreditation or a regulatory approval of any kind. It says nothing about any other run, before or after, and nothing about any unit that does not carry a seal in the recorded range.

Every seal serial checks independently at tekmerisglobal.com/verify/, alongside the run date, the sampling chain and the laboratory result once recorded. A released report stays checkable long after the shipment has cleared.



This is the standard. Put it on your supply chain.

Every engagement begins with an access check: a small fixed fee, for which TEKMERIS contacts your supplier, matches it to the public register, and establishes whether an independent observer will be admitted at the run. The answer comes in writing once the supplier has responded; a refusal is itself information about your supplier, and the fee covers it. The fee is credited against the engagement if you proceed.

START	Start an access check · tekmerisglobal.com/contact/	
VERIFY	Check a seal serial or a badge · tekmerisglobal.com/verify/	
READ	The standard online · tekmerisglobal.com/the-standard/	
ANNEX P	Peptides, APIs & Compounds	tekmerisglobal.com/verification/peptides/
ANNEX N	Nutraceuticals, Supplements & Traditional Medicine	tekmerisglobal.com/verification/nutraceuticals/
ANNEX C	Cosmetics & Topicals	tekmerisglobal.com/verification/cosmetics/
ANNEX F	Olive Oil, Premium Foods & Beverages	tekmerisglobal.com/verification/foods/
ANNEX D	Medical Devices, Equipment & Supplies	tekmerisglobal.com/verification/devices/
ANNEX H	Hospitals & Healthcare Facilities	tekmerisglobal.com/verification/hospitals/
ANNEX W	Longevity Clinics, Med-Spas & Wellness	tekmerisglobal.com/verification/wellness/

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