

# 司美格鲁肽 (Semaglutide)

来源：重组E.coli

Source: recombinant E.coli

贮存条件：-15°C以下避光保存

Storage conditions: Store below -15°C, Protect Products from light

## 产品介绍 PRODUCT INTRODUCTION

司美格鲁肽是新一代胰高血糖素样肽 (GLP-1) 受体激动剂，通过刺激胰岛素分泌降低胰高血糖素分泌。与利拉鲁肽相比其脂肪链更长，疏水性增加，与白蛋白紧密结合，掩盖DPP-4酶水解位点，还能降低肾排泄，可延长生物半衰期，达到长循环的效果，作用周期可以达到一周。降糖、减重、心血管获益、脑部认知功能等临床方面都有着非常不错的效果。

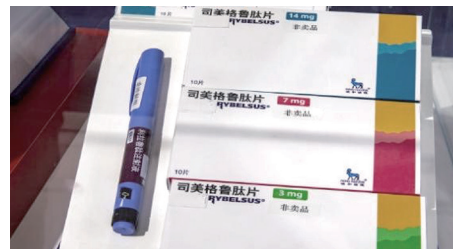
Semaglutide is a new generation glucagon-like peptide (GLP-1) receptor agonist, which reduces glucagon secretion by stimulating insulin secretion. Compared with liraglutide, its fat chain is longer, its hydrophobicity is increased, it is closely bound to albumin, covers the DPP-4 enzymatic hydrolysis site, and can also reduce renal excretion, prolong the biological half-life, and achieve a long cycle effect, the action cycle can reach one week. There are very good clinical effects in reducing blood sugar, weight loss, cardiovascular benefits, and other aspects.

## 本品应用 APPLICATION OF THIS PRODUCT

注射液 (Injection) :

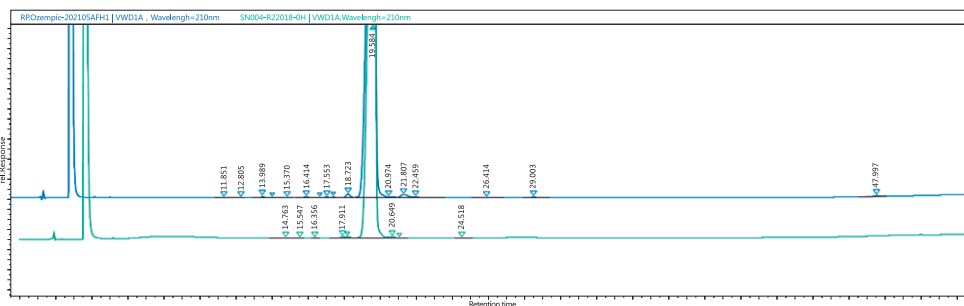


口服片剂 (Oral tablets) :

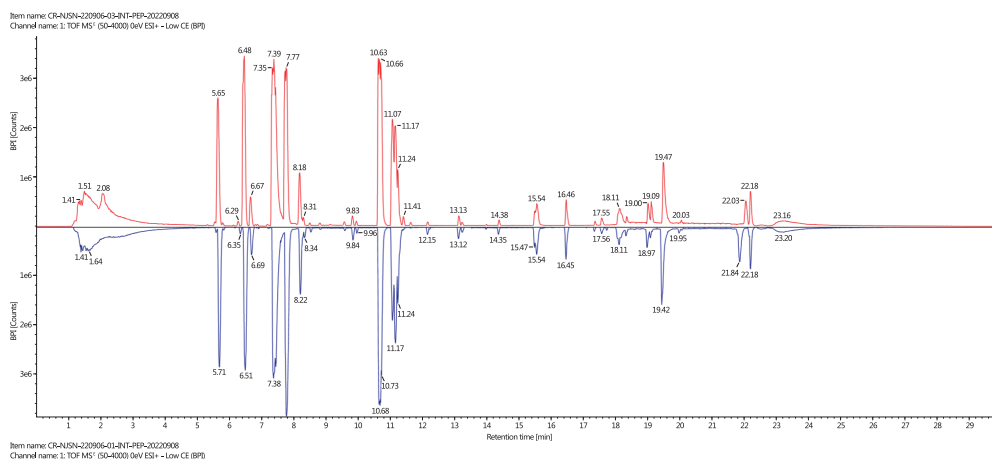


## 产品重点质量分析 PRODUCT FOCUS QUALITY ANALYSIS

有关物质 Related substances	杂质IP02应不得过0.20%	Related impurities IP02 : NMT 0.20%	0.01%
	杂质IP03应不得过1.0% )	Related impurities IP03 : NMT 1.0% )	0.3%
	疏水性杂质1应不得过1.5%	Hydrophobic related protein 1 : NMT 1.5%	0.3%
	( 其中杂质IP04应不得过1.0%	( Related impurities IP04 : NMT 1.0%	0.3%
	杂质IP05应不得过1.50% )	Related impurities IP05 : NMT 1.50% )	0.05%
	杂质IP06应不得过0.50%	Related impurities IP06 : NMT 0.50%	0.001%
	杂质IP07应不得过0.50% )	Related impurities IP07 : NMT 0.50% )	0.01%
	疏水性杂质2应不得过0.15%	Hydrophobic related protein 2 : NMT 0.15%	0.009%
	总杂质应不得过3.0% )	Total miscellaneous : NMT 3.0% )	0.8%



利用本公司产品生产的注射剂产品质量显著优于诺和诺德原研药  
 The quality of injection products produced using our company's products is significantly better than that of Novo Nordisk original research drugs



本品所有肽片段和原研药一致  
 All peptide fragments of this product are consistent with the original research drug

## 产品优势 PRODUCT ADVANTAGES

- 按照国内GMP生产的原料药，并进行生物类似药申报；  
API and biosimilar declaration in accordance with GMP;
- 5000L规模质量研究和工艺文件完整，US-DMF备案成功；  
Complete quality research and process documentation: Ready for US-DMF registration;
- 质量稳定：批量生产，批量可以达到10kg以上，可保证稳定连续的批次生产；产品批次间差异小，质量稳定。  
Stable quality: Mass production(10kg/Batch), can ensure stable and continuous batch production; The product varies from batch to batch and the quality is stable.



南京赛诺生物制药有限公司

Nanjing Cellnuo Biopharmaceutical Co., Ltd.

地址Add：南京市江北新区华康路142号南京生物医药谷加速器三期A02栋1-2层南侧

服务热线TEl：025-52701023 18913840228

