Supplier diligence status

Micelle 60 | Version 1.1 | Status checked October 1, 2026

> This factual register distinguishes material available for review from missing evidence. It is not a certificate, released-product specification, manufacturing approval, insurance schedule or statement of CMS eligibility. Any linked Example lot values are synthetic.

Content is under review. See the dated status and readiness register for the latest record and next actions.

Entity, relationship and contact

NW Micelle Therapeutics, Inc. trades as Micelle Therapeutics and is described on the About page as part of the NW PharmaTech group. This pack does not include a corporate filing or infer intellectual-property ownership or manufacturing engagement from the group relationship. Organizational enquiries: team@nwpharmatech.com or +44 20 3693 3791 (UK number; service hours have not been verified). Correspondence: NW Micelle Therapeutics, Inc., c/o NW PharmaTech Ltd, Beaufort Gardens, Knightsbridge, London SW3 1PW, United Kingdom.

Product and evidence boundary

Micelle 60 is a hemp-derived CBD isolate softgel in development. The planned label amount is 60 mg CBD per softgel and 60 softgels per bottle. A planned target or Example lot record does not establish production specifications, legal compliance, product release, clinical suitability, or eligibility for the Substance Access Beneficiary Engagement Incentive. The separate NW PharmaTech 300 mg investigational programme is not evidence for this 60 mg product.

Evidence class	Current status	Boundary
Product description	Planned approach	Development-only label and formulation; final control records pending.
Ingredient certificates A/B	Pending evidence	Status records A and B identify missing source material; no laboratory values are asserted. Actual controlled isolate certificates have not been supplied.
Finished-product certificate	Pending evidence	Only a format model exists. No measured commercial lot or independent lab report.
Example lot certificates	Published Example	UI demonstration with synthetic values; not laboratory reports.
Manufacturing and insurance	Pending evidence	No verified manufacturing approval, production lot or coverage schedule published.

Data handling and accessibility: See the Privacy Notice and accessibility page. Do not send patient information through the briefing route. Manual assistive-technology and Spanish professional reviews remain pending in the dated register.

MICELLE THERAPEUTICS

STATUS REGISTER

Dated evidence register

Source: website readiness register, checked October 1, 2026. Functional owners identify accountable workstreams, not named approvals or completed reviews.

Product definition and planned specification

Published

Supporting record / gap: Product page, isolate-input specification structure and Label draft v1 are published. These are development documents, not final release specifications.
Functional owner: Product development | **Updated:** 2026-10-01
Next action: Confirm the controlled finished-product specification, manufacturer, storage conditions and shelf life before first release.
Open current supporting page

Scientific and legal interpretation

Pending evidence

Supporting record / gap: Federal primary sources are linked from the transition page. No completed independent scientific or legal review is recorded.
Functional owner: Scientific and legal functions | **Updated:** 2026-10-01
Next action: Obtain and record review of claim-bearing and condition-specific content before its publication.
Open current supporting page

Ingredient certificates

Pending evidence

Supporting record / gap: Two sanitized ingredient-evidence status records are available; actual controlled isolate certificates have not been supplied. Example lot PDFs are not laboratory certificates.
Functional owner: Quality function | **Updated:** 2026-10-01
Next action: Obtain verified source certificates and reconcile identities, methods, dates and acceptance limits.
Open current supporting page

Finished-product testing and laboratory

Pending evidence

Supporting record / gap: A finished-product certificate format model is published without measured laboratory results. No ISO/IEC 17025 laboratory engagement or released commercial lot is evidenced.
Functional owner: Quality function | **Updated:** 2026-10-01
Next action: Document laboratory engagement, validate methods and publish genuine released-lot reports when available.
Open current supporting page

Label, lot and traceability

In progress

Supporting record / gap: Label draft v1 and clearly marked Example A, B and C lot records show the proposed public traceability format only.
Functional owner: Product and quality functions | **Updated:** 2026-10-01
Next action: Approve production labels and reconcile actual lot identifiers, certificates, notices and correction history before release.
Open current supporting page

Organization implementation material

Published

Supporting record / gap: Access framework, planned five-stage workflow and organizational briefing materials are available. Publication is not implementation or CMS approval.
Functional owner: Organization partnerships | **Updated:** 2026-10-01
Next action: Work with each participating organization on its own model election, approved plan and controls.
Open current supporting page

Micelle model-participant election

Not applicable

Supporting record / gap: The CMS Substance Access incentive is elected by participating ACO REACH, EOM or LEAD organizations, not by a prospective product supplier. This does not exempt the product or participant from applicable requirements.
Functional owner: Organization partnerships | **Updated:** 2026-10-01
Next action: Each interested organization must assess eligibility, elect the incentive and obtain its own CMS-approved implementation plan.
Open current supporting page

Enquiry transmission

Pending evidence

Supporting record / gap: Email and telephone routes are visible. The website request form is disabled because controlled database and mail transport have not been tested in production.
Functional owner: Operations and privacy functions | **Updated:** 2026-10-01
Next action: Configure storage and delivery, test validation, errors, receipt and privacy handling before enabling web forms.
Open current supporting page

Product concerns and recall arrangements

In progress

Supporting record / gap: The public concern page provides telephone, correspondence and FDA MedWatch routes. A dedicated Micelle adverse-event owner, formal complaint processing and recall procedure are not evidenced.
Functional owner: Safety and quality functions | **Updated:** 2026-10-01
Next action: Document accountable intake, escalation, investigation and recall arrangements before product release.
Open current supporting page

Spanish language review

Pending evidence

Supporting record / gap: Structural Spanish pages exist; professional human translation review has not been documented.
Functional owner: Communications function | **Updated:** 2026-10-01
Next action: Complete and record professional language review before full Spanish publication.
Open current supporting page

Manual accessibility review

Pending evidence

Supporting record / gap: Automated accessibility, responsive and document checks have run; a documented manual assistive-technology review is not available.
Functional owner: Accessibility function | **Updated:** 2026-10-01
Next action: Complete keyboard and assistive-technology review and record remediations before first product release.
Open current supporting page

Insurance and commercial terms

Pending evidence

Supporting record / gap: No verified coverage schedule, policy limits, approved commercial terms or product price are available for publication.
Functional owner: Operations and commercial functions | **Updated:** 2026-10-01
Next action: Verify coverage and controlled price/contract records before publishing them.
Open current supporting page