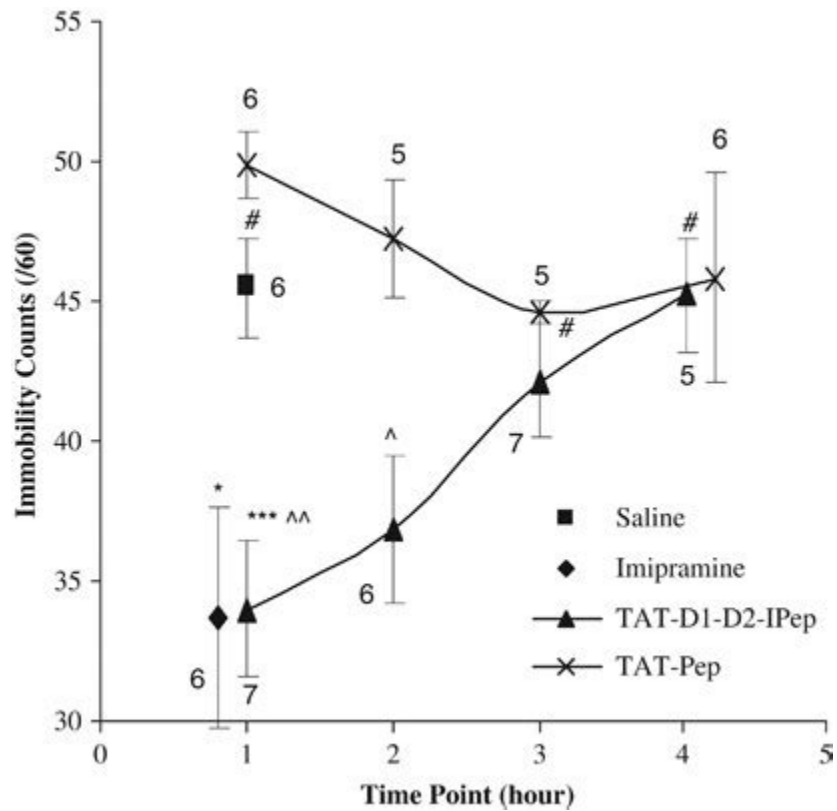


The A1R-CT peptide the scientists developed, which can be administered through a nasal spray, holds promise for tamping down the uncontrolled electrical activity that is common after traumatic .



 VISIT OUR SHOP 

Intranasal Delivery of a Peptide with Antidepressant-Like Effect



In an open-label single-dose study of diazepam nasal spray with DDM in 57 patients experiencing seizures under seizure and nonseizure conditions, 3.5% of patients reported nasal discomfort. In a 6-month safety study of IN sumatriptan 10 mg with DDM, 51 of 167 (30.5%) patients experienced nasal burning or stinging at least once, usually mild.

Co-administration of low doses of intranasal PT-141, a . - PubMed



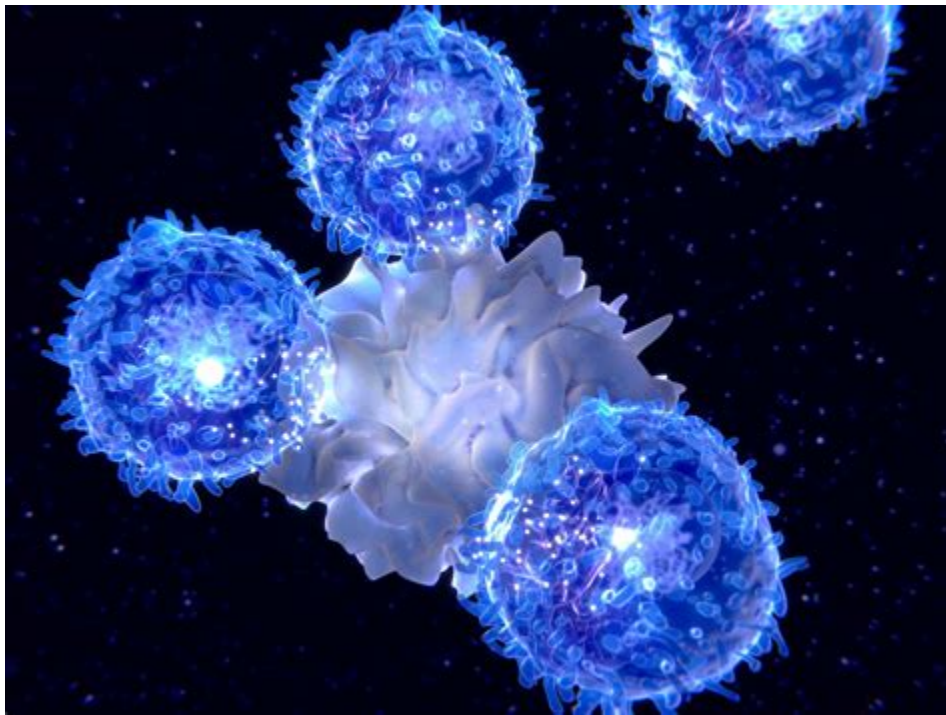
The nasal plexus is actually a very viable route of administration for molecules that are small enough and lipophilic. Glucagon, for example, given intranasally produces systemic bioavailability near that of intravenous injection and is generally superior to subcutaneous injections. Since GHRP/GHRH peptides act on the brain, it would make more .

Biomaterials for intranasal and inhaled vaccine delivery



05 May 2002 Peptides make lousy drugs, especially for the brain. When taken as a pill or by infusion, they either bounce off the blood-brain barrier, or get degraded within minutes. Worse, those peptides that might do some good in brain diseases often have potent, hormone-like side effects elsewhere in the body. Enter the nose (literally).

Sniff This: Therapeutic Peptides Through the Nose? | ALZFORUM



The CriticalSorb absorption vehicle and hGH nasal formulations were well tolerated, with any local nasal irritation being mild and transient. As a nasal spray, the nasal administration of hGH has the advantage of not having side effects associated with hGH injections, including pain, injection site

reactions, inflammation, bruising, and .

Scientific Considerations for Generic Synthetic Salmon Calcitonin Nasal .

The AAPS Journal, Vol. 13, No. 1, March 2011 (© 2010)
DOI: 10.1208/s12248-010-9242-9

Regulatory Note

Scientific Considerations for Generic Synthetic Salmon Calcitonin Nasal Spray Products

Sau L. Lee,¹ Lawrence X. Yu,^{1,3} Bing Cai,¹ Gibbs R. Johnsons,² Amy S. Rosenberg,² Barry W. Cherney,² Wei Guo,² and Andre S. Raw¹

Received 27 August 2010; accepted 19 October 2010; published online 30 October 2010

Abstract. Under the Abbreviated New Drug Application pathway, a proposed generic salmon calcitonin nasal spray is required to demonstrate pharmaceutical equivalence and bioequivalence to the brand-name counterpart or the reference listed drug. This review discusses two important aspects of pharmaceutical equivalence for this synthetic peptide nasal spray product. The first aspect is drug substance sameness, in which a proposed generic salmon calcitonin product is required to demonstrate that it contains the same active ingredient as that in the brand-name counterpart. The second aspect is comparability in product- and process-related factors that may influence immunogenicity (i.e., peptide-related impurities, aggregates, formulation, and leachates from the container/closure system). The comparability of these factors helps to ensure the product safety, particularly with respect to immunogenicity. This review also highlights the key features of *in vitro* and/or *in vivo* studies for establishing bioequivalence for a solution nasal spray containing a systemically acting salmon calcitonin.

KEY WORDS: bioequivalence; generic; immunogenicity; nasal spray; pharmaceutical equivalence; salmon calcitonin.

INTRODUCTION

Calcitonin is a peptide hormone produced by the parafollicular cells of the thyroid in mammals and by the ultimobranchial gland of birds and fish (1). This peptide has an inhibiting effect on the activity of osteoclasts and reduces the resorption of bone salts into the blood. Calcitonin has been used for the treatment of osteoporosis, the management of Paget's disease, and the initial treatment of hypercalcemia (2,3). Two calcitonin peptide drugs have been approved in the USA. They are salmon calcitonin and human calcitonin. Salmon calcitonin has a 50-fold greater potency than human calcitonin and has much less propensity for aggregation than human calcitonin (4). Therefore, salmon calcitonin is the favored therapeutic and is presently the only marketed form of this peptide drug in the USA. It is available as an injectable product and a nasal spray (5).

Whether produced by synthetic methods or by recombinant DNA technology, salmon calcitonin is a 32 amino acid

residue peptide of known primary structure (amino acid sequence) and does not exhibit complex higher-order structures in aqueous solutions. The molecular structure of this peptide drug can be characterized and verified by a variety of analytical technologies. Thus, it is possible for a drug manufacturer to produce a salmon calcitonin drug product containing an active ingredient that is the same as the active ingredient in a brand-name counterpart. For generic versions of a synthetic salmon calcitonin drug product, although the active ingredient may be identical, product- and process-related factors, including peptide-related impurities, aggregates, formulation variables such as excipients, and leachates from the container/closure system, may differ and affect product safety, particularly in the area of immunogenicity. Therefore, the development of a generic synthetic salmon calcitonin drug product warrants, among other scientific considerations, deliberations of the effect of these product- and process-related factors on drug product safety and efficacy.

This review discusses a scientific evaluation of generic versions of a synthetic salmon calcitonin nasal spray drug product. We provide background information on the Food and Drug Administration (FDA) requirements for generic drug approvals, followed by a discussion of the scientific issues unique to a generic synthetic salmon calcitonin nasal spray drug product. In particular, we emphasize the scientific data that are critical for drug substance (active pharmaceutical ingredient) sameness, comparability of product- and process-related factors known to influence immunogenicity, and bioequivalence for this peptide drug

The opinions expressed in this review by the authors do not necessarily reflect the views or policies of the Food and Drug Administration (FDA).

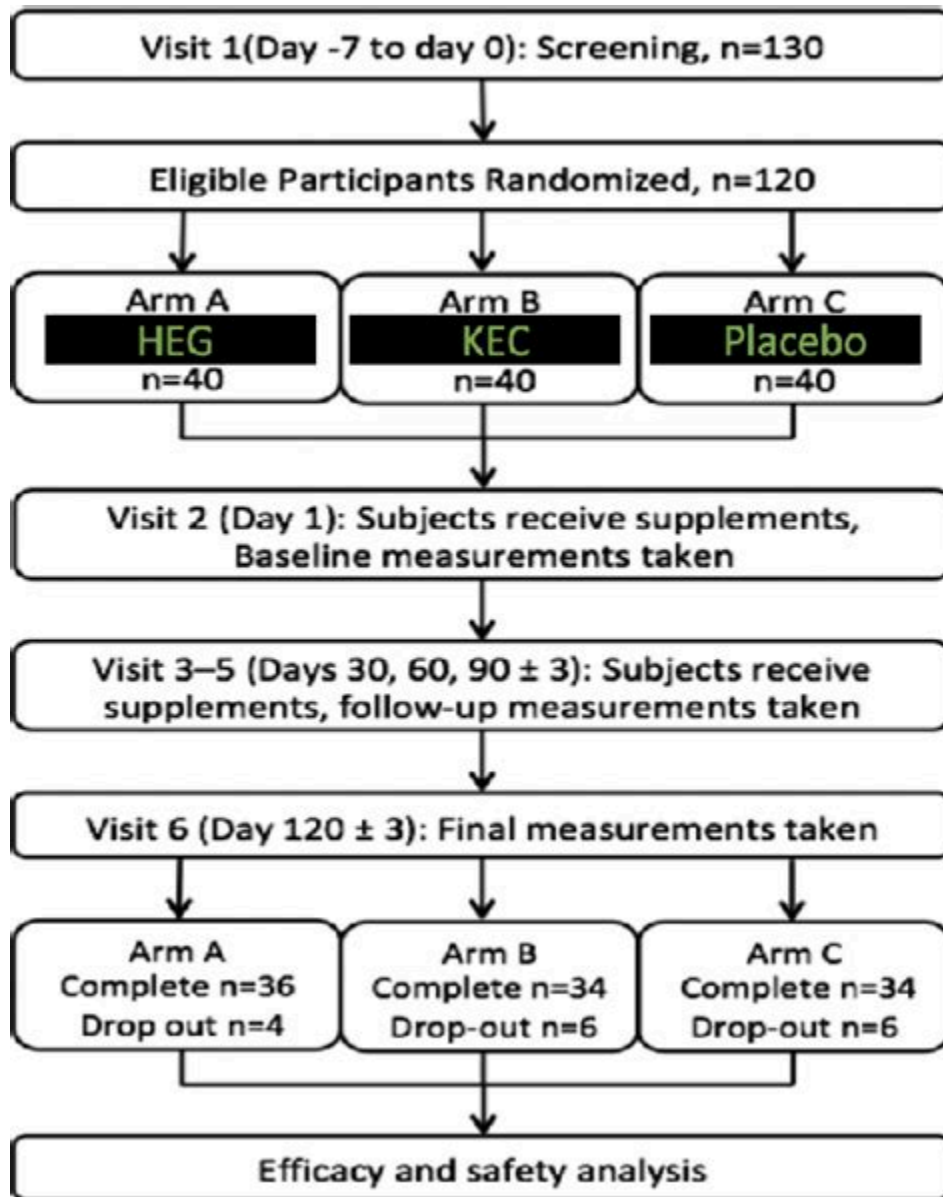
¹Office of Generic Drugs, Center for Drug Evaluation and Research, US Food and Drug Administration, 7519 Standish Place, Rockville, Maryland 20855, USA.

²Office of Biotechnology Products, Center for Drug Evaluation and Research, US Food and Drug Administration, 9000 Rockville Pike, Bethesda, Maryland 20892, USA.

³To whom correspondence should be addressed. (e-mail: lawrence.yu@fda.hhs.gov)

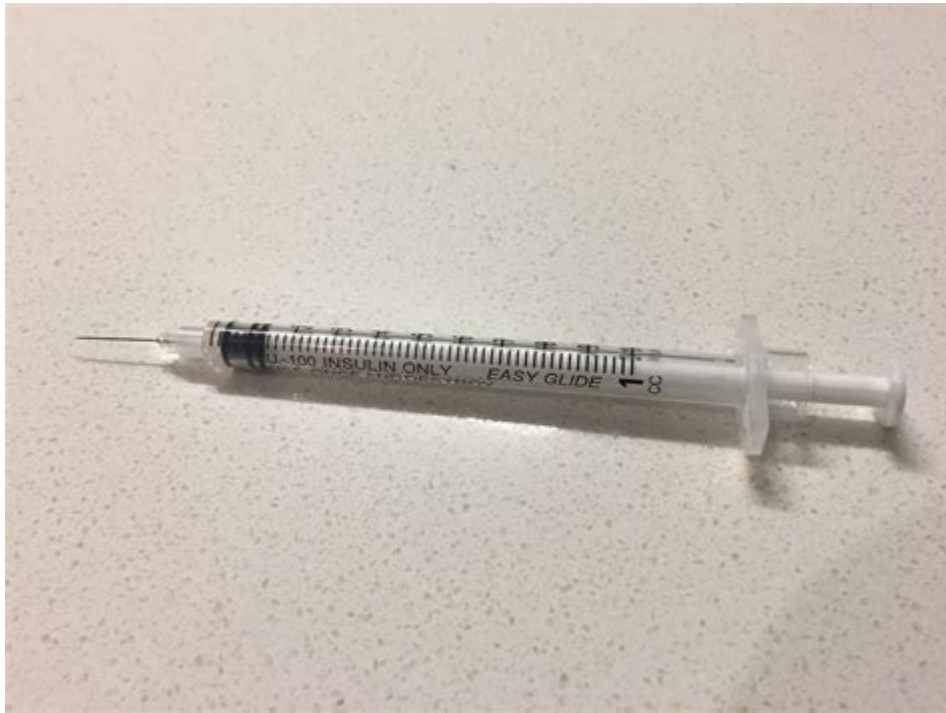
Peptides, Cyclic alpha-MSH bremelanotide Sildenafil Citrate Co-administration of intranasal PT-141 and a phosphodiesterase type 5 inhibitor may constitute a treatment alternative for patients in whom higher doses of a single therapy are not effective or well tolerated.

Double-blind, placebo-controlled evaluation of the safety .



The research community has known for many years that nasal spray painkillers can be a good alternative. In Norway, a standard pre-dosed nasal spray is only intended and approved for adults, but .

How peptides made me feel like 25 again | by High Dose Wisdom - Medium



This article reviews nasal structure and function in the light of intranasal pharmacotherapy. The nose provides an accessible, fast route for local treatment of nose and sinus diseases, with lower doses than are necessary systemically and few adverse effects. It can also be used for other medications as it has sufficient surface area protected from local damage by mucociliary clearance .

Peptide delivered by nasal spray can reduce seizure . - ScienceDaily



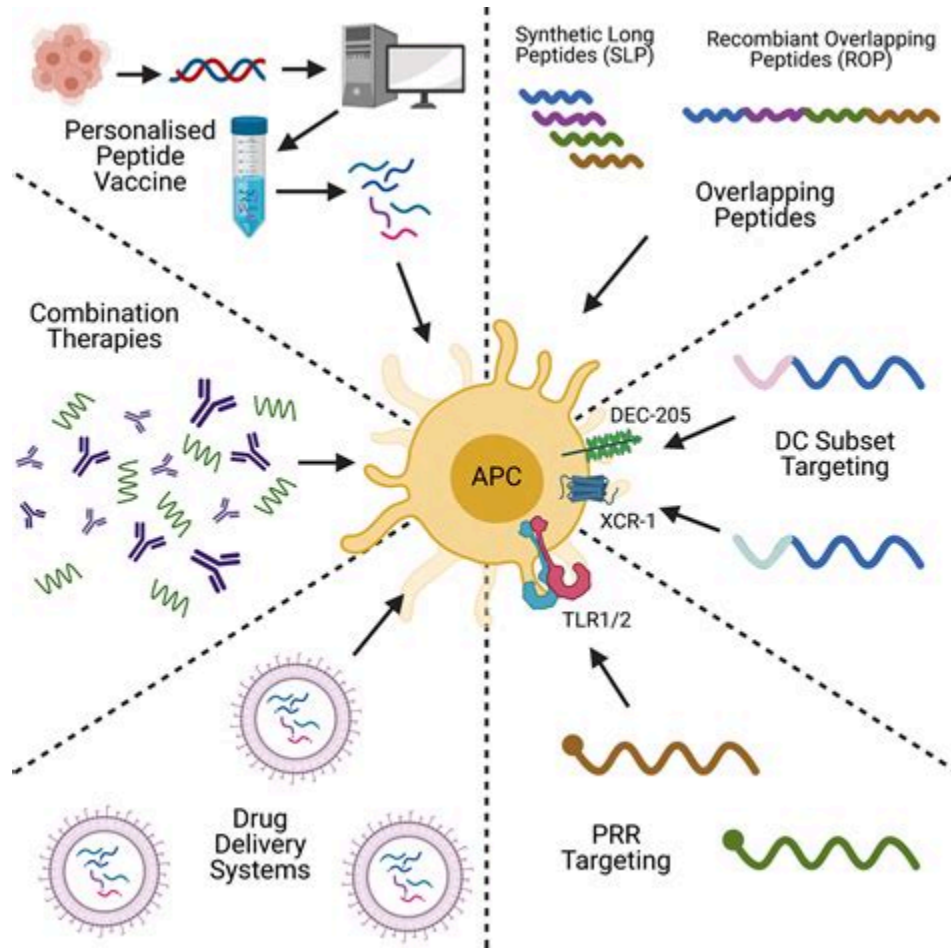
Vyleesi; Descriptions. But at least GH secretagogues seem to be more cost-effective SQ than intranasal, so maybe just stick to injections in these kind of peptides. Sep 16, 2022 · The nasal spray is inhaled through the nostrils, and the mucous membrane of the nose is thin and has many blood vessels allowing spray to penetrate the system.

Sermorelin Therapy Benefits, Uses, Side Effects, Risks, More - Healthline



We compared immobility behavior in animals that received IN injections of the D1-D2 interfering peptide or TAT-Pep (1.67 nmol/g) at 1, 2, 3, . A third possibility is that the D1-D2 interfering peptide is absorbed into the systemic circulation through the nasal capillary bed, as the nasal cavity contains extensive capillaries and .

Overview of intranasally delivered peptides: key considerations for .



Injections are superior. The pharmacists that I've spoken to have said that the nasal is made for people that don't like injections but it doesn't really work. Fluid_Support1292 • 2 yr. ago • Edited 2 yr. ago

Pt141 Nasal Spray Vs Injection Evaluating The Best Administration .



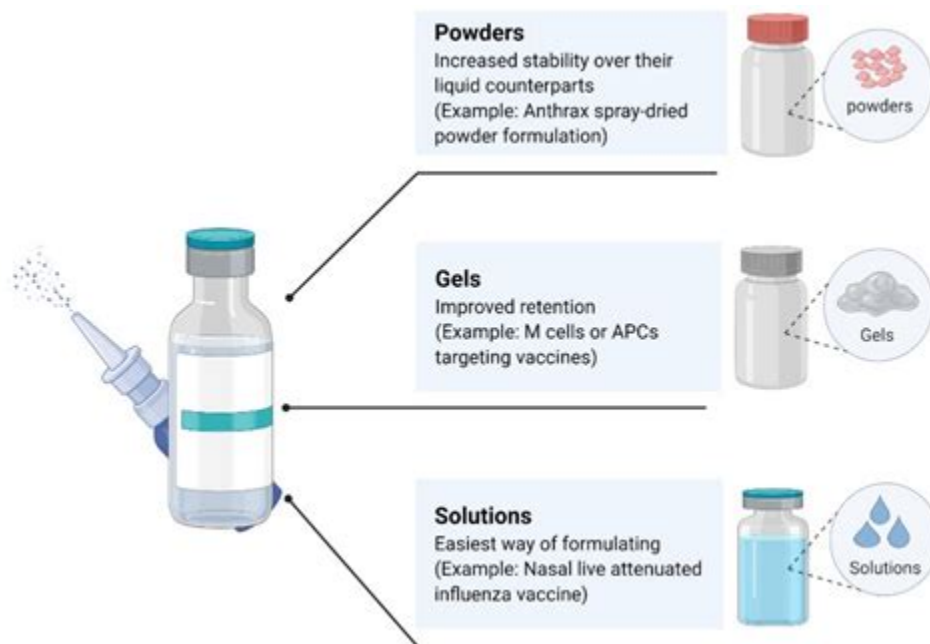
Abstract Intranasal drug delivery has attracted increasing attention as a noninvasive route of administration for therapeutic proteins and peptides. The delivery of therapeutic peptides through the nasal route provides an alternative to intravenous or subcutaneous injections.

Nasal Spray VS Injecting: Ipamorelin and CJC : r/Peptides - Reddit



Abstract. In recent years ample studies have reported that intranasal administration of the neuropeptide oxytocin can facilitate social motivation and cognition in healthy and clinical populations .

Different Methods and Formulations of Drugs and Vaccines for Nasal .



1. 1. Mucosal Environment of Nasal Cavity. The nasal mucosa consists of the epithelium, basement membrane, and lamina propria. There are four main cell types in nasal mucosa: basal cells, goblet cells, ciliated columnar cells, and non-ciliated columnar cells []. Basal cells are found only on the basement membrane, and the other three cell types are found on the whole apical epithelial surface .



99 FARMS

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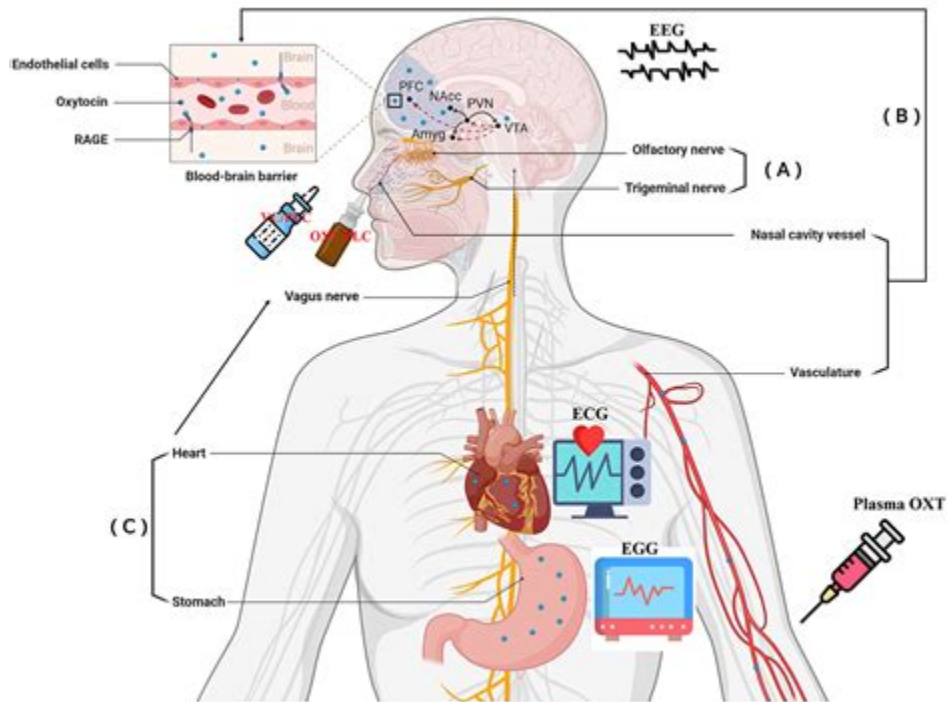
5mg \geq 99% pure
Research use only

LOT: 0216-61

EXP: 2022/08/24

Delivery of vaccines by nasal sprays may enable more robust, protective mucosal immune responses against infectious diseases, such as COVID-19, compared with intramuscular injection. In this.

Sniffing oxytocin: Nose to brain or nose to blood?



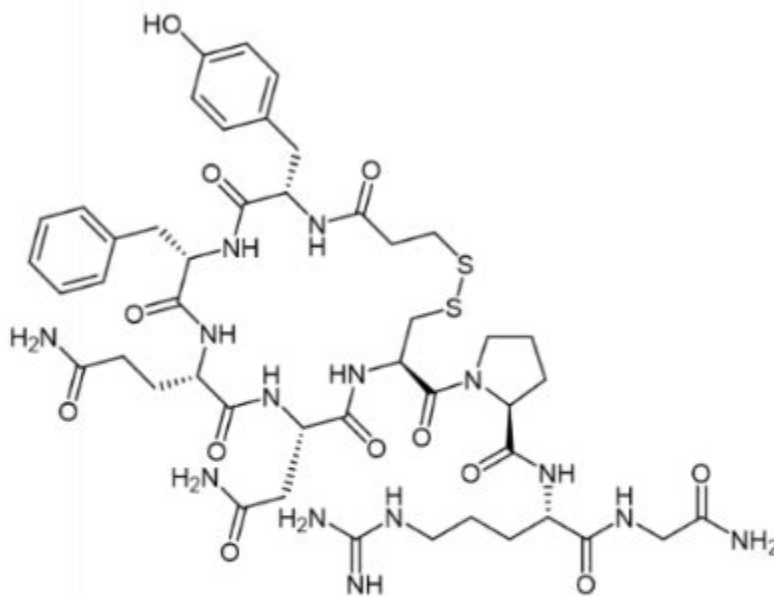
TB-500 What Does TB-500 Do? While TB4 has been more heavily researched, researchers and clinicians consider TB-500 to be functionally identical. As such, studies on the therapeutic benefits of TB4.

Nasal spray a better alternative to injections for many children



10. 1080/17425247. 2018. 1517742 Bioavailability; formulation; intranasal drug delivery; molecular weight; nasal saturation capacity; peptides; pharmacokinetics; solubility. Administration, Intranasal Biological Availability Drug Development / methods* Peptides / administration & dosage* Pharmaceutical Preparations / administration & dosage

Drug development of intranasally delivered peptides - PubMed



desmopressin

Chemical Formula: $C_{46}H_{64}N_{14}O_{12}S_2$

Molecular Weight: 1069.22

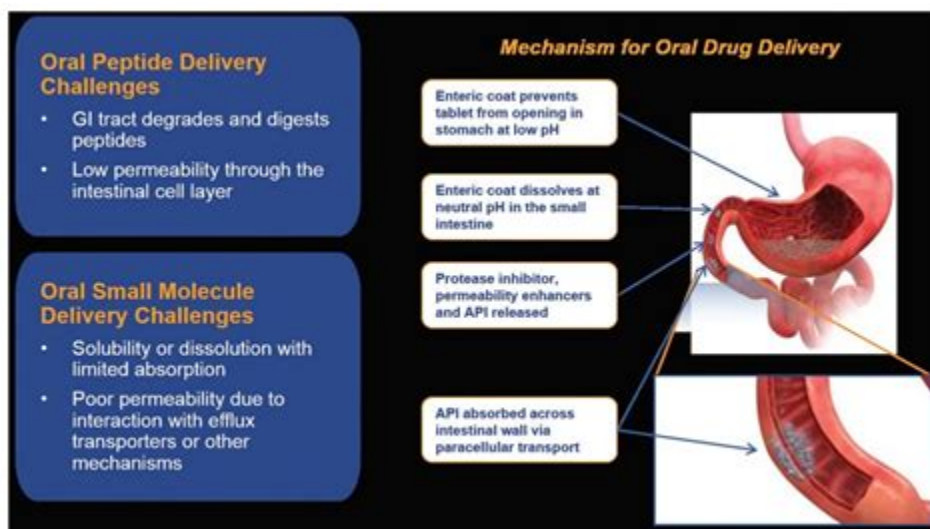
In the Phase 2A Study, PT-141 (or matching placebo) was administered as an i. n. spray at doses of 7 or 20 mg approximately 1 h after breakfast, and patients were kept under observation until 12 h .

Peptide Nasay Sprays? : r/Peptides - Reddit



This review presents a scientific evaluation of generic versions of a synthetic salmon calcitonin nasal spray drug product. In the context of an ANDA, a proposed generic salmon calcitonin nasal spray is required to be pharmaceutically equivalent to the RLD. Two key aspects of pharmaceutical equivalence are discussed: the demonstration of drug .

Advances in oral peptide therapeutics | Nature Reviews Drug Discovery



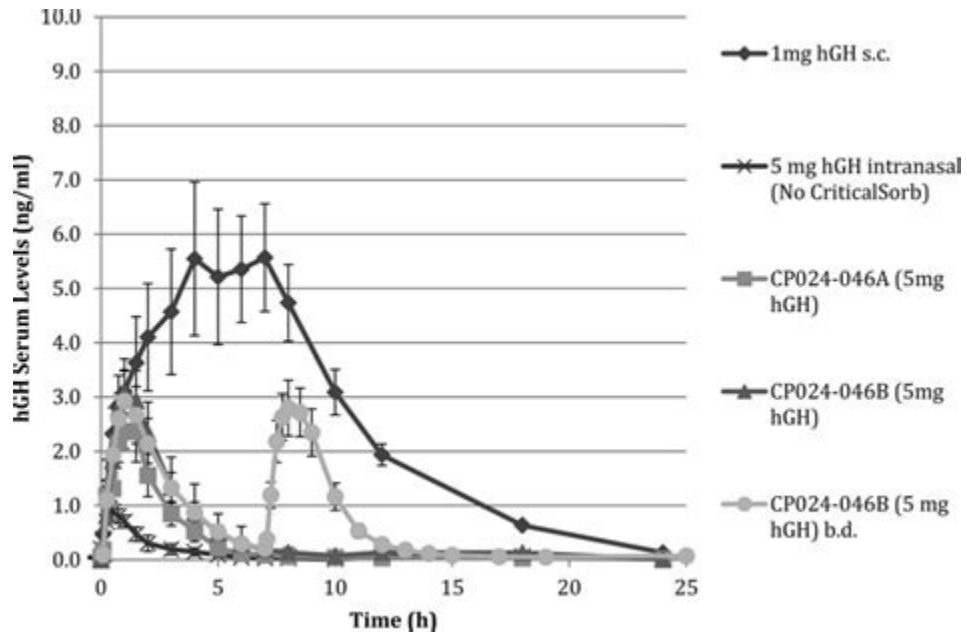
Salmon calcitonin shares 50% amino acid identity with human calcitonin, yet it is more biologically potent in humans in vivo and was approved as a parenteral injection for the treatment of .

Understanding Injection Administration



Summary If your blood test indicates low levels of hGH, your doctor may recommend injections of a synthetic form of GHRH, called sermorelin. To properly grow and develop, your body needs human.

Intranasal Human Growth Hormone (hGH) Induces IGF-1 Levels Comparable .



The classical way to administer peptides is injection. Some are available as topical serum like the GHK-CU copper peptide or as a nasal spray in case of the nootropic ones like Selank and Semax.

The Nose as a Route for Therapy: Part 1. Pharmacotherapy



The Nose as a Route for Therapy: Part 1. Pharmacotherapy

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Ludger Klimek⁶, Anu Laulajainen-Hongisto⁷, Maja Hytönen⁸,
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This article reviews nasal structure and function in the light of intranasal pharmacotherapy. The nose provides an accessible, fast route for local treatment of nose and sinus diseases, with lower doses than are necessary systemically and few adverse effects. It can also be used for other medications as it has sufficient surface area protected from local damage by mucociliary clearance, absence of digestive enzymes, responsive blood flow, and provides a rapid route to the central nervous system.

Keywords: intranasal route, nasal epithelium, mucociliary clearance, allergic rhinitis, chronic rhinosinusitis, lysine aspirin, saline douche, drug delivery

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INTRODUCTION

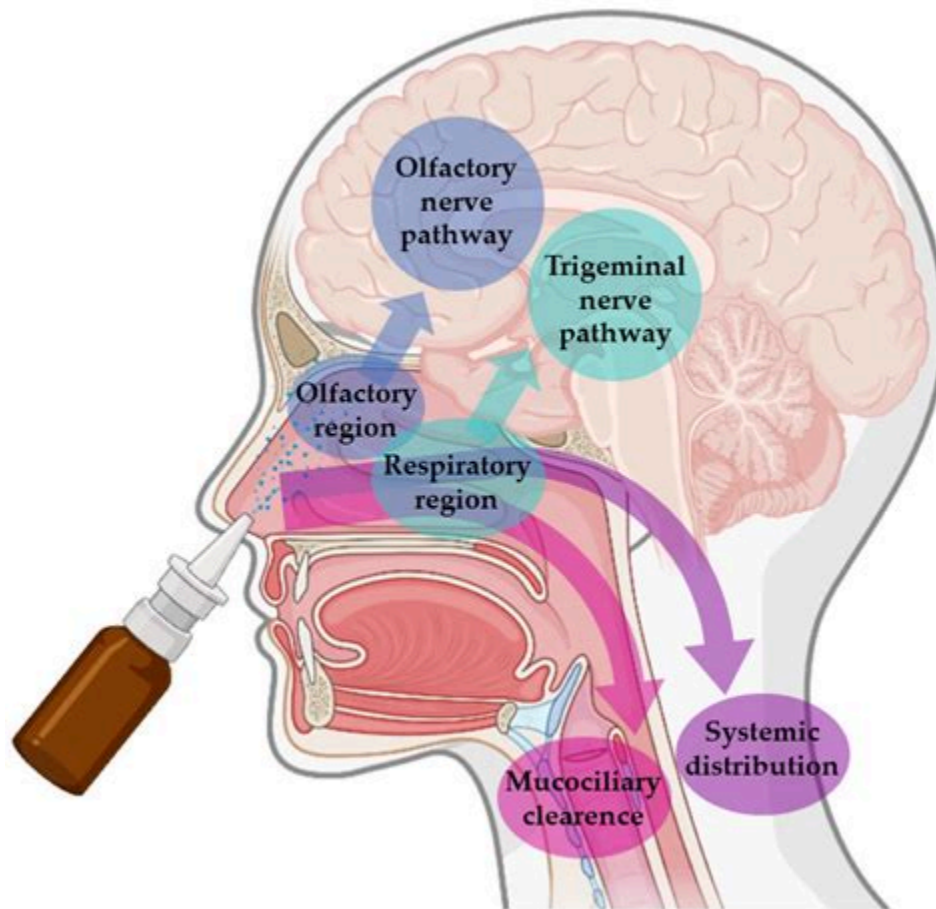
Medicines are usually given orally or systemically by injection: intramuscular or intravenous. Indeed when patients are asked about their drug history the use of inhalers or sprays is often inadvertently omitted, unless specifically requested. However, other routes not only exist, but can prove more effective in placing a drug accurately, often using smaller doses. One such is the intranasal route, now brought to prominence by SARS-CoV2, which uses it to invade the body.

The nose, even though obvious, "it's as plain as the nose on your face" is an English expression, is often disregarded by non-otorhinolaryngologists. However, it has much to recommend it: as an organ for conditioning inspired air, for immune defense, for hosting smell receptors and for application of therapy. The leading role of the epithelium in respiratory diseases such as Allergic Rhinitis (AR) and Chronic Rhinosinusitis with Nasal Polyps (CRSwNPs) has become apparent in recent years and the ability to interact with it by direct application of molecules, rather than allowing them to reach it via the circulation, having been absorbed via the gut or injected into the system, seems sensible.

Part 1 of this review article involves nasal pharmacotherapy. It begins with a consideration of nasal structure and function, including the nature of the pseudostratified columnar ciliated respiratory epithelium. It is important to understand nasal anatomy, histology, innervation, and blood supply in order to assess the nasal cavity as a route for a particular drug. Necessary factors are a large surface area for absorption and high blood flow for transport. Factors which might interfere with drug absorption are vasoconstriction secondary to stimulation of the adrenergic nerves or irritation stimulating the 5th nerve and causing the 7th to respond by increased glandular mucus secretion, washing away the therapeutic product into the nasopharynx, where it is swallowed. Nasal pH and the lipophilicity of a drug are also relevant.

In this study, we have identified a new usage strategy for nasal sprays available over-the-counter, that registers an average 8-fold improvement in topical delivery of drugs at diseased sites.,

Improvement of Intranasal Drug Delivery with Intravail



Nasal spray is a non-invasive administration method for PT-141, offering advantages in absorption and bioavailability through the nasal mucosa, providing a convenient alternative to injections. This delivery method allows PT-141 to bypass the digestive system and first-pass metabolism, leading to faster onset of action and potentially improved .

- <https://dbol-steroid-benefits.gitbook.io/store/how-much-weight-gain-with-dianabol-dianabol-dbol-an-in-depth-guide>
- <https://publiclab.org/notes/print/43395>
- <https://publiclab.org/notes/print/45473>