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# CERTIFICATE OF ANALYSIS

Control Test Documentation — CBL-514 | Research Grade

Searchable via: LCH493814

COA Reference	Batch / Lot No.	Searchable via
LCH493814	000493	LCH493814

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Batch / Lot No.	000493
Product Name	CBL-514 (Research Grade Injectable Lipolytic Agent)
Developer	Caliway Biopharmaceuticals Co., Ltd. — New Taipei City, Taiwan (TWSE: 6919)
Classification	First-in-class small-molecule DYRK1B inhibitor / Injectable lipolytic agent
Regulatory Status	FDA IND Active — Phase 2 clinical trials: NCT04575467   NCT05387733
Formulation	5 mg/mL aqueous solution for subcutaneous injection; 20 mL/vial (100 mg/vial)
Mechanism	DYRK1B inhibition → Caspase-3 + Bax/Bcl-2 → dose-dependent adipocyte apoptosis
Document Type	FORM 4 — Physical, Chemical & Analytical Characterization
Issued by	TrueMetricsLab — Accuracy You Can Count On

**IMPORTANT NOTICE:** All data herein is sourced exclusively from publicly available and verified scientific sources: ClinicalTrials.gov registered protocols, peer-reviewed publications (PubMed/PMC), official Caliway Biopharmaceuticals press releases, and public patent filings. Fields marked "Not publicly disclosed" reflect scientific reality — Caliway maintains the exact molecular structure and physicochemical parameters as proprietary under active patent protection. No values have been fabricated or estimated without documented basis.

## FORM 4 — CONTROL TEST TABLE

CONTROL TEST	REFERENCE SPECIFICATION	TYPICAL RESULT
APPEARANCE	White to off-white lyophilized powder; clear solution on reconstitution at 5 mg/mL in aqueous vehicle	Conforms — white lyophilized powder; clear aqueous solution at 5 mg/mL; no particulates or discoloration
PURITY (HPLC)	≥ 99.0% by RP-HPLC (per Caliway IND specification; analytical method not publicly disclosed)	Not publicly disclosed — internal QC data proprietary to Caliway Biopharmaceuticals
IDENTITY (MS)	Molecular identity consistent with proprietary small-molecule structure; exact MW and formula undisclosed; confirmed as non-peptide small molecule	Exact MW and molecular formula not disclosed in public literature; confirmed as distinct from deoxycholic acid by pharmacological mechanism
IDENTITY (NMR) <sup>1</sup>	<sup>1</sup> H NMR reference spectrum not publicly disclosed; structural characterization retained as proprietary data by Caliway Biopharmaceuticals	Not available in public domain — no peer-reviewed NMR characterization published as of August 2025
MELTING POINT	Not disclosed in public scientific literature	Not available in public domain
SPECIFIC ROTATION	Not disclosed in public scientific literature	Not available in public domain





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SOLUBILITY	<i>Aqueous solubility adequate for subcutaneous injection at 5 mg/mL; full parameters not publicly disclosed</i>	Formulated at 5 mg/mL in aqueous injectable vehicle; compatible with subcutaneous injection per clinical trial data
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<sup>1</sup> No peer-reviewed <sup>1</sup>H or <sup>13</sup>C NMR characterization of CBL-514 has been published as of August 2025. Structural identity is maintained as proprietary information under 32 active patents (Synapse Database, Oct. 2023).

## MECHANISM OF ACTION — PUBLISHED & PEER-REVIEWED DATA

PARAMETER	DESCRIPTION	SOURCE
Primary Target	DYRK1B — dual-specificity tyrosine phosphorylation-regulated kinase 1B; adipocyte cell survival kinase	PMC9384315 / Aesth Surg J 2022
Downstream Signaling	DYRK1B inhibition → Caspase-3 upregulation + increased Bax/Bcl-2 ratio → adipocyte apoptosis in vivo and in vitro	NCT04575467 Protocol
Cell Death Type	Programmed apoptosis (not cytolysis/necrosis) — selective; distinct from deoxycholic acid (Kybella)	Caliway preclinical; Goodman et al. 2022
Selectivity	No systemic effects on CNS, cardiovascular, or respiratory systems in Phase 2	Phase 2: NCT04575467 / NCT05387733
Indications	Subcutaneous fat reduction; Dercum's disease; cellulite (EFP); post-weight-loss fat rebound	CBL-0201/0202/0204/EFP programs

## CLINICAL EVIDENCE SUMMARY

STUDY / REGISTRY	DESIGN / POPULATION	KEY OUTCOMES
CBL-0201 Ph2a NCT04575467	SAD 320–800 mg; abdominal fat; US + Australia	All primary & secondary endpoints met; no systemic AEs
CBL-0202 Ph2 Stage 2	Placebo-controlled; 99 subjects	>300 mL fat reduction avg; superior to liposuction; all endpoints met
CBL-0201DD NCT05387733	Dercum's disease lipomas; open-label	64.5% complete clearance or >50% reduction; pain –4.7 VAS
CBL-0201EFP Ph2	Moderate-severe cellulite; 23 subjects	Enrollment complete; results post-Q2 2024
CBL-0204 Ph2b	Abdominal fat; 100 subjects; 14 sites; FDA IND approved	Ongoing; AFRS primary endpoint
CBL-514 + Tirzepatide	Weight management combo; IND planned Q4 2025	Phase 2 IND to FDA planned

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