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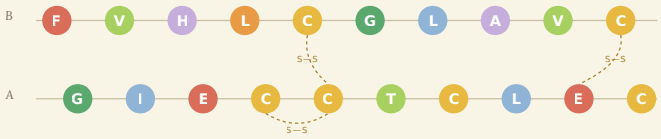
VOLUME ONE · SEVENTY THERAPEUTICS

The Peptide Pocket Guide

A reference to seventy peptide therapeutics, biologics, and mixtures.

INSULIN · THE FIRST PEPTIDE DRUG



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Founder & CEO, Hormonaly.ai

2026 EDITION

The Peptide Pocket Guide

Seventy entries: peptide therapeutics, peptide-derived biologics, and peptide mixtures

A bench-side reference covering the major regulated and unregulated peptides — with GRADE evidence ratings, mechanism, dosing, and regulatory status, one page per therapeutic.

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How to use this guide

This pocket guide covers seventy entries — peptide therapeutics, peptide-derived biologics, peptide mixtures, and one non-peptide comparator (orforglipron, included because it competes directly with established peptide GLP-1 RAs in the same clinical decision). FDA- and EMA-approved drugs sit alongside investigational and compounding-accessible agents commonly encountered in modern practice.

Each entry occupies **one page** and follows a consistent template: the header carries the GRADE rating and therapeutic class; then name and brand names, mechanism of action, indications, dosing, evidence summary, safety, adverse reactions, a clinical caveat, and up to three key references. The body type is one uniform size throughout the book, and wording is kept concise so every peptide fits a single page without a mechanism diagram or amino-acid sequence taking up space.

READING AN ENTRY

The header carries two things:

- **GRADE letter** — A through D, the evidence rating for the listed clinical use (see the GRADE page for definitions). It appears as a coloured pill at the top-left of every entry.
- **Therapeutic class** — the drug class or mechanism family, at the top-right.

Regulatory and trial status (approved, investigational, compounding-accessible, research-only) is stated in plain language in the status line and clinical caveat, rather than as a separate header flag. **Regulatory and trial statuses reflect information available at publication (2026 edition)** and should be re-verified before clinical or legal reliance.

HOW THE BOOK IS ORGANIZED

Entries are grouped by therapeutic class — metabolic, growth-hormone axis, regenerative, dermatology, bone, somatostatin, melanocortin, reproductive, mitochondrial / longevity, neurological, oncology, and gut / antimicrobial — ordered most-evidence-rich first within each class. The back matter contains clinical pearls, a lab and monitoring reference, an adverse-effects and GH-excess primer, the regulatory landscape (including the Lilly v. FDA retatrutide ruling), and a fully claim-mapped bibliography.

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GRADE evidence ratings

Every entry carries a GRADE letter rating derived from the Hormonaly.ai evidence database, which adapts the standard GRADE framework to peptide pharmacology:

GRADE A	**High-quality evidence.** Multiple pivotal RCTs with consistent findings; broadly accepted standard of care for the listed indications.
GRADE B	**Moderate-quality evidence.** Some RCTs and substantial observational data; conclusions reasonably stable but not yet definitive.
GRADE C	**Low-quality evidence.** Limited human data, mostly observational or small trials; mechanistic and animal data may be strong but human translation incomplete.
GRADE D	**Very low-quality evidence.** Mostly preclinical, anecdotal, or industry-driven claims; clinical use carries meaningful uncertainty.

A GRADE C or D rating does not mean a peptide is ineffective — only that the evidence supporting its use does not yet meet the standard of approved therapeutics.

Editorial Standards & Evidence Philosophy

This guide is a clinical reference, not a recommendation or endorsement. Inclusion does not imply that a peptide is approved, recommended for practice, appropriate for any individual patient, or standard-of-care.

EVIDENCE-FIRST, BY GRADE

Every entry is rated A–D by GRADE methodology, which reflects the strength of *clinical evidence* — not molecular plausibility, popularity, compounding availability, or fashion. An FDA-approved drug with one good RCT may rate lower than an investigational compound with a compelling mechanism; both are contextualized accurately. GRADE A does not mean "use this"; GRADE D does not mean "do not." Clinical decisions require GRADE *plus* regulatory status, contraindications, patient preference, and judgment.

WHY INVESTIGATIONAL AND GRAY-MARKET COMPOUNDS ARE INCLUDED

The guide spans approved drugs, investigational peptides in active trials, 503A-compounded agents, and research-only substances seen in gray-market settings. Inclusion is not endorsement — it reflects clinical reality: agents like BPC-157, TB-500, and Dihexa are used off-label without approval, and clinicians need their preclinical evidence, known harms, and evidentiary gaps to manage patients who use them.

FOUR TIERS, KEPT SEPARATE

Each entry separates what is known from what is hoped, in plain language:

- **Established evidence** — FDA approval, positive Phase 3 RCTs, meta-analysis consensus.
- **Emerging evidence** — Phase 2 human data, small observational studies, mechanism validated in humans.
- **Clinical culture** — usage in anti-aging clinics, bodybuilding, and biohacker communities; documented, never conflated with evidence.
- **Mechanistic plausibility** — in-vitro activity and animal models; not clinical evidence until translated to human efficacy and safety.

A peptide supported by **animal or preclinical data only** has no human efficacy evidence, regardless of GRADE rating or mechanistic appeal.

CONTEXT WITHOUT ENDORSEMENT

Descriptions like "widely used in anti-aging clinics" or "common microdosing protocol" are observations, not endorsements. For Grade C/D, "Research only," "Not approved," or "Gray market" entries, the clinical caveat states plainly whether *use carries unjustifiable risk* or *no human efficacy trials support this use* — factual statements, not hedges. A clinician meeting a patient on an off-label peptide should leave each entry knowing what the culture believes, what the evidence shows, and where the gaps are.

Peptide Fundamentals

Definitions, classification, manufacturing, regulatory grades, and how to read a Certificate of Analysis — the foundation behind every entry in this guide.

WHAT IS A PEPTIDE?

A peptide is a short chain of amino acids linked by peptide bonds. The biochemical distinction from a protein is conventionally one of length: peptides are typically **2–50 residues**; proteins are longer, fold into stable tertiary structures, and usually exceed 10 kDa. The boundary is genuinely fuzzy — insulin (51 residues, two disulfide-linked chains) crosses the threshold by one residue and is variably classified as a polypeptide or a small protein. We list it as a 51-residue exception under the polypeptide class.

THE FDA'S REGULATORY LINE

The biochemical definition above is descriptive; the FDA's definition is operational and consequential. Under the BPCIA (2009) as amended by the Further Consolidated Appropriations Act (2020), the agency draws the peptide/protein line at **40 alpha amino acids**:

- **≤ 40 alpha amino acids** — peptide, regulated as a drug under the FD&C Act (NDA pathway).
- **41–99 alpha amino acids, chemically synthesized** — "chemically synthesized polypeptide", still regulated as a drug under the FD&C Act.
- **> 40 alpha amino acids, not chemically synthesized** (recombinant or extracted) — protein, regulated as a biological product under the PHS Act (BLA pathway).
- **≥ 100 alpha amino acids** — always a protein/biologic regardless of synthesis route.

The classification matters: biologics face additional statutory protections (12-year exclusivity, biosimilar pathway), more rigorous CMC review, and are largely ineligible for 503A pharmacy compounding. Drugs follow the smaller-molecule NDA pathway with shorter exclusivity and a more permissive compounding regime.

Classification & chain length

CLASSIFICATION BY CHAIN LENGTH

CLASS	RESIDUES	EXAMPLES IN THIS GUIDE
Dipeptides & tripeptides	2–3	GHK (3), KPV (3)
Oligopeptides	4–20	Oxytocin (9), GnRH (10), Octreotide (8), Kisspeptin-10 (10), BPC-157 (15)
Polypeptides	20–50	GLP-1 analogues (30–31), Glucagon (29), Calcitonin (32), Tesamorelin (44)
Small proteins	≥ 51	Insulin (51, boundary case), GH (191), Follistatin (315), Cerebrolysin (mixture)

WHY CHAIN LENGTH MATTERS

Residue count drives pharmacology and, near 40 residues, regulatory status:

LENGTH RANGE	PHARMACOLOGY, SYNTHESIS, AND REGULATION
≤ 10 residues	Solid-phase synthesis. Half-life often minutes (oxytocin ≈ 3 min); rapidly cleared by peptidases, needing frequent or sustained-release dosing.
10–30 residues	Solid-phase synthesis still cost-effective. Half-life extended by D-amino-acid substitution (octreotide), N-methylation, cyclization, or PEGylation.
> 30 residues	Recombinant production becomes attractive. Half-life extended by fatty-acid acylation (semaglutide t½ ~7 days), Fc-fusion (dulaglutide), or depot (lanreotide).

A NOTE ON BIOREGULATORS

One *functional* class cuts across chain length: the **bioregulators** (Khavinson "cytomedines") — very short di-/tripeptides claimed to regulate tissue-specific genes. Examples here include **Epitalon** and **Pinealon** (with Cortagen and Vesugen). Defined by mechanism rather than structure, the category rests on one Russian group without independent Western replication — as the GRADE C/D ratings reflect.

Routes of administration

Route selection is determined by molecular weight, gut stability, target tissue, and the half-life the formulation needs to achieve.

ROUTE	BIOAVAILABILITY	CLINICAL REALITY
Subcutaneous (SC)	~70–90%	The default for most peptide drugs. Self-administered with a 29–31 gauge insulin syringe; rotate injection sites to avoid lipohypertrophy.
Intramuscular (IM)	~75–95%	Faster onset than SC, more painful. Used for depot formulations (leuprolide, lanreotide), emergency glucagon, and a few clinic-administered peptides.
Intravenous (IV)	100%	Clinical setting only — insulin for DKA, glucagon for hypoglycemia, octreotide infusions for variceal bleeding.
Oral	< 1% native	Most peptides are destroyed in the gut. Successful oral peptides either use absorption enhancers (SNAC for oral semaglutide) or are not meant to be absorbed (linaclotide acts in the gut lumen).
Intranasal	~5–30%	Useful for calcitonin, desmopressin, oxytocin, Selank, Semax. Direct CNS access via the olfactory nerve makes intranasal attractive for neuropeptides.
Sublingual / buccal	Variable	Bypasses first-pass metabolism. Limited by peptide molecular weight and lipophilicity; mostly research-grade preparations.
Topical	Local only	Skin barrier limits systemic absorption. GHK-Cu cosmetics, BPC-157 ointments. Local effects only — claims of systemic activity from topical application are usually unsupported.

Reconstitution & storage

RECONSTITUTION

Most injectable peptides ship as lyophilized (freeze-dried) powder that must be reconstituted before use. The mechanics matter — incorrect technique can denature 20–40% of the peptide before the first dose is drawn.

> **Reconstitution calculator:** visit **www.hormonaly.ai/calculator** to compute reconstitution volumes, syringe units (U-100), and dose conversions for any peptide vial — useful for verifying that the volume + concentration combination gives a clean dose draw on the syringe scale you have.

- **Solvent.** Bacteriostatic water for injection (BWFI, 0.9% benzyl alcohol) for multi-dose vials; sterile water for single-use only.
- **Technique.** Inject solvent slowly down the inside wall of the vial. *Do not* aim the stream at the powder. Swirl gently — do not shake. Shaking creates foam and can denature the peptide.
- **Concentration.** Pick a reconstitution volume that gives convenient dosing. A 5 mg vial reconstituted in 2.5 mL BWFI yields 2 mg/mL; a 250 µg dose is then 0.125 mL, or 12.5 units on a U-100 insulin syringe.
- **Pre-dose inspection.** The reconstituted solution should be clear and colourless. Any cloudiness, particulate matter, or yellowing indicates the peptide has degraded — discard and start a new vial.

STORAGE RULES

- **Lyophilized vial:** refrigerate at 2–8 °C. Frozen (−20 °C) for long-term storage. Many peptides tolerate room temperature for weeks if dry and well-sealed.
- **Reconstituted vial (BWFI):** refrigerate at 2–8 °C; use within ~28 days. The benzyl alcohol provides bacteriostatic protection but does not prevent peptide degradation.
- **Reconstituted vial (sterile water):** refrigerate and use within 24–48 hours. No preservative against bacterial growth.
- **Light and heat:** store in original container, away from direct light. Avoid leaving in a hot car, a window, or near radiators. Cold-chain shipping with ice packs preserves the molecule; ambient overnight shipping in summer can degrade it noticeably.
- **Travel:** for travel, transfer vials to an insulated bag with refrigerated ice packs. A 24-hour ambient exposure is generally tolerated; longer requires re-evaluation.

Stability & degradation

Peptides are intrinsically unstable molecules. Knowing the degradation pathways tells you how to store, when to discard, and what to look for in the vial.

THE FIVE DEGRADATION PATHWAYS

- **Oxidation** of methionine, cysteine, and tryptophan residues. Mitigated by antioxidants and oxygen-free packaging.
- **Hydrolysis** of peptide bonds in solution — accelerated by extreme pH, heat, and time. Lyophilized form is dramatically more stable.
- **Deamidation** of asparagine and glutamine to acidic forms — a major cause of slow potency loss in stored solutions, occurring even refrigerated.
- **Aggregation** — peptides dimerize, oligomerize, or precipitate at high concentration. Surfactants and gentle handling help.
- **Adsorption** — peptides stick to glass and plastic surfaces, silently depleting low-concentration solutions over weeks.

VISUAL SIGNS OF DEGRADED PRODUCT

Cloudy or particulate solution after reconstitution · yellowing of the powder or solution · loss of clinical effect at a previously effective dose · precipitate that fails to redissolve on gentle warming · off-smell from the vial (rare but a hard signal).

PREFILLED PEN STABILITY

Prefilled pens are factory-formulated with preservatives and tested under cGMP. The manufacturer-validated in-use stability of the major GLP-1 pens, per FDA-approved labelling:

- **Ozempic and Wegovy (semaglutide):** 56 days at controlled room temperature (15–30 °C / 59–86 °F) after first use; refrigeration permitted but does not extend the window.
- **Mounjaro KwikPen (tirzepatide, multi-dose):** 30 days at room temperature once in use. Single-dose Mounjaro and Zepbound pens: 21-day room-temperature limit before use, then single injection and disposal.
- **Compounded semaglutide and tirzepatide:** pharmacy-assigned beyond-use dates (BUDs) governed by USP <797>, typically shorter than the labelled in-use windows for branded pens.
- **Gray-market pens and vials:** sold without manufacturer stability validation, cGMP oversight, or independent testing. Stability is undocumented and unverifiable; the most conservative of the above limits should be presumed at best.

Manufacturing

SOLID-PHASE PEPTIDE SYNTHESIS (SPPS)

Invented by Bruce Merrifield in 1963 (Nobel Prize 1984). The peptide is built one amino acid at a time on a polymer resin. Each cycle deprotects the chain, couples the next Fmoc-protected amino acid, and washes — typically 30–60 minutes per residue. After assembly, the peptide is cleaved from resin, side-chains deprotected, and the crude product purified by reverse-phase HPLC.

Yields fall geometrically: 98% per coupling step × 50 cycles ≈ 36% overall yield. The practical ceiling for routine pharmaceutical manufacture is ~50 residues. Beyond that, recombinant approaches become more economical.

HALF-LIFE EXTENSION STRATEGIES

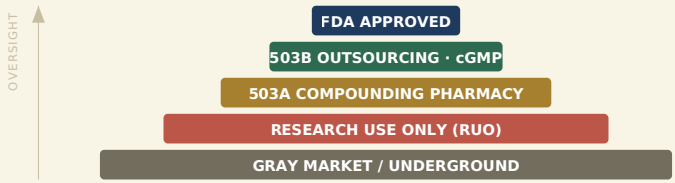
STRATEGY	EXAMPLE	t½
Fatty-acid acylation	Semaglutide (C18 diacid)	**~7 days**
Fc fusion	Dulaglutide (IgG4 Fc)	**~5 days**
Depot formulation	Lanreotide autogel	**~28 days**

RECOMBINANT DNA TECHNOLOGY

For longer peptides and proteins. The peptide-coding DNA is inserted into a host organism — *E. coli* (insulin), *Pichia pastoris* (some calcitonin), or mammalian CHO cells (Fc-fusion drugs). Used for insulin, growth hormone, and most GLP-1 analogues; the recombinant backbone is then chemically conjugated with fatty acids or other half-life extenders.

Regulatory grades

The same molecule can exist in five radically different regulatory states. Understanding the hierarchy is essential before prescribing or recommending any peptide.



FDA — **FDA-approved (or equivalent).** Full Phase 3 trials completed; approved label, indications, dosing, contraindications. Manufactured to cGMP; post-market surveillance active; insurance reimbursable. Examples: insulin, semaglutide, tesamorelin, leuprolide, octreotide. About half the peptides in this guide.

503B — **503B outsourcing facility.** Compounded under cGMP for office-use stock. Registered with the FDA and inspected. The compound itself is not FDA-approved — only the manufacturing standard is. Used for shortages, off-label needs, or patient-specific requirements. Quality bar is high; documentation is comprehensive.

503A — **503A compounding pharmacy.** State-licensed pharmacy compounding for a specific patient prescription; lower bar than 503B. Must use bulk substances on the FDA compounding list, a USP/NF monograph, or an approved drug product. In September 2023 the **FDA 503A Category 2 list** identified certain bulk substances — including several peptides (BPC-157, TB-500, melanotan II, and others) — as presenting significant safety risks for compounding, pending PCAC review.

RUO — **Research Use Only.** Sold by chemical-supply companies (Bachem, Sigma, Anaspec, others) labeled "for research only — not for human consumption." Purity varies from pharmaceutical-grade (Bachem) to unverified (smaller suppliers). Outside pharmaceutical regulation. The disclaimer provides *no* legal protection — the FDA regulates based on inferred intended use.

GRAY — **Gray market / underground.** "Peptide research" websites with deliberate ambiguity. Quality ranges from acceptable to dangerous. May contain wrong peptides, sub-potent material, bacterial endotoxin, residual TFA, or heavy metals. No regulatory oversight. Independent testing has found peptide content from 60–110% of stated amount.

Reading a Certificate of Analysis

A COA is the supplier's quality attestation. A serious COA tells you the molecule is what it claims, how pure it is, what counter-ion it carries, and whether it is safe to inject.

IDENTITY

Mass spectrometry confirms the molecular weight matches the expected peptide. The theoretical monoisotopic mass should be reported alongside the observed mass. Deviations > 1 Da indicate sequence problems.

PURITY

HPLC chromatogram with retention time and peak integration. Pharmaceutical grade is ≥ 98%; RUO is typically 95–99%; below 95% is significant impurity load.

WATER CONTENT

Karl Fischer titration. Lyophilized peptides typically retain 3–10% residual moisture. Higher water content reduces stability.

COUNTER-ION (TFA / ACETATE)

Synthetic peptides ship as TFA or acetate salts. A 5 mg "peptide" vial may contain 4.2 mg net peptide after subtracting the counter-ion. Pharmaceutical preparations always report this.

ENDOTOXIN (LAL)

For injectable use, endotoxin must be < 0.5 EU/mg by Limulus Amebocyte Lysate assay. RUO peptides frequently have no endotoxin testing — a hard contraindication to injection.

MICROBIAL CONTAMINATION

Total aerobic count, yeast and mold count, absence of pathogens. Critical for any injectable preparation.

HEAVY METALS

Lead, cadmium, mercury, arsenic by ICP-MS. Within ICH Q3D limits.

RESIDUAL SOLVENTS

DMF, DMSO, methanol from SPPS. Within ICH Q3C limits.

Quality red flags

WHAT YOU SHOULD NOT SEE ON A SERIOUS COA

- A bare claim of "purity > 99%" with no chromatogram or supporting data.
- No mass spectrum, or a spectrum without a labelled expected mass.
- No batch or lot number; no manufacture date.
- A COA dated more than 12 months before purchase — peptides degrade in storage.
- Generic identical-looking COAs across different products from the same vendor.
- No endotoxin or microbial data on a product marketed for injection.
- A COA referring to a "typical" batch rather than the specific batch shipped.

Practical heuristic. Legitimate peptide suppliers attach a lot-specific COA to every vial sold and respond to documentation requests within hours. If you must request a COA and the response is delayed, generic, or never arrives, the product is probably not what it claims to be — and certainly not safe to inject.

FOR 503A/503B COMPOUNDED PEPTIDES

Compounding pharmacies should provide a COA documenting identity, purity, sterility, and endotoxin. Ask which testing laboratory ran the analysis, the date of testing, the USP-797 / 800 compliance status of the facility, and the lot number that links the COA to the vial in hand. A pharmacy that cannot produce this documentation on request is not operating to the standards their license requires.

FOR RESEARCH-USE-ONLY PEPTIDES

If the product is being used outside its labelled purpose, the standard of evidence shifts to the user. At minimum: confirm identity by independent mass spectrometry, confirm purity by independent HPLC, run an endotoxin test before any injectable use, and document the source, lot, and date for every dose. None of this turns RUO into pharmaceutical grade, but it surfaces problems before they reach a patient.