Microcrystalline Cellulose

Enterprise Excipient Certificate of Analysis Review

Material	Microcrystalline Cellulose — pharmaceutical excipient	**Issuer shown**	ExciPharma Solutions Ltd., Dubai, UAE
CoA / analysis number	EXP-COA-MCC-2026-0614	**Batch / lot**	MCC-2026-0614-A
CAS	not stated	**Batch size / package**	5,000 kg
Manufactured	14 Jun 2026	**Expiry / retest**	**14 Jun 2029 (retest) — VALID**
Testing date	14–17 Jun 2026	**Claimed basis**	USP/NF & Ph. Eur.
Issue date	20 Jun 2026	**Review date**	2026-08-24
Source pages	2 pages, text-based	**Engine gate**	CONDITIONAL

CONDITIONAL — EVIDENCE REQUIRED BEFORE USE

No result fails its printed limit and no printed limit is wider than the retrieved official criterion, but the certificate does not carry every piece of evidence expected (26 major open items).

100%
Supplier printed limits
21 of 21 rows meet the limits printed on this certificate

2 / 16
USP 2024 limit comparison
2 of 16 monograph requirement groups align with the official limits; 14 open for review

0%
Sampling / method evidence
0 of 4 execution-evidence controls verified from the submitted package

Document completeness 96.9% (16 of 18 WHO / ICH documentation fields present) • Universal CoA core: 11 confirmed, 5 partial, 0 not confirmed of 16 • Engine gate: CONDITIONAL

What remains for enterprise release

1	Core certificate fields not fully confirmed: Specification reference (partial); Method / method reference (partial); Result (partial); Overall conclusion (partial); Authorised signature / e-approval (partial).
2	Monograph tests not reported on the certificate: CONDUCTIVITY.
3	11 row(s) hold a proposed official limit that a qualified reviewer must confirm before it can decide anything.
4	2 row(s) could be checked only against the supplier's own limit (no official criterion retrieved).
5	5 result(s) are declarations ('Complies') rather than reported observations.
6	Sampling, sample quantity and test-portion evidence are not verifiable from the certificate (this is an evidence gap, not a failed test).

Required before acceptance

Also obtain confirmed manufacturer / testing-site details, dated approval by an identified authorised person, method references for each test, the analytical worksheets needed to verify the quantities used in testing.

Sampling/method score: 0% means 0 of 4 execution-evidence controls were verifiable from the submitted package. It is not a statement that the chemical tests failed.

How the result was calculated

The assessments are intentionally separate. They are not blended into one compliance percentage.

Assessment	Calculation	Result	Correct interpretation
Expiry / retest status	Review date 2026-08-24 vs stated retest 2029-06-14	Within date	Independent HOLD trigger. Any retest or extension must be formally controlled and approved.
Supplier-limit result check	21 rows meeting printed limits / 21 reported test rows × 100	100.0%, rounded to 100%	Checks the supplier's own table only. It does not prove pharmacopoeial compliance. Declarations ('Complies') count as reported, not as numeric evidence.
Pharmacopoeial analytical evidence map	2 aligned / 16 monograph requirement groups — 1 direct numeric alignment, 1 supplier declaration aligns, 1 required test not reported, 11 review required, 2 not retrieved, 7 supplier only	2 / 16 (not a pass percentage)	Different evidence states remain visible so missing or contradictory evidence cannot be hidden by averaging.
Universal CoA core	16 active core fields: 11 confirmed; 5 partially confirmed or needing verification; 0 not confirmed	Completeness profile, not compliance	Measures document structure and traceability. It is not a batch-quality score.
Sampling / method-execution evidence	0 confirmed / 4 controls × 100: laboratory sample quantity; sampling plan / reference; actual test portions / preparations; supporting worksheets / raw records	0% — NOT VERIFIABLE	Measures submitted execution evidence; missing records are not a chemical-test failure.

Pharmacopoeial edition normalisation

Attribute	Certificate	Library comparator	Controlled decision
Pharmacopoeia	USP/NF & Ph. Eur.	USP-NF	**MATCH**
Claimed / comparator edition	edition not stated	2024	**EDITION NOT STATED — library edition applied**
Product article	Microcrystalline Cellulose	Microcrystalline Cellulose requirement set	**MATCH**
Formula / basis	not stated	not parsed from the library text	**NOT COMPARED — formula or basis not stated on both sides**

Rule routing

Routing item	Decision	Reason
Material type	Pharmaceutical excipient	the certificate states excipient
Claimed pharmacopoeia / standard	USP/NF & Ph. Eur.	The certificate states this basis.
Active structural rules	PharmaTrust Universal CoA Core Rules	WHO-anchored applicability model: 16 core fields, conditional rules only when triggered, optional fields without default penalty (WHO TRS 1010 / 1052 Annex 4, ICH Q7 § 11.4 wording for attributability).
Active excipient context	WHO excipient GMP (TRS 1060 Annex 3) and IPEC CoA Guide 2024	Used for excipient-specific traceability and CoA practice.
ICH Q7	Not applied	ICH Q7 is API / intermediate-specific and is not forced onto an excipient CoA.

Product monograph	Microcrystalline Cellulose (library)	Official criteria are taken only from the retrieved monograph sections.
WHO Model Certificate of Analysis	Applicability-aware reference	General international structure; optional or inactive conditional fields receive no automatic penalty.
Market-specific pharmacopoeias (IP, JP, CP …)	Not applied	Conditional on the intended market, dossier or customer specification; no comparison is made without the controlled monograph, and no compliance or non-compliance is implied.

Deterministic decision logic

Trigger	System outcome
The review date is later than the stated expiry date	EXPIRED → HOLD; do not use / release under normal controls.
A reported result fails the certificate's own printed limit	Confirmed supplier-specification failure → HOLD and supplier investigation.
A reported result falls outside the controlled official criterion	Pharmacopoeial claim not demonstrated for that attribute → HOLD.
A printed limit is wider than the controlled official criterion	MISMATCH → HOLD; a pass against the wider limit does not establish compliance.
Required identity or limit-test evidence is absent	NOT VERIFIED / EVIDENCE REQUEST — never infer a silent pass or an untested failure.
A per-analyte row's official limit came from a section-level number	REVIEW REQUIRED — the proposal is kept; no decisive outcome until a qualified reviewer approves.
A field is optional or its conditional trigger is inactive	No default penalty; record as N/A or optional missing.
The result is only the word 'Complies'	Retain as supplier declaration; do not upgrade it to independently verified numerical evidence.
The submitted copy cannot be read	INSUFFICIENT DATA — a reading limitation, never missing certificate content.

Extraction provenance: values were read by text layer + claude-opus-5 over 2 of 2 page(s). Every value in this review traces to the stored reading with page and cell provenance.

Universal CoA core assessment

Checked against the PharmaTrust Universal CoA Core Rules: 16 universal core fields. Missing evidence is not called fraud and is not converted into a batch failure.

Rule ID	Core field	Document evidence	Status	Expert interpretation
L1-DOC-001	Document title / type	CERTIFICATE OF ANALYSIS	**CONFIRMED**	Clearly identified.
L1-DOC-002	CoA / report number	EXP-COA-MCC-2026-0614	**CONFIRMED**	Unique certificate number visible.
L1-DOC-004	Issue / approval date	20 Jun 2026	**CONFIRMED**	Issue / approval date stated.
L1-ORG-001	Issuing / testing laboratory name and address	ExciPharma Solutions Ltd., Dubai, UAE; address present	**CONFIRMED**	Issuer and address identified.
L1-ORG-004	Original manufacturer name and address	reader-verified field 'manufacturer' = 'ExciPharma Solutions Ltd., Dubai, UAE'	**CONFIRMED**	Manufacturer stated.
L1-ID-001	Product / material name	Microcrystalline Cellulose	**CONFIRMED**	Name visible.
L1-ID-002	Material description / type	Pharmaceutical excipient	**CONFIRMED**	the certificate states excipient
L1-ID-008	Batch / lot number	MCC-2026-0614-A	**CONFIRMED**	Batch traceability present.
L1-TEST-001	Specification reference	USP/NF & Ph. Eur.	**PARTIAL**	No edition, monograph revision or controlled specification ID.
L1-TEST-002	Test / parameter	22 test rows	**CONFIRMED**	Parameters individually listed.
L1-TEST-003	Method / method reference	method / chapter reference present for 1 of 22 rows	**PARTIAL**	Method names are given; compendial execution cannot be reproduced from the certificate alone.
L1-TEST-004	Acceptance criterion / limit	acceptance criterion present for all 22 rows	**CONFIRMED**	Limits visible.
L1-TEST-005	Result	result present for 21 of 22 rows	**PARTIAL**	Presence confirmed; evidence strength varies (numeric vs declaration).
L1-TEST-008	Overall conclusion	label 'batch disposition' found on the certificate	**PARTIAL**	Conclusion statement present.
L1-AUTH-001	Authorised approver identity	label 'approved by' found on the certificate; names printed: Ms. Fatima Khalil	**CONFIRMED**	Approver identified.
L1-AUTH-002	Authorised signature / e-approval	label 'signature' found on the certificate	**PARTIAL**	Presence confirmed from the printed label; authority and approval date remain unverified.

Core result: 11 confirmed, 5 partially confirmed / needs verification, 0 not confirmed. This is a document-completeness profile, not proof of product compliance or non-compliance.

Traceability, authorisation and sample review

This page separates what is visible on the CoA from what is only externally discoverable or still unverified.

Visible personnel and approval evidence

Role shown	Visible identity	Visible approval evidence	Decision
Analyst	role label only	role label without a legible name	Role without an identifiable person
Reviewer	Ms. Fatima Khalil	typed / printed name beside the role label	Identity visible; signature authority partial — a typed name is not a verifiable signature
Approver	role label only	role label without a legible name	Role without an identifiable person
Head of QC / Director	role label only	role label without a legible name	Role without an identifiable person
Quality Assurance	role label only	role label without a legible name	Role without an identifiable person
Company control / seal	ExciPharma Solutions Ltd., Dubai, UAE	label 'signature' found on the certificate	Seal / signature label present; authenticity and approval date are not independently verified.

Issuer, manufacturer and laboratory address

Evidence level	Information	Decision
Printed on CoA	ExciPharma Solutions Ltd., Dubai, UAE; contacts: telephone, e-mail	Company/contact identity present; physical address printed.
Original manufacturer / factory	reader-verified field 'manufacturer' = 'ExciPharma Solutions Ltd., Dubai, UAE'	Manufacturer stated; verify site against supplier qualification.
Testing laboratory	No separate laboratory name, accreditation number or outsourced-lab statement	Testing site remains not verified; request the laboratory identity and its relationship to the issuer.
External look-up	Not performed by this automated review	Public company data, if consulted, is external metadata only and does not establish a factory or laboratory site.

Batch, package and sample information

Field	Value / status	Regulatory treatment
Batch size	**5,000 kg**	Manufacturing quantity, not analytical sample size.
Package size	**not stated**	Not stated; verify on the shipping documents.
Sample quantity delivered to laboratory	**NOT STATED — NOT VERIFIABLE**	WHO TRS 1052 places sample size in the test request / sampling records; underlying evidence, not a universal printed-CoA field.
Weight / volume used for each test	**NOT STATED — NOT VERIFIABLE**	21 CFR 211.194(a)(3) requires this in laboratory records where appropriate; the CoA alone cannot demonstrate it.
Sampling plan / representativeness	**NOT STATED — NOT VERIFIABLE**	Verify in controlled sampling records; absence from the CoA is an evidence gap, not proof of incorrect sampling.
Stability support	**Not attached**	The retest / expiry date is current; ICH Q7 11.60–11.63 expects supporting stability data in the quality system.

Conditional and optional information

Field	Applicability	CoA status	Treatment
Grade	Active for excipients / APIs	**Not stated**	Request the grade if the specification depends on it.

Manufacture and expiry / retest dates	Active	**Within stated retest date (2029-06-14; 1025 days remaining)**	Dates present; no action.
Sample registration number	Conditional — independent / QC laboratory workflow	**Absent**	No penalty unless an external laboratory workflow is established.
Sample size / quantity received	Required in WHO test-request / sampling records; not universally printed on a manufacturer CoA	**NOT STATED**	Record as NOT VERIFIABLE, not as a confirmed sampling failure.
Weight / volume used for each test	Required in laboratory records where appropriate	**NOT STATED**	The monograph test portions cannot be verified from this CoA; request worksheets.
Sampling plan / reference	Required in controlled sampling records when the laboratory is responsible for sampling	**NOT STATED**	Representativeness cannot be verified from the CoA; do not infer failure.
Storage condition	Relevant where the monograph states packaging / storage requirements	**Present**	Verify in specification / label; absence from the CoA alone is not a batch failure.

Sampling and test-portion verification

The total batch, the sample delivered to the laboratory and the test portion used in each procedure are different quantities and must not be combined.

Regulatory basis

Source	Requirement	Application to this CoA
WHO TRS 1052 Annex 4, 6.3 and 6.9–6.10	Sampling records should identify the amount sampled; the test request should state sample size; the laboratory should confirm the amount is sufficient for all requested tests.	Sample size and sampling record are absent. Mark NOT VERIFIABLE, not failed.
WHO TRS 1052 Annex 4, 6.98	The minimum quantity delivered for testing should be communicated, with sufficient retained sample for at least two re-analyses.	Sufficiency and retention cannot be assessed from the CoA.
21 CFR 211.160 and 211.194	Sampling / test controls must be documented; laboratory records include quantity received and weight or measure used for each test where appropriate.	Request controlled laboratory records to verify execution.

Monograph preparation requirements versus CoA evidence

Monograph test	Monograph test portion / preparation	CoA evidence	Decision
Water-Soluble Substances	5.0 g	0.09%; no sample mass, volume or preparation detail stated	**LIMIT PASS; PREPARATION NOT VERIFIABLE**
Ether-Soluble Substances	10.0 g	0.02%; no sample mass, volume or preparation detail stated	**LIMIT PASS; PREPARATION NOT VERIFIABLE**
B. ▲ (NF 1-Dec-2019)	10 mg; 20 g; 6.5 g; 0.5 g	Test not reported	**REQUIRED TEST AND PORTION NOT VERIFIED**
C. ▲ (NF 1-Dec-2019)	1.3 g of Microcrystalline Cellulose, accurate; 1.3 g	Test not reported	**REQUIRED TEST AND PORTION NOT VERIFIED**
CONDUCTIVITY	5 g	Test not reported	**REQUIRED TEST AND PORTION NOT VERIFIED**

TEST-PORTION COMPLIANCE: NOT VERIFIABLE FROM COA

The monograph states defined portions or preparations for the tests listed. The certificate does not state the quantities actually used. This is a material evidence gap, but it is not proof that the laboratory used the wrong quantities.

Required evidence: Sample receipt / test request, sampling plan, analytical worksheets or ELN records, preparation calculations, balance records, chromatograms and any approved method-deviation or alternative-method validation. The submitted sample should be sufficient for all tests, replicates and retained / reanalysis portions.

Supplier results against printed limits

Supplier score = 21 of 21 rows meet the limits printed on this certificate = 100.0%, rounded to 100%. This is not a pharmacopoeial score.

Test	Printed specification	Result	Outcome	Expert note
Identification (IR Spectroscopy)	Conforms to reference spectrum	Conforms	**PASS AS REPORTED**	supplier declaration; no numeric result; REPORTED PASS — identity declared on the certificate; spectrum not reviewed
Description (Appearance)	White or almost white, fine or granular powder	White, fine granular powder	**PASS**	supplier-only / additional control — not in the product monograph
pH (20% w/v Slurry)	5.0 – 7.5	6.2	**PASS**	1.2 above the lower limit; 1.3 below the upper; OFFICIAL CRITERION NOT RETRIEVED
Loss on Drying	NMT 7.0% (105°C, 3 hrs)	4.8%	**PASS**	2.2 percentage point margin
Residue on Ignition	NMT 0.1%	0.03%	**PASS**	0.07 percentage point margin; MONOGRAPH SECTION 'Residue on Ignition <281>' APPLIES
Heavy Metals (as Pb)	NMT 10 ppm	< 5 ppm	**PASS**	5 ppms margin; supplier-only / additional control — not in the product monograph
Nickel	NMT 1 ppm	—	**NOT ASSESSABLE**	supplier-only / additional control — not in the product monograph
Water-Soluble Substances	NMT 0.24%	0.09%	**PASS**	0.15 percentage point margin; NOT COMPARABLE AUTOMATICALLY
Ether-Soluble Substances	NMT 0.05%	0.02%	**PASS**	0.03 percentage point margin; NOT COMPARABLE AUTOMATICALLY
Degree of Polymerization	NMT 350	220	**PASS**	130 units margin; supplier-only / additional control — not in the product monograph
Particle Size (D90)	90.0 – 130.0 µm	108.5 µm	**PASS**	18.5 above the lower limit; 21.5 below the upper; MONOGRAPH SECTION 'BULK DENSITY' APPLIES
Particle Size (D50)	75.0 – 100.0 µm	88.2 µm	**PASS**	13.2 above the lower limit; 11.8 below the upper; MONOGRAPH SECTION 'BULK DENSITY' APPLIES
Bulk Density (Untapped)	0.25 – 0.45 g/mL	0.31 g/mL	**PASS**	0.06 above the lower limit; 0.14 below the upper; MONOGRAPH SECTION 'BULK DENSITY' APPLIES
Tapped Density	0.35 – 0.55 g/mL	0.42 g/mL	**PASS**	0.07 above the lower limit; 0.13 below the upper; MONOGRAPH SECTION 'BULK DENSITY' APPLIES
Hausner Ratio	NMT 1.35	1.21	**PASS**	0.14 units margin; supplier-only / additional control — not in the product monograph
Microbial Enumeration (TAMC)	NMT 1000 CFU/g	< 10 CFU/g	**PASS**	990 CFU/gs margin; MONOGRAPH SECTION 'MICROBIAL ENUMERATION TESTS <61> and TES' APPLIES
Microbial Enumeration (TYMC)	NMT 100 CFU/g	< 10 CFU/g	**PASS**	90 CFU/gs margin; MONOGRAPH SECTION 'MICROBIAL ENUMERATION TESTS <61> and TES' APPLIES
E. coli	Absent in 1 g	Absent	**PASS AS REPORTED**	supplier declaration; no numeric result; MONOGRAPH SECTION 'MICROBIAL ENUMERATION TESTS <61> and TES' APPLIES — criterion not machine-readable; qualified review required

Salmonella spp.	Absent in 10 g	Absent	**PASS AS REPORTED**	supplier declaration; no numeric result; MONOGRAPH SECTION 'MICROBIAL ENUMERATION TESTS <61> and TES' APPLIES — criterion not machine-readable; qualified review required
Residual Solvents (ICH Class 1 & 2)	Meets USP requirements	Conforms+	**PASS AS REPORTED**	supplier declaration; no numeric result; supplier-only / additional control — not in the product monograph
Arsenic (in-process)*	NMT 2 ppm	< 1 ppm	**PASS**	1 ppm margin; supplier-only / additional control — not in the product monograph
Elemental Impurities (quarterly)+	Meets USP <232> limits	Conforms	**PASS AS REPORTED**	supplier declaration; no numeric result; OFFICIAL CRITERION NOT RETRIEVED — the library copy of the monograph holds no section for this test; supplier limit applied; confirm against the monograph text

Enterprise interpretation

No reported result fails its printed limit. Declarations ('Complies') are counted as reported, not as independently verified numbers.

Pharmacopoeial evidence matrix

Basis: Microcrystalline Cellulose (library). Official criteria come only from the retrieved monograph sections; "not retrieved" means the library holds no usable criterion for that row.

Requirement	Controlled criterion	CoA evidence	Assessment
Identification (IR Spectroscopy)	SPECTROSCOPIC IDENTIFICATION TESTS <197> , Infrared	Conforms; printed limit Conforms to reference spectrum	**REPORTED PASS — identity declared on the certificate; spectrum not reviewed**
Description (Appearance)	—	White, fine granular powder; printed limit White or almost white, fine or granular powder	**SUPPLIER-ONLY — appearance is not listed as a test in the product monograph; excluded from the pharmacopoeial count**
pH (20% w/v Slurry)	—	6.2; printed limit 5.0 – 7.5	**OFFICIAL CRITERION NOT RETRIEVED — the library copy of the monograph holds no section for this test; supplier limit applied; confirm against the monograph text**
Loss on Drying	library: NMT 7.0%	4.8%; printed limit NMT 7.0% (105°C, 3 hrs)	**PASS — printed limit equals the library section criterion (NMT 7.0%); method execution open**
Residue on Ignition	see monograph section	0.03%; printed limit NMT 0.1%	**MONOGRAPH SECTION 'Residue on Ignition <281>' APPLIES — criterion not machine-readable; qualified review required**
Heavy Metals (as Pb)	—	< 5 ppm; printed limit NMT 10 ppm	**SUPPLIER-ONLY / ADDITIONAL CONTROL — not listed in the product monograph; excluded from the pharmacopoeial count**
Nickel	—	—; printed limit NMT 1 ppm	**SUPPLIER-ONLY / ADDITIONAL CONTROL — not listed in the product monograph; excluded from the pharmacopoeial count**
Water-Soluble Substances	see monograph section 'WATER -SOLUBLE SUBSTANCES'	0.09%; printed limit NMT 0.24%	**NOT COMPARABLE AUTOMATICALLY — the library section 'WATER -SOLUBLE SUBSTANCES' states NMT 12.5mg, which is not in the units of the printed limit (NMT 0.24%); qualified review required**
Ether-Soluble Substances	see monograph section 'ETHER -SOLUBLE SUBSTANCES'	0.02%; printed limit NMT 0.05%	**NOT COMPARABLE AUTOMATICALLY — the library section 'ETHER -SOLUBLE SUBSTANCES' states NMT 5.0mg, which is not in the units of the printed limit (NMT 0.05%); qualified review required**
Degree of Polymerization	—	220; printed limit NMT 350	**SUPPLIER-ONLY / ADDITIONAL CONTROL — not listed in the product monograph; excluded from the pharmacopoeial count**
Particle Size (D90)	see monograph section	108.5 µm; printed limit 90.0 – 130.0 µm	**MONOGRAPH SECTION 'BULK DENSITY' APPLIES — criterion not machine-readable; qualified review required**

Particle Size (D50)	see monograph section	88.2 µm; printed limit 75.0 – 100.0 µm	**MONOGRAPH SECTION 'BULK DENSITY' APPLIES — criterion not machine-readable; qualified review required**
Bulk Density (Untapped)	see monograph section	0.31 g/mL; printed limit 0.25 – 0.45 g/mL	**MONOGRAPH SECTION 'BULK DENSITY' APPLIES — criterion not machine-readable; qualified review required**
Tapped Density	see monograph section	0.42 g/mL; printed limit 0.35 – 0.55 g/mL	**MONOGRAPH SECTION 'BULK DENSITY' APPLIES — criterion not machine-readable; qualified review required**
Hausner Ratio	—	1.21; printed limit NMT 1.35	**SUPPLIER-ONLY / ADDITIONAL CONTROL — not listed in the product monograph; excluded from the pharmacopoeial count**
Microbial Enumeration (TAMC)	see monograph section	< 10 CFU/g; printed limit NMT 1000 CFU/g	**MONOGRAPH SECTION 'MICROBIAL ENUMERATION TESTS <61> and TES' APPLIES — criterion not machine-readable; qualified review required**
Microbial Enumeration (TYMC)	see monograph section	< 10 CFU/g; printed limit NMT 100 CFU/g	**MONOGRAPH SECTION 'MICROBIAL ENUMERATION TESTS <61> and TES' APPLIES — criterion not machine-readable; qualified review required**
E. coli	see monograph section	Absent; printed limit Absent in 1 g	**MONOGRAPH SECTION 'MICROBIAL ENUMERATION TESTS <61> and TES' APPLIES — criterion not machine-readable; qualified review required**
Salmonella spp.	see monograph section	Absent; printed limit Absent in 10 g	**MONOGRAPH SECTION 'MICROBIAL ENUMERATION TESTS <61> and TES' APPLIES — criterion not machine-readable; qualified review required**
Residual Solvents (ICH Class 1 & 2)	—	Conforms+; printed limit Meets USP requirements	**ADDITIONAL GENERAL CONTROL — residual solvent; not a product-monograph test (USP <467> / ICH Q3C basis); excluded from the pharmacopoeial count**
Arsenic (in-process)*	—	< 1 ppm; printed limit NMT 2 ppm	**SUPPLIER-ONLY / ADDITIONAL CONTROL — not listed in the product monograph; excluded from the pharmacopoeial count**
Elemental Impurities (quarterly)+	—	Conforms; printed limit Meets USP <232> limits	**OFFICIAL CRITERION NOT RETRIEVED — the library copy of the monograph holds no section for this test; supplier limit applied; confirm against the monograph text**
CONDUCTIVITY	NLT 75.0	Not reported	**NOT REPORTED — required monograph test absent from the certificate**

Evidence categories

Evidence category	Count	Items
Direct numeric alignment	1	Loss on Drying

Supplier declaration under an equal or stricter printed limit	1	Identification (IR Spectroscopy)
Required monograph test not reported	1	CONDUCTIVITY
Review required (section-level limit withheld)	11	Residue on Ignition; Water-Soluble Substances; Ether-Soluble Substances; Particle Size (D90); Particle Size (D50); Bulk Density (Untapped) …
Official limit not retrieved from the library	2	pH (20% w/v Slurry); Elemental Impurities (quarterly)+
Supplier-only (no monograph)	7	Description (Appearance); Heavy Metals (as Pb); Nickel; Degree of Polymerization; Hausner Ratio; Residual Solvents (ICH Class 1 & 2) …

General and additional requirements

Requirement	Official / general basis	CoA evidence	Decision
Packaging and storage	・▲◆▲ (NF 1-Dec-2019) PACKAGING AND STORAGE : Preserve in tight	Store in a cool, dry place. T: 15-30°C. RH: ⩽60%. Original Manufacturer	**PARTIAL — compare the certificate's statement with the monograph wording; confirm in the approved specification and label**
Description (Appearance)	Not listed in the product monograph	White, fine granular powder; printed limit White or almost white, fine or granular powder	**ADDITIONAL SUPPLIER PASS — excluded from the pharmacopoeial count**
Heavy Metals (as Pb)	Not listed in the product monograph	< 5 ppm; printed limit NMT 10 ppm	**ADDITIONAL SUPPLIER PASS — excluded from the pharmacopoeial count**
Nickel	Not listed in the product monograph	—; printed limit NMT 1 ppm	**ADDITIONAL SUPPLIER CONTROL — see supplier table**
Degree of Polymerization	Not listed in the product monograph	220; printed limit NMT 350	**ADDITIONAL SUPPLIER PASS — excluded from the pharmacopoeial count**
Hausner Ratio	Not listed in the product monograph	1.21; printed limit NMT 1.35	**ADDITIONAL SUPPLIER PASS — excluded from the pharmacopoeial count**
Residual Solvents (ICH Class 1 & 2)	Not listed in the product monograph	Conforms+; printed limit Meets USP requirements	**ADDITIONAL SUPPLIER PASS — excluded from the pharmacopoeial count**
Arsenic (in-process)*	Not listed in the product monograph	< 1 ppm; printed limit NMT 2 ppm	**ADDITIONAL SUPPLIER PASS — excluded from the pharmacopoeial count**

Pharmacopoeial conclusion

2 of 16 monograph requirement groups align with the official criteria; the remaining items are open for qualified review (library criteria not applied automatically, or tests not reported). No contradiction with the retrieved official criteria was found.

Deterministic rule trace and expert handoff

Each material finding is linked to extracted evidence, a controlled rule and a non-ambiguous action. Edition differences are normalised only after exact article identity is established. Missing evidence is never coloured green.

Rule	Check	Evidence	Outcome	Required action
PT-COMP-VER-001	Same pharmacopoeia / article; different edition year	edition not stated claimed vs 2024 comparator	**EDITION NOT STATED**	Compare against the controlled library edition; the year alone does not block
PT-COMP-ID-001	Exact article identity guard	Microcrystalline Cellulose vs Microcrystalline Cellulose requirement set	**CONFIRMED**	Never substitute base, salt, hydrate, API or dosage-form articles
PT-USP-001	Reported product-monograph groups vs official limits	2 of 16 groups aligned	**OPEN**	Record official alignment; execution evidence remains separate
PT-EVID-CLASS-001	Classify every test by authority	16 monograph groups; 7 supplier-only / additional control(s)	**CONFIRMED**	Never include supplier-only / additional tests in the pharmacopoeial count
PT-DATE-001	Review date vs expiry / retest	Within stated retest date (2029-06-14; 1025 days remaining)	**WITHIN DATE**	None
PT-COMP-002	Official criterion awaiting qualified confirmation	Residue on Ignition: MONOGRAPH SECTION 'Residue on Ignition <281>' APPLIES — criterion not machine-readable; qualified review required	**REVIEW REQUIRED**	Qualified reviewer to confirm the official limit before it decides anything
PT-COMP-002	Official criterion awaiting qualified confirmation	Water-Soluble Substances: NOT COMPARABLE AUTOMATICALLY — the library section 'WATER -SOLUBLE SUBSTANCES' states NMT 12.5mg, which is not in the units of the printed limit (NMT 0.24%); qualified review required	**REVIEW REQUIRED**	Qualified reviewer to confirm the official limit before it decides anything
PT-COMP-002	Official criterion awaiting qualified confirmation	Ether-Soluble Substances: NOT COMPARABLE AUTOMATICALLY — the library section 'ETHER -SOLUBLE SUBSTANCES' states NMT 5.0mg, which is not in the units of the printed limit (NMT 0.05%); qualified review required	**REVIEW REQUIRED**	Qualified reviewer to confirm the official limit before it decides anything
PT-COMP-002	Official criterion awaiting qualified confirmation	Particle Size (D90): MONOGRAPH SECTION 'BULK DENSITY' APPLIES — criterion not machine-readable; qualified review required	**REVIEW REQUIRED**	Qualified reviewer to confirm the official limit before it decides anything
PT-COMP-002	Official criterion awaiting qualified confirmation	Particle Size (D50): MONOGRAPH SECTION 'BULK DENSITY' APPLIES — criterion not machine-readable; qualified review required	**REVIEW REQUIRED**	Qualified reviewer to confirm the official limit before it decides anything
PT-COMP-002	Official criterion awaiting qualified confirmation	Bulk Density (Untapped): MONOGRAPH SECTION 'BULK DENSITY' APPLIES — criterion not machine-readable; qualified review required	**REVIEW REQUIRED**	Qualified reviewer to confirm the official limit before it decides anything

PT-COMP-002	Official criterion awaiting qualified confirmation	Tapped Density: MONOGRAPH SECTION 'BULK DENSITY' APPLIES — criterion not machine-readable; qualified review required	**REVIEW REQUIRED**	Qualified reviewer to confirm the official limit before it decides anything
PT-COMP-002	Official criterion awaiting qualified confirmation	Microbial Enumeration (TAMC): MONOGRAPH SECTION 'MICROBIAL ENUMERATION TESTS <61> and TES' APPLIES — criterion not machine-readable; qualified review required	**REVIEW REQUIRED**	Qualified reviewer to confirm the official limit before it decides anything
PT-COMP-002	Official criterion awaiting qualified confirmation	Microbial Enumeration (TYMC): MONOGRAPH SECTION 'MICROBIAL ENUMERATION TESTS <61> and TES' APPLIES — criterion not machine-readable; qualified review required	**REVIEW REQUIRED**	Qualified reviewer to confirm the official limit before it decides anything
PT-COMP-002	Official criterion awaiting qualified confirmation	E. coli: MONOGRAPH SECTION 'MICROBIAL ENUMERATION TESTS <61> and TES' APPLIES — criterion not machine-readable; qualified review required	**REVIEW REQUIRED**	Qualified reviewer to confirm the official limit before it decides anything
PT-COMP-002	Official criterion awaiting qualified confirmation	Salmonella spp.: MONOGRAPH SECTION 'MICROBIAL ENUMERATION TESTS <61> and TES' APPLIES — criterion not machine-readable; qualified review required	**REVIEW REQUIRED**	Qualified reviewer to confirm the official limit before it decides anything
PT-TEST-001	Monograph tests reported	CONDUCTIVITY	**NOT REPORTED**	Request results for the missing tests
PT-AUTH-001	Authorisation	Authorised signature / e-approval: PARTIAL	**PARTIAL**	Verify authorised signatory and approval date
PT-DATA-001	Evidence strength	5 result(s) state only a declaration ('Complies' or similar)	**DECLARATION**	Do not count as independent numerical verification
PT-SAMPLE-001	Laboratory sample quantity	Sample delivered and retained quantity absent	**NOT VERIFIABLE**	Request test request / sample receipt record; do not call this a CoA failure
PT-PORTION-001	Monograph test portions	Test portions / preparations not documented on the CoA	**NOT VERIFIABLE**	Compare worksheets with the monograph and flag any unjustified deviation
PT-LAB-001	Separate laboratory trigger	Manufacturer-issued format; no outsourced laboratory stated	**NOT APPLIED**	Do not penalise; activate ICH Q7 11.44 information if a repacker / reprocessor / broker / laboratory is involved
PT-MARKET-001	Market-specific pharmacopoeia applicability (IP, JP, CP …)	No market / dossier trigger supplied with the certificate	**NOT APPLIED**	Use the controlled monograph of that pharmacopoeia if the trigger becomes active; no penalty, no implied compliance

Required evidence package for official release

Priority	Evidence	Purpose
Major	Verifiable signed / e-approved certificate or controlled signature-authority evidence	Close the authorisation gap (ICH Q7 11.43 / WHO model certificate)
Major	Supplier qualification, GMP status and manufacturing / testing-site confirmation	Authenticate manufacturer, site and quality system

Major	Results for the monograph tests not reported on the certificate	Demonstrate the full monograph (identity and limit tests)
Major	Qualified reviewer confirmation of the library criteria listed as REVIEW REQUIRED	Turn proposed official limits into applied ones
Required to verify execution	Sample receipt / test request, analytical worksheets, preparation calculations and sampling records	Confirm that actual test portions / concentrations match the monograph or an approved validated equivalent
As needed	Chromatograms, system suitability and reference-standard traceability	Technical verification, audit or investigation based on risk and the quality agreement

Controlled product rules

PHARMA-COMP-EDITION-001	**Edition year alone does not block comparison. The later controlled edition must be present and checked; normalise only when the exact article and applicable requirements match.** Trigger: same pharmacopoeia and the exact same article (name, salt/base, hydrate/solvate, API/dosage-form type, route/use qualifier, calculation basis); only the edition year differs. Action: use the later controlled edition; if requirements are unchanged return VERSION NORMALIZED and continue the full assessment; if a requirement changed, apply the later one and list the change. Prohibition: never return NOT VERIFIED merely because of the year; never substitute a related but different monograph (base for salt, salt for base, hydrate for anhydrous, API for dosage form, one route/use qualifier for another).
PHARMA-EVIDENCE-CLASS-001	**Classify every CoA row as PRODUCT MONOGRAPH, REFERENCED GENERAL CHAPTER, OTHER APPLICABLE GENERAL REQUIREMENT, or SUPPLIER-ONLY.** Calculate the official monograph result from PRODUCT MONOGRAPH rows only. Display additional controls separately and preserve the source, chapter, criterion, result and evidence status for every row.

Controlled evidence hierarchy

Source	Role in this review	Reference
Supplier CoA	Primary evidence for printed identity, limits, results and visible authorisation.	EXP-COA-MCC-2026-0614; batch MCC-2026-0614-A
Microcrystalline Cellulose monograph (USP 2024)	Product-specific requirements; controlled library copy.	identifier not recorded
WHO TRS 1010 Annex 4; TRS 1052 Annex 4	CoA / analytical-report structure and traceability basis.	WHO Model CoA; sampling and test-request records
21 CFR 211.160 and 211.194	Sampling / test controls, sample quantity received, weight or measure used per test, method-modification records.	FDA laboratory records
WHO TRS 1060 Annex 3	Current excipient GMP and quality-system context.	WHO excipient GMP
IPEC CoA Guide 2024 v2.1	Excipient-specific industry best practice; not a legal universal mandate.	IPEC
ICH Q3C(R9) / USP <467>	General residual-solvent basis for additional supplier controls (Class 3 default 5000 ppm).	ICH Q3C(R9)
USP general chapters cited in the detailed records	Method and execution evidence rules (<11>, <197>, <621>, <921>, <281>, <467>, <61>/<1111>, <85> as applicable).	USP-NF 2024, listed in the controlled source register
External company / website data	Not consulted by this automated review.	Would be external metadata only; never factory / laboratory verification

Qualified expert review

To be completed by the qualified reviewer.

Reviewer / organisation	
Role / qualification	
Records reviewed	[ ] Test request / sample receipt [ ] Sampling plan [ ] Analytical worksheets / ELN [ ] Method validation / deviation
Sample-size conclusion	[ ] Sufficient and representative [ ] Insufficient [ ] Not assessed
Test-portion conclusion	[ ] Matches the monograph [ ] Validated equivalent [ ] Unjustified deviation [ ] Not assessed
Overall decision	[ ] Confirm HOLD [ ] Amend findings [ ] Additional evidence required [ ] Release under quality-system controls
Rationale / evidence references	
Signature / date	

Limitations: Raw data, method execution, supplier qualification, site authenticity and signatory authority were not independently verified. Final procurement, release or rejection remains with qualified personnel under the applicable quality system and law.

Appendix A — source Certificate of Analysis

Original image reproduced for visual verification of extracted fields, printed limits / results, personnel roles, signature and stamp. Source: supplier CoA EXP-COA-MCC-2026-0614, batch MCC-2026-0614-A. Reproduction supports document review only and is not independent authentication.

EXCIPHARMA SOLUTIONS LTD.
Industrial Zone, Block 7 | Dubai, UAE | Tel: +971-4-XXX-XXXX | quality@excipharma.ae

CERTIFICATE OF ANALYSIS

Doc. No: EXP-COA-MCC-2026-0614 | Date of Issue: 20 Jun 2026 | Page 1 of 1

SECTION 1 — PRODUCT & BATCH INFORMATION

Product Name (Compendial):	Microcrystalline Cellulose	**Trade Name:**	EXCIPCEL® 102
Compendial Designation:	USP/NF & Ph. Eur.	**Grade:**	PH-102 (Pharmaceutical)
Batch Number:	MCC-2026-0614-A	**Date of Manufacture:**	14 Jun 2026
Batch Quantity:	5,000 kg	**Recommended Retest Date:**	14 Jun 2029
Container Type:	25 kg Double Polyethylene-lined HDPE Drums	**Storage Conditions:**	Store in a cool, dry place. T: 15-30°C. RH: ≤60%.
Original Manufacturer:	ExciPharma Solutions Ltd., Dubai, UAE	**Manufacturing Site:**	Plant A, Industrial Zone Block 7, Dubai, UAE
Specification Reference:	EXP-SPEC-MCC-001, Ver. 4.0	**Customer PO Reference:**	N/A (Manufacturer Release)

SECTION 2 — TEST RESULTS

[All tests performed on finished excipient batch unless noted. Dates of testing: 14–17 Jun 2026]

Identification (IR Spectroscopy)	USP <197K> / Ph. Eur. 2.2.24	Conforms to reference spectrum	Conforms	PASS
Description (Appearance)	Visual Examination	White or almost white, fine or granular powder	White, fine granular powder	PASS
pH (20% w/v Slurry)	USP <791>	5.0 – 7.5	6.2	PASS
Loss on Drying	USP <731> / Ph. Eur. 2.2.32	NMT 7.0% (105°C, 3 hrs)	4.8%	PASS
Residue on Ignition	USP <281> / Ph. Eur. 2.4.14	NMT 0.1%	0.03%	PASS
Heavy Metals (as Pb)	USP <231> Method II	NMT 10 ppm	< 5 ppm	PASS
Nickel	USP <231>	NMT 1 ppm	< 0.5 ppm*	PASS
Water-Soluble Substances	USP MCC Monograph	NMT 0.24%	0.09%	PASS
Ether-Soluble Substances	USP MCC Monograph	NMT 0.05%	0.02%	PASS
Degree of Polymerization	USP MCC Monograph	NMT 350	220	PASS
Particle Size (D90)	Supplier Method SM-PS-001 (Laser Diffraction)	90.0 – 130.0 µm	108.5 µm	PASS
Particle Size (D50)	Supplier Method SM-PS-001 (Laser Diffraction)	75.0 – 100.0 µm	88.2 µm	PASS
Bulk Density (Untapped)	USP <616>	0.25 – 0.45 g/mL	0.31 g/mL	PASS
Tapped Density	USP <616>	0.35 – 0.55 g/mL	0.42 g/mL	PASS
Hausner Ratio	Calculated from BD/TD	NMT 1.35	1.21	PASS
Microbial Enumeration (TAMC)	USP <61>	NMT 1000 CFU/g	< 10 CFU/g	PASS
Microbial Enumeration (TYMC)	USP <61>	NMT 100 CFU/g	< 10 CFU/g	PASS
E. coli	USP <62>	Absent in 1 g	Absent	PASS
Salmonella spp.	USP <62>	Absent in 10 g	Absent	PASS
Residual Solvents (ICH Class 1 & 2)	USP <467>	Meets USP requirements	Conforms+	PASS

* *Nickel: Tested in-process on each batch; material shown not to change in finished excipient sample.*
+ *Residual Solvents: Evidence of compliance available in separate correspondence (EXP-RS-MCC-2026-001).*

SECTION 3 — ADDITIONAL & PERIODIC TEST RESULTS

Arsenic (in-process)*	Ph. Eur. 2.4.2	NMT 2 ppm	< 1 ppm	PASS
Elemental Impurities (quarterly)+	USP <232> / Ph. Eur. 5.20	Meets USP <232> limits	Conforms	PASS

* *Arsenic: Performed in-process on each batch; demonstrated not to change in finished excipient.*
+ *Elemental Impurities: Periodic (quarterly) monitoring per validated process capability data. Last tested: 01 Mar 2026 — Conforms.*

SECTION 4 — CERTIFICATION & COMPLIANCE STATEMENTS

GMP Compliance	This batch of EXCIPCEL® 102 (Microcrystalline Cellulose) has been manufactured in full compliance with the Joint IPEC-PQG Good Manufacturing Practices Guide for Pharmaceutical Excipients (2017) and 21 CFR Part 211.
Compendial Standards	This batch complies with all current requirements of the United States Pharmacopeia/National Formulary (USP-NF) Microcrystalline Cellulose Monograph and the European Pharmacopoeia (Ph. Eur.) Microcrystalline Cellulose Monograph.
Residual Solvents	The manufacturing process for this product does not utilize ICH Class 1 or Class 2 solvents. The product conforms to requirements of USP General Chapter <467>.
GMO Status	This product is derived from wood pulp (non-food-chain) and is not produced using genetically modified organisms (GMO-free).
TSE / BSE Status	This product is of vegetable origin (wood pulp). It does not contain material of animal origin and is free from TSE/BSE risk.
Allergen Statement	This product does not contain or is produced in the presence of any declared food allergens as listed in EU Regulation 1169/2011 or FDA CFR 21 Part 101.

BATCH DISPOSITION: RELEASED — CONFORMS TO ALL SPECIFICATIONS

SECTION 5 — AUTHORIZATION

Prepared By: Dr. Ahmed Al-Rashidi, QC Analyst	Date: 18 Jun 2026
Reviewed By: Ms. Fatima Khalil, QC Supervisor	Date: 19 Jun 2026
Approved By (QA Release): Dr. Sara Mohammed, Head of Quality Assurance	Date of Approval: 20 Jun 2026

Electronic Signature Notice: This COA has been issued from an electronic quality management system in compliance with 21 CFR Part 11 and ALCOA+ data integrity principles. The electronic approval records, audit trail, and signatory credentials are maintained in the ExciPharma QMS (System ID: QMS-EXP-003, Validated: Jan 2025). Physical signatures are available on request.

This Certificate of Analysis has been prepared in accordance with the IPEC Federation Certificate of Analysis Guide for Pharmaceutical Excipients, Version 2.1, 2024. Retain this document for a minimum of one year after the recommended retest date.

Appendix B — detailed decision records

Technical findings, calculations, sources, monograph comparison and expert-review information — every conclusion as a decision record

Decision-support notice — Automated Analysis

PharmaTrust COA Validator produces an automated analysis of a Certificate of Analysis using rule-based checks and AI-assisted reading. Automated analysis may contain errors and may not detect every problem. It is decision support, not a decision: the findings must be reviewed by qualified QA, QC, regulatory, laboratory or other relevant experts before any important decision is made.

- The analysis may contain errors, including reading (OCR) errors, field-extraction errors and specification-comparison errors.
- The analysis may not detect every problem with a certificate, a supplier or a batch; a finding of "no issue" is not proof of compliance.
- PharmaTrust is not a pharmacopoeia, does not act as one, does not certify compliance with any pharmacopoeia or regulation, and does not grant or imply regulatory approval.
- Automated findings must be reviewed by qualified QA, QC, regulatory, laboratory or other relevant experts before procurement, release, rejection or any other important decision is made.
- An Expert-Reviewed Analysis, where provided, records the opinion of the named reviewer on the automated findings; responsibility for the final decision remains with the customer's qualified personnel.
- Every report states the software, rule and source versions it was produced with so that a qualified reviewer can reproduce and challenge each finding.

Notice version 2026.08.21-1

Report	PTR-ee282b80-eaee-40ba	**Assessment date**	2026-08-24
CoA number	EXP-COA-MCC-2026-0614	**Batch**	MCC-2026-0614-A
Issuer	ExciPharma Solutions Ltd., Dubai, UAE	**Claimed standard**	USP/NF & Ph. Eur.
Article	Microcrystalline Cellulose	**Official source**	Microcrystalline Cellulose monograph (USP 2024; printed from @2024 USPC)

Final outcome

CONDITIONAL

No reported result fails, and no printed limit is wider than the official requirement — but items of evidence needed to complete the assessment are missing from the certificate. Close the open items below, or record a qualified person's rationale for accepting each one, before releasing on this certificate.

- 26 major evidence items remain open, affecting: Arsenic (in-process)*, Bulk Density (Untapped), Compendial execution evidence, Degree of Polymerization, Description (Appearance), Document identity and authorization, Elemental Impurities (quarterly)+, Ether-Soluble Substances, Hausner Ratio, Heavy Metals (as Pb), Identification (IR Spectroscopy), Loss on Drying, Nickel, Particle Size (D50), Particle Size (D90), Residual Solvents (ICH Class 1 & 2), Residue on Ignition, Tapped Density, Water-Soluble Substances, pH (20% w/v Slurry). None of them is a failed result; each is evidence the certificate does not carry.

127 / 131	3 / 3	20 / 20	1 / 20	0
Documentation points completeness of the certificate as a document	Requirement groups aligned printed limits equal to or stricter than official	Analytical groups passing reported results meeting the applied requirement	Verified compendial passes of the passing results, how many passed against a retrieved official requirement; the remainder passed only the supplier's own printed limit	Limit mismatches printed limits wider than the official requirement

Release gate. Close the open findings below, or record a qualified person's rationale for accepting each one, before releasing on this certificate.

Client decision summary

Assessment	Outcome	What it means
Document identity and authorization	COMPLIES	Issuer, article, batch, dates, conclusion and quality unit authorisation are all identifiable on the certificate.
Supplier results against printed limits	PASS	Every reported result is within the limit printed beside it on the certificate.
Pharmacopoeial specification alignment	ALIGNED	All 3 directly comparable limits match or are stricter than the official requirement; no numerical mismatch was found.
Compendial execution evidence	NOT COMPLETE	8 items of method or execution evidence the applicable chapters call for are not carried on the certificate.
Overall recommendation	CONDITIONAL	No reported result fails, and no printed limit is wider than the official requirement — but items of evidence needed to complete the assessment are missing from the certificate. Close the open items below, or record a qualified person's rationale for accepting each one, before releasing on this certificate.

Official comparison

Official requirement, supplier specification, result, reason and source for every test

Test	Certificate specification and result	Official requirement	Outcome and reason	Reference
Identification (IR Spectroscopy) CRITICAL	Conforms to reference spectrum **Result:** Conforms	Acceptance criteria: The substance takes on a violet-blue color.	PASS AGAINST SUPPLIER LIMIT The reported result meets the limit applied to it, but that limit could not be confirmed against an official requirement, so this is a pass against the supplier's specification rather than a verified compendial pass. Also open: method identification, the official limit could not be retrieved.	Microcrystalline Cellulose monograph, Identification (IR Spectroscopy) (USP 2024; printed from @2024 USPC)
Description (Appearance) MINOR	White or almost white, fine or granular powder **Result:** White, fine granular powder	not stated	PASS AGAINST SUPPLIER LIMIT The reported result meets the limit applied to it, but that limit could not be confirmed against an official requirement, so this is a pass against the supplier's specification rather than a verified compendial pass. Also open: the official limit could not be retrieved.	Microcrystalline Cellulose monograph, Description (Appearance) (USP 2024; printed from @2024 USPC)
pH (20% w/v Slurry) MAJOR	5.0 – 7.5 **Result:** 6.2	not stated	PASS AGAINST SUPPLIER LIMIT The reported result meets the limit applied to it, but that limit could not be confirmed against an official requirement, so this is a pass against the supplier's specification rather than a verified compendial pass. Also open: the official limit could not be retrieved.	Microcrystalline Cellulose monograph, pH (20% w/v Slurry) (USP 2024; printed from @2024 USPC)
Loss on Drying MAJOR	NMT 7.0% (105°C, 3 hrs) **Result:** 4.8%	not stated	PASS AGAINST SUPPLIER LIMIT The reported result meets the limit applied to it, but that limit could not be confirmed against an official requirement, so this is a pass against the supplier's specification rather than a verified compendial pass. Also open: the official limit could not be retrieved.	Microcrystalline Cellulose monograph, Loss on Drying (USP 2024; printed from @2024 USPC)
Residue on Ignition MAJOR	NMT 0.1% **Result:** 0.03%	not stated	PASS AGAINST SUPPLIER LIMIT The reported result meets the limit applied to it, but that limit could not be confirmed against an official requirement, so this is a pass against the supplier's specification rather than a verified compendial pass. Also open: method identification, the official limit could not be retrieved.	Microcrystalline Cellulose monograph, Residue on Ignition (USP 2024; printed from @2024 USPC)

Heavy Metals (as Pb) MAJOR	NMT 10 ppm **Result:** < 5 ppm	not stated	PASS AGAINST SUPPLIER LIMIT The reported result meets the limit applied to it, but that limit could not be confirmed against an official requirement, so this is a pass against the supplier's specification rather than a verified compendial pass. Also open: the official limit could not be retrieved.	Microcrystalline Cellulose monograph, Heavy Metals (as Pb) (USP 2024; printed from @2024 USPC)
Nickel MAJOR	NMT 1 ppm **Result:** not stated	not stated	NOT VERIFIED Neither the limit nor the result for 'Nickel' could be established well enough to state an outcome: the result could not be judged.	Microcrystalline Cellulose monograph, Nickel (USP 2024; printed from @2024 USPC)
Water-Soluble Substances MAJOR	NMT 0.24% **Result:** 0.09%	not stated	PASS AGAINST SUPPLIER LIMIT The reported result meets the limit applied to it, but that limit could not be confirmed against an official requirement, so this is a pass against the supplier's specification rather than a verified compendial pass. Also open: method identification, the official limit could not be retrieved.	Microcrystalline Cellulose monograph, Water-Soluble Substances (USP 2024; printed from @2024 USPC)
Ether-Soluble Substances MAJOR	NMT 0.05% **Result:** 0.02%	not stated	PASS AGAINST SUPPLIER LIMIT The reported result meets the limit applied to it, but that limit could not be confirmed against an official requirement, so this is a pass against the supplier's specification rather than a verified compendial pass. Also open: the official limit could not be retrieved.	Microcrystalline Cellulose monograph, Ether-Soluble Substances (USP 2024; printed from @2024 USPC)
Degree of Polymerization MAJOR	NMT 350 **Result:** 220	not stated	PASS AGAINST SUPPLIER LIMIT The reported result meets the limit applied to it, but that limit could not be confirmed against an official requirement, so this is a pass against the supplier's specification rather than a verified compendial pass. Also open: the official limit could not be retrieved.	Microcrystalline Cellulose monograph, Degree of Polymerization (USP 2024; printed from @2024 USPC)
Particle Size (D90) MAJOR	90.0 – 130.0 µm **Result:** 108.5 µm	not stated	PASS AGAINST SUPPLIER LIMIT The reported result meets the limit applied to it, but that limit could not be confirmed against an official requirement, so this is a pass against the supplier's specification rather than a verified compendial pass. Also open: the official limit could not be retrieved.	Microcrystalline Cellulose monograph, Particle Size (D90) (USP 2024; printed from @2024 USPC)

Particle Size (D50) MAJOR	75.0 – 100.0 µm **Result:** 88.2 µm	not stated	PASS AGAINST SUPPLIER LIMIT The reported result meets the limit applied to it, but that limit could not be confirmed against an official requirement, so this is a pass against the supplier's specification rather than a verified compendial pass. Also open: the official limit could not be retrieved.	Microcrystalline Cellulose monograph, Particle Size (D50) (USP 2024; printed from @2024 USPC)
Bulk Density (Untapped) MAJOR	0.25 – 0.45 g/mL **Result:** 0.31 g/mL	not stated	PASS AGAINST SUPPLIER LIMIT The reported result meets the limit applied to it, but that limit could not be confirmed against an official requirement, so this is a pass against the supplier's specification rather than a verified compendial pass. Also open: the official limit could not be retrieved.	Microcrystalline Cellulose monograph, Bulk Density (Untapped) (USP 2024; printed from @2024 USPC)
Tapped Density MAJOR	0.35 – 0.55 g/mL **Result:** 0.42 g/mL	not stated	PASS AGAINST SUPPLIER LIMIT The reported result meets the limit applied to it, but that limit could not be confirmed against an official requirement, so this is a pass against the supplier's specification rather than a verified compendial pass. Also open: the official limit could not be retrieved.	Microcrystalline Cellulose monograph, Tapped Density (USP 2024; printed from @2024 USPC)
Hausner Ratio MAJOR	NMT 1.35 **Result:** 1.21	not stated	PASS AGAINST SUPPLIER LIMIT The reported result meets the limit applied to it, but that limit could not be confirmed against an official requirement, so this is a pass against the supplier's specification rather than a verified compendial pass. Also open: the official limit could not be retrieved.	Microcrystalline Cellulose monograph, Hausner Ratio (USP 2024; printed from @2024 USPC)
Microbial Enumeration (TAMC) CRITICAL	NMT 1000 CFU/g **Result:** < 10 CFU/g	not stated	PASS The certificate's limit for 'Microbial Enumeration (TAMC)' matches or is tighter than the official requirement, the reported result meets it, and the method and execution evidence the applicable chapters call for is present.	USP <1111> Microbiological Examination of Nonsterile Products: Acceptance Criteria for Pharmaceutical Preparations and Substances for Pharmaceutical Use, Table 2 — Substances for Pharmaceutical Use (USP-NF 2024; printed from @2024 USPC)

Microbial Enumeration (TYMC) CRITICAL	NMT 100 CFU/g **Result:** < 10 CFU/g	not stated	**PASS** The certificate's limit for 'Microbial Enumeration (TYMC)' matches or is tighter than the official requirement, the reported result meets it, and the method and execution evidence the applicable chapters call for is present.	USP <1111> Microbiological Examination of Nonsterile Products: Acceptance Criteria for Pharmaceutical Preparations and Substances for Pharmaceutical Use, Table 2 — Substances for Pharmaceutical Use (USP-NF 2024; printed from @2024 USPC)
E. coli CRITICAL	Absent in 1 g **Result:** Absent	not stated	**PASS** The certificate's limit for 'E. coli' matches or is tighter than the official requirement, the reported result meets it, and the method and execution evidence the applicable chapters call for is present.	USP <1111> Microbiological Examination of Nonsterile Products: Acceptance Criteria for Pharmaceutical Preparations and Substances for Pharmaceutical Use, Table 2 — Substances for Pharmaceutical Use (USP-NF 2024; printed from @2024 USPC)
Salmonella spp. CRITICAL	Absent in 10 g **Result:** Absent	not stated	**PASS AGAINST SUPPLIER LIMIT** The reported result meets the limit applied to it, but that limit could not be confirmed against an official requirement, so this is a pass against the supplier's specification rather than a verified compendial pass.	Microcrystalline Cellulose monograph, Salmonella spp. (USP 2024; printed from @2024 USPC)
Residual Solvents (ICH Class 1 & 2) MAJOR	Meets USP requirements **Result:** Conforms+	not stated	**PASS AGAINST SUPPLIER LIMIT** The reported result meets the limit applied to it, but that limit could not be confirmed against an official requirement, so this is a pass against the supplier's specification rather than a verified compendial pass. Also open: execution evidence (reference standards or system suitability), general-chapter applicability.	Microcrystalline Cellulose monograph, Residual Solvents (ICH Class 1 & 2) (USP 2024; printed from @2024 USPC)
Arsenic (in-process)* MAJOR	NMT 2 ppm **Result:** < 1 ppm	not stated	**PASS AGAINST SUPPLIER LIMIT** The reported result meets the limit applied to it, but that limit could not be confirmed against an official requirement, so this is a pass against the supplier's specification rather than a verified compendial pass. Also open: the official limit could not be retrieved.	Microcrystalline Cellulose monograph, Arsenic (in-process)* (USP 2024; printed from @2024 USPC)

Elemental Impurities (quarterly)+ MAJOR	Meets USP <232> limits **Result:** Conforms	not stated	**NOT VERIFIED** Neither the limit nor the result for 'Elemental Impurities (quarterly)+' could be established well enough to state an outcome: execution evidence (reference standards or system suitability), the official limit could not be retrieved, the result could not be judged.	Microcrystalline Cellulose monograph, Elemental Impurities (quarterly)+ (USP 2024; printed from @2024 USPC)

Every row states the certificate's own specification and result, the official requirement retrieved for it, the outcome, the reasoning, and the source the requirement came from. An outcome that mentions open evidence is reporting a missing document, not a failed measurement.

Supplementary tests and general chapters

Tests printed on the certificate that fall outside, or are governed more broadly than, the monograph

Test	Certificate	Official requirement	Outcome	Reason and applicability
Microbial Enumeration (TAMC)	NMT 1000 CFU/g **Result:** < 10 CFU/g	For substances for pharmaceutical use, USP <1111> Table 2 gives acceptance criteria of 10^3 CFU/g total aerobic microbial count and 10^2 CFU/g total combined yeasts and moulds; USP <61> supplies the enumeration methods. A manufacturing route intended for a more demanding use may justify tighter in-house controls.	ALIGNED	The certificate's microbial limits are at or below the USP <1111> Table 2 criteria for substances for pharmaceutical use: total aerobic microbial count limited at 1000 CFU/g, equal to the Table 2 criterion of 1000 CFU/g. Tighter in-house limits are consistent with a manufacturing route intended for a more demanding use and satisfy the general criterion. **Applies because:** 'Microbial Enumeration (TAMC)' reports microbial counts for a non-sterile substance for pharmaceutical use. USP <61> supplies the enumeration methods and USP <1111> Table 2 the acceptance criteria for that category.
Microbial Enumeration (TYMC)	NMT 100 CFU/g **Result:** < 10 CFU/g	For substances for pharmaceutical use, USP <1111> Table 2 gives acceptance criteria of 10^3 CFU/g total aerobic microbial count and 10^2 CFU/g total combined yeasts and moulds; USP <61> supplies the enumeration methods. A manufacturing route intended for a more demanding use may justify tighter in-house controls.	ALIGNED	The certificate's microbial limits are at or below the USP <1111> Table 2 criteria for substances for pharmaceutical use: total combined yeasts and moulds limited at 100 CFU/g, equal to the Table 2 criterion of 100 CFU/g. Tighter in-house limits are consistent with a manufacturing route intended for a more demanding use and satisfy the general criterion. **Applies because:** 'Microbial Enumeration (TYMC)' reports microbial counts for a non-sterile substance for pharmaceutical use. USP <61> supplies the enumeration methods and USP <1111> Table 2 the acceptance criteria for that category.
E. coli	Absent in 1 g **Result:** Absent	For substances for pharmaceutical use, USP <1111> Table 2 requires absence of Escherichia coli in 1 g; USP <62> supplies the test method.	ALIGNED	The certificate's acceptance criterion for 'E. coli' is stated as absence, which is the USP <1111> Table 2 criterion for Escherichia coli in substances for pharmaceutical use. **Applies because:** 'E. coli' is a test for a specified microorganism (presence/absence). USP <62> supplies the test methods; the acceptance criteria for the product category live in USP <1111>.

Salmonella spp.	Absent in 10 g **Result:** Absent	USP <1111> Table 2 does not assign an acceptance criterion for this organism to the substances-for-pharmaceutical-use category; the printed presence/absence criterion is a supplier control beyond the compendial baseline. USP <62> supplies the test methods for specified microorganisms.	INFORMATIONAL	'Salmonella spp.' tests for a specified organism for which USP <1111> Table 2 assigns no criterion in this product category. The certificate's own criterion and result are compared in the analytical section; no official limit exists to align against, and none was invented. **Applies because:** 'Salmonella spp.' is a test for a specified microorganism (presence/absence). USP <62> supplies the test methods; the acceptance criteria for the product category live in USP <1111>.
Residual Solvents (ICH Class 1 & 2)	Meets USP requirements **Result:** Conforms+	USP <467> classifies residual solvents by toxicity: Class 1 solvents are to be avoided, Class 2 solvents are limited by named concentration limits, and Class 3 solvents are regarded as less toxic, with 5000 ppm normally acceptable without further justification.	NOT VERIFIED	The certificate reports a residual-solvent test but does not name the individual solvents controlled, so each solvent's USP <467> class and the concentration permitted for it cannot be established from the certificate. **Applies because:** 'Residual Solvents (ICH Class 1 & 2)' reports solvents remaining from manufacture. USP <467> applies to residual solvents in every article tested to a USP-NF standard and classifies each solvent by toxicity, which is what determines the concentration that may be accepted.

Tests printed on the certificate that fall outside the monograph, or that a general chapter governs more broadly than the monograph does. Each row states why the chapter applies to this material and use.

Open findings and required actions

Every unresolved item with its severity, requirement, observed evidence, source and closure action

ID	Severity	Finding	Requirement, evidence and source	Required action
U-01	MAJOR	**Arsenic (in-process)*** No official limit for this test was retrievable from the approved source library, so the certificate's limit could not be checked against one. The certificate's own limit (NMT 2.0ppm) is therefore the only limit available for this test, and it is applied as a supplier limit rather than as a verified official requirement.	The acceptance limit a certificate prints for 'Arsenic (in-process)*' must be at least as strict as the limit the applicable official source sets for it. A wider in-house limit would let material pass the certificate while failing the official requirement. **Observed:** NMT 2 ppm (page 0; acceptance-criterion cell, row 21) Microcrystalline Cellulose monograph, Arsenic (in-process)* (USP 2024; printed from @2024 USPC)	Load the applicable monograph section for 'Arsenic (in-process)*' into the approved source library, or confirm with the issuer which official requirement the printed limit derives from.
U-02	MAJOR	**Bulk Density (Untapped)** No official limit for this test was retrievable from the approved source library, so the certificate's limit could not be checked against one. The certificate's own limit (0.25 to 0.45) is therefore the only limit available for this test, and it is applied as a supplier limit rather than as a verified official requirement.	The acceptance limit a certificate prints for 'Bulk Density (Untapped)' must be at least as strict as the limit the applicable official source sets for it. A wider in-house limit would let material pass the certificate while failing the official requirement. **Observed:** 0.25 – 0.45 g/mL (page 0; acceptance-criterion cell, row 13) Microcrystalline Cellulose monograph, Bulk Density (Untapped) (USP 2024; printed from @2024 USPC)	Load the applicable monograph section for 'Bulk Density (Untapped)' into the approved source library, or confirm with the issuer which official requirement the printed limit derives from.
U-03	MAJOR	**Compendial execution evidence** Test-procedure references and their revisions are not printed consistently across the certificate: 21 of 22 tests state a limit and a result without naming the procedure that produced them. The reported values are not disputed; what is missing is the link from each value to a controlled, versioned method.	The WHO model certificate requires each test to be accompanied by a reference to the test procedure used, so that a limit and a result can be read against the method that produced them. **Observed:** 1 of 22 tests carry a procedure reference; 21 do not (Identification (IR Spectroscopy), Description (Appearance), pH (20% w/v Slurry), Loss on Drying, Residue on Ignition, Heavy Metals (as Pb) and 15 more) (test table) WHO Technical Report Series No. 1010 (2018), Annex 4 — Model certificate of analysis, model certificate — test-procedure reference (TRS 1010 (2018); official 2018-01-01)	Obtain the controlled analytical-method list, or a revised certificate or addendum showing the method number and revision for each test.

U-04	MAJOR	**Degree of Polymerization** No official limit for this test was retrievable from the approved source library, so the certificate's limit could not be checked against one. The certificate's own limit (NMT 350.0) is therefore the only limit available for this test, and it is applied as a supplier limit rather than as a verified official requirement.	The acceptance limit a certificate prints for 'Degree of Polymerization' must be at least as strict as the limit the applicable official source sets for it. A wider in-house limit would let material pass the certificate while failing the official requirement. **Observed:** NMT 350 (page 0; acceptance-criterion cell, row 10) Microcrystalline Cellulose monograph, Degree of Polymerization (USP 2024; printed from @2024 USPC)	Load the applicable monograph section for 'Degree of Polymerization' into the approved source library, or confirm with the issuer which official requirement the printed limit derives from.
U-05	MAJOR	**Description (Appearance)** No official limit for this test was retrievable from the approved source library, so the certificate's limit could not be checked against one. The certificate's own limit (White or almost white, fine or granular powder) is therefore the only limit available for this test, and it is applied as a supplier limit rather than as a verified official requirement.	The acceptance limit a certificate prints for 'Description (Appearance)' must be at least as strict as the limit the applicable official source sets for it. A wider in-house limit would let material pass the certificate while failing the official requirement. **Observed:** White or almost white, fine or granular powder (page 0; acceptance-criterion cell, row 2) Microcrystalline Cellulose monograph, Description (Appearance) (USP 2024; printed from @2024 USPC)	Load the applicable monograph section for 'Description (Appearance)' into the approved source library, or confirm with the issuer which official requirement the printed limit derives from.
U-06	MAJOR / CLARIFICATION	**Document identity and authorization** The certificate carries a date labelled 'Date of Issue' but does not separately identify the date of release. The two are commonly the same and the certificate is likely correct; what cannot be read off the document is which event the printed date records.	ICH Q7 requires the certificate to carry the date on which the batch was released, alongside the identity and batch information. A single undifferentiated date does not show whether it is the date of testing, of issue, or of release. **Observed:** Date of Issue (certificate header) ICH Q7 Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients, Section 11.4 (Certificates of Analysis), paragraphs 11.40-11.44, paragraph 11.41 (Step 4 version, 10 November 2000; official 2000-11-10)	Confirm with the issuer whether the printed date is the formal batch release date, or request a certificate that states the release date separately.
U-07	MAJOR	**Elemental Impurities (quarterly)+** The certificate reports a quantitative result but does not establish which reference-standard lot the measurement was made against, so the result cannot be traced to a specified, valid standard. The reported value is not disputed; what is missing is the traceability evidence behind it.	Where a compendial procedure specifies a USP Reference Standard, USP <11> requires that a current, valid lot be used; the standard's identity and lot are what make the quantitative result traceable. **Observed:** Not present on the certificate — the certificate names no reference standard, lot or validity for this procedure USP <11> USP Reference Standards, USP Reference Standards (USP-NF 2024; printed from @2024 USPC)	Request reference-standard traceability summaries (standard identity, lot and validity) for the quantitative procedures, or verify them during supplier qualification or audit.

U-08	MAJOR	**Elemental Impurities (quarterly)+** A result is reported for 'Elemental Impurities (quarterly)+', but neither the certificate's own criterion nor the approved source library yielded a limit this result can be measured against, so no pass or fail can be stated without inventing a limit.	A reported result for 'Elemental Impurities (quarterly)+' has to be judged against a stated acceptance limit; without one, the number certifies nothing. **Observed:** Conforms (page 0; result cell, row 22) Microcrystalline Cellulose monograph, Elemental Impurities (quarterly)+ (USP 2024; printed from @2024 USPC)	Load the applicable monograph section for 'Elemental Impurities (quarterly)+', or obtain a certificate that prints an acceptance limit for it.
U-09	MAJOR	**Elemental Impurities (quarterly)+** No official limit for this test was retrievable from the approved source library, so the certificate's limit could not be checked against one. The certificate's own limit (not stated) is therefore the only limit available for this test, and it is applied as a supplier limit rather than as a verified official requirement.	The acceptance limit a certificate prints for 'Elemental Impurities (quarterly)+' must be at least as strict as the limit the applicable official source sets for it. A wider in-house limit would let material pass the certificate while failing the official requirement. **Observed:** Meets USP <232> limits (page 0; acceptance-criterion cell, row 22) Microcrystalline Cellulose monograph, Elemental Impurities (quarterly)+ (USP 2024; printed from @2024 USPC)	Load the applicable monograph section for 'Elemental Impurities (quarterly)+' into the approved source library, or confirm with the issuer which official requirement the printed limit derives from.
U-10	MAJOR	**2 tests** A numerical chromatographic result is reported, but the certificate carries no system-suitability data for the run that produced it. The number is therefore reported as the supplier states it, while the evidence that the chromatographic system was fit at the time of the run is absent. This is an evidence gap in the certificate, not a failure of the batch. The same gap is present on 2 tests: Elemental Impurities (quarterly)+, Residual Solvents (ICH Class 1 & 2).	USP <621> treats system suitability as an integral part of a chromatographic procedure: the parameters (resolution, tailing, repeatability, plate count) must be met at the time of the run for the chromatographic result to be a compendial result. **Observed:** Residual Solvents (ICH Class 1 & 2): Not present on the certificate — no system-suitability parameters or results are printed anywhere on the certificate; Elemental Impurities (quarterly)+: Not present on the certificate — no system-suitability parameters or results are printed anywhere on the certificate USP <621> Chromatography, System Suitability (USP-NF 2024; printed from @2024 USPC)	Request the system-suitability results for this run, or verify them against the analytical test report during supplier qualification or audit.
U-11	MAJOR	**Ether-Soluble Substances** No official limit for this test was retrievable from the approved source library, so the certificate's limit could not be checked against one. The certificate's own limit (NMT 0.05%) is therefore the only limit available for this test, and it is applied as a supplier limit rather than as a verified official requirement.	The acceptance limit a certificate prints for 'Ether-Soluble Substances' must be at least as strict as the limit the applicable official source sets for it. A wider in-house limit would let material pass the certificate while failing the official requirement. **Observed:** NMT 0.05% (page 0; acceptance-criterion cell, row 9) Microcrystalline Cellulose monograph, Ether-Soluble Substances (USP 2024; printed from @2024 USPC)	Load the applicable monograph section for 'Ether-Soluble Substances' into the approved source library, or confirm with the issuer which official requirement the printed limit derives from.

U-12	MAJOR	**Hausner Ratio** No official limit for this test was retrievable from the approved source library, so the certificate's limit could not be checked against one. The certificate's own limit (NMT 1.35) is therefore the only limit available for this test, and it is applied as a supplier limit rather than as a verified official requirement.	The acceptance limit a certificate prints for 'Hausner Ratio' must be at least as strict as the limit the applicable official source sets for it. A wider in-house limit would let material pass the certificate while failing the official requirement. **Observed:** NMT 1.35 (page 0; acceptance-criterion cell, row 15) Microcrystalline Cellulose monograph, Hausner Ratio (USP 2024; printed from @2024 USPC)	Load the applicable monograph section for 'Hausner Ratio' into the approved source library, or confirm with the issuer which official requirement the printed limit derives from.
U-13	MAJOR	**Heavy Metals (as Pb)** No official limit for this test was retrievable from the approved source library, so the certificate's limit could not be checked against one. The certificate's own limit (NMT 10.0ppm) is therefore the only limit available for this test, and it is applied as a supplier limit rather than as a verified official requirement.	The acceptance limit a certificate prints for 'Heavy Metals (as Pb)' must be at least as strict as the limit the applicable official source sets for it. A wider in-house limit would let material pass the certificate while failing the official requirement. **Observed:** NMT 10 ppm (page 0; acceptance-criterion cell, row 6) Microcrystalline Cellulose monograph, Heavy Metals (as Pb) (USP 2024; printed from @2024 USPC)	Load the applicable monograph section for 'Heavy Metals (as Pb)' into the approved source library, or confirm with the issuer which official requirement the printed limit derives from.
U-14	MAJOR	**Identification (IR Spectroscopy)** The identification result itself is reported, but the certificate does not print the reference standard the spectrum was compared against. Without it the reported spectral correspondence cannot be tied to a specific compendial procedure, so the result is credited as reported while the method's traceability stays open.	Identification by infrared spectroscopy is performed under USP <197>, which defines the sample-preparation variants (197K, 197M, 197S, 197A); the variant used and the reference standard compared against are both part of the method's identity. **Observed:** Conforms to reference spectrum | Result: Conforms (page 0; test table, row 1) USP <197> Spectroscopic Identification Tests, USP <197> Spectroscopic Identification Tests (USP-NF 2024; printed from @2024 USPC)	Obtain a revised certificate or method addendum naming the <197> procedure variant and the reference standard (with its lot) used for the identification.
U-15	MAJOR	**Loss on Drying** No official limit for this test was retrievable from the approved source library, so the certificate's limit could not be checked against one. The certificate's own limit (NMT 7.0%) is therefore the only limit available for this test, and it is applied as a supplier limit rather than as a verified official requirement.	The acceptance limit a certificate prints for 'Loss on Drying' must be at least as strict as the limit the applicable official source sets for it. A wider in-house limit would let material pass the certificate while failing the official requirement. **Observed:** NMT 7.0% (105°C, 3 hrs) (page 0; acceptance-criterion cell, row 4) Microcrystalline Cellulose monograph, Loss on Drying (USP 2024; printed from @2024 USPC)	Load the applicable monograph section for 'Loss on Drying' into the approved source library, or confirm with the issuer which official requirement the printed limit derives from.

U-16	MAJOR	**Nickel** The result in this row failed the reader's 'E_NOT_PARSEABLE' check (value not parseable as a number), so the value was not carried into comparison. No value was assumed, so this row is reported as unread rather than judged.	A certificate must report, for 'Nickel', a result that can be read against the acceptance limit printed beside it. **Observed:** Not present on the certificate — the certificate prints no result for this test Microcrystalline Cellulose monograph, Nickel (USP 2024; printed from @2024 USPC)	Re-scan the certificate, or have a reviewer read the 'Nickel' row manually and re-enter it.
U-17	MAJOR	**Particle Size (D50)** No official limit for this test was retrievable from the approved source library, so the certificate's limit could not be checked against one. The certificate's own limit (75.0 to 100.0) is therefore the only limit available for this test, and it is applied as a supplier limit rather than as a verified official requirement.	The acceptance limit a certificate prints for 'Particle Size (D50)' must be at least as strict as the limit the applicable official source sets for it. A wider in-house limit would let material pass the certificate while failing the official requirement. **Observed:** 75.0 – 100.0 µm (page 0; acceptance-criterion cell, row 12) Microcrystalline Cellulose monograph, Particle Size (D50) (USP 2024; printed from @2024 USPC)	Load the applicable monograph section for 'Particle Size (D50)' into the approved source library, or confirm with the issuer which official requirement the printed limit derives from.
U-18	MAJOR	**Particle Size (D90)** No official limit for this test was retrievable from the approved source library, so the certificate's limit could not be checked against one. The certificate's own limit (90.0 to 130.0) is therefore the only limit available for this test, and it is applied as a supplier limit rather than as a verified official requirement.	The acceptance limit a certificate prints for 'Particle Size (D90)' must be at least as strict as the limit the applicable official source sets for it. A wider in-house limit would let material pass the certificate while failing the official requirement. **Observed:** 90.0 – 130.0 µm (page 0; acceptance-criterion cell, row 11) Microcrystalline Cellulose monograph, Particle Size (D90) (USP 2024; printed from @2024 USPC)	Load the applicable monograph section for 'Particle Size (D90)' into the approved source library, or confirm with the issuer which official requirement the printed limit derives from.
U-19	MAJOR	**Residual Solvents (ICH Class 1 & 2)** The certificate reports a residual-solvent test but does not name the individual solvents controlled, so each solvent's USP <467> class and the concentration permitted for it cannot be established from the certificate.	USP <467> classifies residual solvents by toxicity: Class 1 solvents are to be avoided, Class 2 solvents are limited by named concentration limits, and Class 3 solvents are regarded as less toxic, with 5000 ppm normally acceptable without further justification. **Observed:** Meets USP requirements | Result: Conforms+ (page 0; test table, row 20) USP <467> Residual Solvents, Residual Solvents (USP-NF 2024; printed from @2024 USPC)	Request a certificate or addendum naming each residual solvent controlled and its limit.

U-20	MAJOR	**Residue on Ignition** The reported value meets the limit printed beside it, but the certificate does not identify which USP <281> procedure produced it. The result is credited as reported; the method detail behind it remains open.	USP <281> prescribes the ignition procedure, including the crucible material (platinum, or another material shown not to contribute to or lose weight under the conditions) and the ignition temperature. **Observed:** Not present on the certificate — the 'Residue on Ignition' row states a limit and a result but names no procedure, method variant or measurement conditions USP <281> Residue on Ignition, Residue on Ignition (USP-NF 2024; printed from @2024 USPC)	Obtain confirmation of the crucible material and ignition conditions used.
U-21	MAJOR	**Residue on Ignition** No official limit for this test was retrievable from the approved source library, so the certificate's limit could not be checked against one. The certificate's own limit (NMT 0.1%) is therefore the only limit available for this test, and it is applied as a supplier limit rather than as a verified official requirement.	The acceptance limit a certificate prints for 'Residue on Ignition' must be at least as strict as the limit the applicable official source sets for it. A wider in-house limit would let material pass the certificate while failing the official requirement. **Observed:** NMT 0.1% (page 0; acceptance-criterion cell, row 5) Microcrystalline Cellulose monograph, Residue on Ignition (USP 2024; printed from @2024 USPC)	Load the applicable monograph section for 'Residue on Ignition' into the approved source library, or confirm with the issuer which official requirement the printed limit derives from.
U-22	MAJOR	**Tapped Density** No official limit for this test was retrievable from the approved source library, so the certificate's limit could not be checked against one. The certificate's own limit (0.35 to 0.55) is therefore the only limit available for this test, and it is applied as a supplier limit rather than as a verified official requirement.	The acceptance limit a certificate prints for 'Tapped Density' must be at least as strict as the limit the applicable official source sets for it. A wider in-house limit would let material pass the certificate while failing the official requirement. **Observed:** 0.35 – 0.55 g/mL (page 0; acceptance-criterion cell, row 14) Microcrystalline Cellulose monograph, Tapped Density (USP 2024; printed from @2024 USPC)	Load the applicable monograph section for 'Tapped Density' into the approved source library, or confirm with the issuer which official requirement the printed limit derives from.
U-23	MAJOR	**Water-Soluble Substances** The reported value meets the limit printed beside it, but the certificate does not identify which USP <921> procedure produced it. The result is credited as reported; the method detail behind it remains open.	USP <921> defines several determinations of water and, within Method I (titrimetric), the variants Ia, Ib and Ic; which one was used is part of the method's identity and determines what the number means. **Observed:** Not present on the certificate — the 'Water-Soluble Substances' row states a limit and a result but names no procedure, method variant or measurement conditions USP <921> Water Determination, Method I (Titrimetric) (USP-NF 2024; printed from @2024 USPC)	Obtain the water-determination method and variant (for example <921> Method Ia) actually used.

U-24	MAJOR	**Water-Soluble Substances** No official limit for this test was retrievable from the approved source library, so the certificate's limit could not be checked against one. The certificate's own limit (NMT 0.24%) is therefore the only limit available for this test, and it is applied as a supplier limit rather than as a verified official requirement.	The acceptance limit a certificate prints for 'Water-Soluble Substances' must be at least as strict as the limit the applicable official source sets for it. A wider in-house limit would let material pass the certificate while failing the official requirement. **Observed:** NMT 0.24% (page 0; acceptance-criterion cell, row 8) Microcrystalline Cellulose monograph, Water-Soluble Substances (USP 2024; printed from @2024 USPC)	Load the applicable monograph section for 'Water-Soluble Substances' into the approved source library, or confirm with the issuer which official requirement the printed limit derives from.
U-25	MAJOR	**pH (20% w/v Slurry)** No official limit for this test was retrievable from the approved source library, so the certificate's limit could not be checked against one. The certificate's own limit (5.0 to 7.5) is therefore the only limit available for this test, and it is applied as a supplier limit rather than as a verified official requirement.	The acceptance limit a certificate prints for 'pH (20% w/v Slurry)' must be at least as strict as the limit the applicable official source sets for it. A wider in-house limit would let material pass the certificate while failing the official requirement. **Observed:** 5.0 – 7.5 (page 0; acceptance-criterion cell, row 3) Microcrystalline Cellulose monograph, pH (20% w/v Slurry) (USP 2024; printed from @2024 USPC)	Load the applicable monograph section for 'pH (20% w/v Slurry)' into the approved source library, or confirm with the issuer which official requirement the printed limit derives from.
D-01	MINOR / CONTEXT SPECIFIC	**Document identity and authorization** Date sample received / sampled could not be established from the certificate. The sampling or receipt date shows the analysis belongs to this batch's timeline. Because the field is absent rather than contradicted, this is a documentation gap in the certificate, not evidence about the batch.	The sampling or receipt date shows the analysis belongs to this batch's timeline. **Observed:** Not present on the certificate — none of the labels or wording that would evidence 'Date sample received / sampled' appear anywhere in the certificate text WHO Technical Report Series No. 902 (2002), Annex 10 — Model certificate of analysis, WHO Technical Report Series No. 902 (2002), Annex 10 — Model certificate of analysis (TRS 902 (2002); official 2002-01-01)	Confirm the sampling or receipt date in the internal laboratory record where applicable.
D-02	MINOR / CONTEXT SPECIFIC	**Document identity and authorization** Laboratory licence / registration number could not be established from the certificate. The issuing site's licence or registration number lets the certificate be checked against the licensing authority's register. Because the field is absent rather than contradicted, this is a documentation gap in the certificate, not evidence about the batch.	The issuing site's licence or registration number lets the certificate be checked against the licensing authority's register. **Observed:** Not present on the certificate — none of the labels or wording that would evidence 'Laboratory licence / registration number' appear anywhere in the certificate text WHO Technical Report Series No. 902 (2002), Annex 10 — Model certificate of analysis, WHO Technical Report Series No. 902 (2002), Annex 10 — Model certificate of analysis (TRS 902 (2002); official 2002-01-01)	Request the issuing site's licence or registration number, so the certificate can be checked against the licensing register.

D-03	MINOR / CLARIFICATION	**Identification (IR Spectroscopy)** Both limits are descriptive rather than numeric, and their wording differs, so whether the certificate's wording is as strict as the official wording is a judgement that cannot be made deterministically from the text.	The acceptance limit a certificate prints for 'Identification (IR Spectroscopy)' must be at least as strict as the limit the applicable official source sets for it. A wider in-house limit would let material pass the certificate while failing the official requirement. **Observed:** Conforms to reference spectrum (page 0; acceptance-criterion cell, row 1) Microcrystalline Cellulose monograph, Identification (IR Spectroscopy) (USP 2024; printed from @2024 USPC)	Have a qualified person compare the certificate's limit for 'Identification (IR Spectroscopy)' (Conforms to reference spectrum) against the official requirement (Acceptance criteria: The substance takes on a violet-blue color.); the two are stated in forms this engine will not rank without guessing.

Release gate

Close the open findings below, or record a qualified person's rationale for accepting each one, before releasing on this certificate.

Every unresolved item, most serious first. Each carries the requirement it comes from, what was observed, why that leaves the item open, and the specific action that closes it.

Scores and their basis

The documentation score is kept separate from pharmacopoeial matching and from the analytical results

Documentation completeness

Category	Fields	Points each	Maximum	Awarded	Outcome
CRITICAL	10	10	100	100	All confirmed
MAJOR	5	5	25	25	All confirmed
MINOR	3	2	6	2	2 not confirmed: Laboratory licence / registration number, Date sample received / sampled
TOTAL	**18**	—	**131**	**127**	**96.9%**

This score measures how complete and attributable the certificate is as a document. It is deliberately kept separate from whether the results comply: a complete certificate can still report a failing batch, and an incomplete certificate can report a good one. The overall recommendation below is not derived from this percentage.

Analytical results

Measure	Value
Requirement groups whose printed limit is equal to or stricter than the official one	3 of 3
Reported results meeting the requirement applied to them	20 of 20
Printed limits wider than the official requirement	0
Weighted result score	44.0 of 48.0 (91.7%)

Each test carries a weight set by what a failure of that test would mean: identity, assay, endotoxin, sterility and microbial tests weigh 3, purity and quality attributes 2, descriptive characteristics 1. A result that meets its requirement earns the full weight; a result that could not be judged earns a quarter of it, because an unjudged result is not evidence of failure but cannot be credited as a pass; a failed result earns nothing.

Score and recommendation. The documentation score is 96.9% and the overall recommendation is CONDITIONAL. These answer different questions and are not derived from one another: the score measures how complete the certificate is as a document, the recommendation reflects whether the batch can be released on it.

Limitations of this assessment

- This is a comparison of a document against approved requirements. It verifies what the certificate states; it cannot authenticate the issuer, confirm that the tests described were actually performed, or validate the raw laboratory data behind the printed results.
- It does not replace supplier qualification, method verification, GMP oversight, or authorised batch release by a qualified person.
- Findings marked as evidence gaps describe what the certificate does not carry. They are not allegations that the underlying work was not done, and several are routinely closed by records held outside the certificate.

Controlled source register

Version provenance for every source this comparison relied on

Source	Authority	Version in force	Identifier
ICH Q7 Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients, Section 11.4 (Certificates of Analysis), paragraphs 11.40-11.44	ICH	Step 4 version, 10 November 2000; official 2000-11-10	not recorded
USP-NF Description and Relative Solubility of USP and NF Articles	USP	USP-NF 2024; printed from @2024 USPC	10.31003/ USPNF_M99995_22_01
USP <1111> Microbiological Examination of Nonsterile Products: Acceptance Criteria for Pharmaceutical Preparations and Substances for Pharmaceutical Use	USP	USP-NF 2024; printed from @2024 USPC	10.31003/ USPNF_M99830_01_01
USP <11> USP Reference Standards	USP	USP-NF 2024; printed from @2024 USPC	10.31003/ USPNF_M98740_03_01
USP <197> Spectroscopic Identification Tests	USP	USP-NF 2024; printed from @2024 USPC	10.31003/ USPNF_M98947_05_01
USP <281> Residue on Ignition	USP	USP-NF 2024; printed from @2024 USPC	10.31003/ USPNF_M99040_01_01
USP <467> Residual Solvents	USP	USP-NF 2024; printed from @2024 USPC	10.31003/ USPNF_M99226_08_01
USP <621> Chromatography	USP	USP-NF 2024; printed from @2024 USPC	10.31003/ USPNF_M99380_08_01
USP <921> Water Determination	USP	USP-NF 2024; printed from @2024 USPC	10.31003/ USPNF_M99710_02_01
WHO Technical Report Series No. 1010 (2018), Annex 4 — Model certificate of analysis	WHO	TRS 1010 (2018); official 2018-01-01	not recorded
WHO Technical Report Series No. 902 (2002), Annex 10 — Model certificate of analysis	WHO	TRS 902 (2002); official 2002-01-01	not recorded
WHO Technical Report Series No. 957 (2010), Annex 2 — WHO GMP for active pharmaceutical ingredients	WHO	TRS 957 (2010); official 2010-01-01	not recorded
WHO Technical Report Series No. 986 (2014), Annex 2 — WHO GMP for pharmaceutical products: main principles, documentation	WHO	TRS 986 (2014); official 2014-01-01	not recorded

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