MSN SCIENTIFIC SPARKLES

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MSN SEMAGLUTIDE

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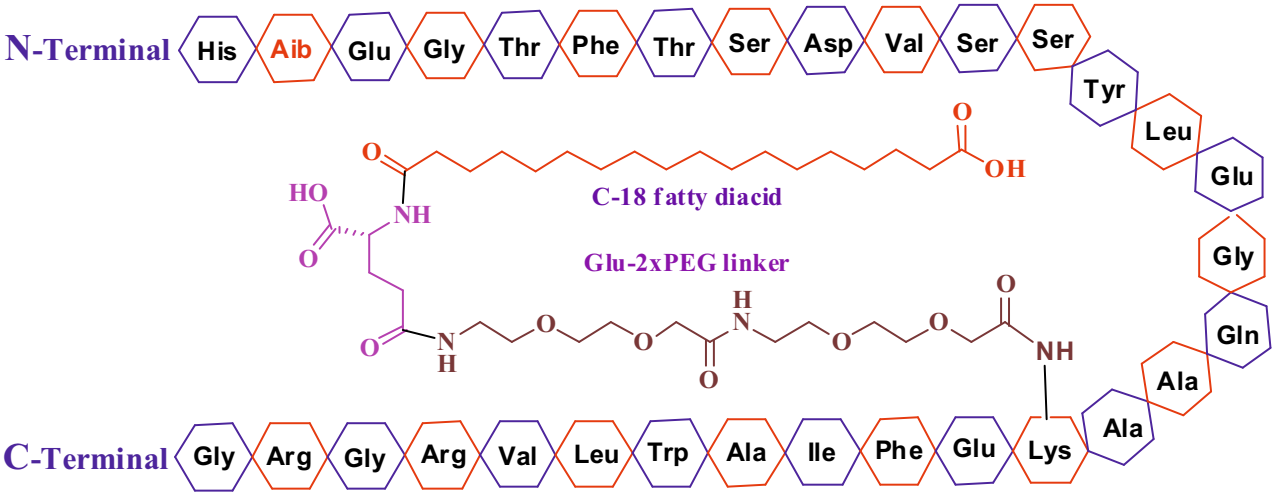
STRATEGICALLY DESIGNED FRAGMENT BASED SYNTHESIS OF SEMAGLUTIDE – SYSTEMATIC CONTROL OF IMPURITY PROFILE LEADING TO REPRODUCIBLE AND HIGHLY PURE API

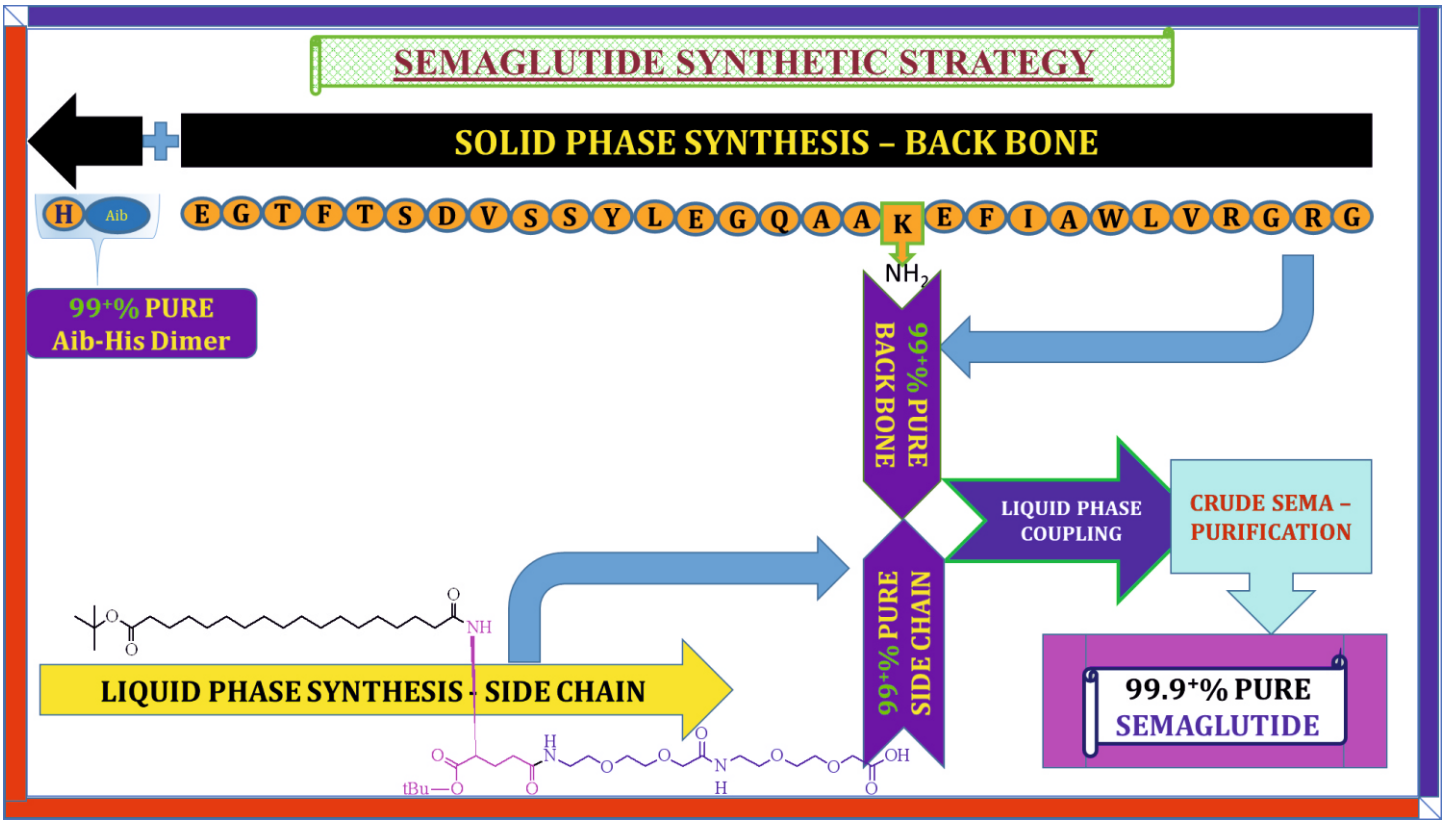
PRODUCT PROFILE



Semaglutide, a glucagon like peptide-1 (GLP-1) receptor agonist is developed by Novo Nordisk in 2012, used for the treatment of type 2 diabetes (T2D) and for long-term weight management (Obesity). Semaglutide is used as monotherapy as a subcutaneous injection and also as an oral dosage form (first approved oral GLP-1 receptor agonist). Semaglutide is sold under the brand names Ozempic (Injection) for T2D, Rybelsus (Oral tablet) for T2D and Wegovy (Injection) for obesity (weight management).

DESIGN AND SYNTHESIS OF SEMAGLUTIDE – OVERCOMING THE PURITY CHALLENGES

GLP-1 peptide with linkers are more challenging to synthesize and isolate in highly pure form with physicochemical properties similar to RLD. Liraglutide and Semaglutide are couple of them invented by Novo-Nordisk. As part of our organization's continuous efforts to synthesize highly pure peptides, a process has been developed with most precise strategic design by systematic control of impurities for MSN-Semaglutide. Our design mainly focused on controlled impurity profile of intermediate fragments to obtain crude Semaglutide without purification challenges. Different strategies are applied to understand the impurity profile of crude Semaglutide for hassle-free purification. Three highly pure fragments are synthesized using the combination of solid phase and liquid phase to get crude Semaglutide with the desired quality. The strategy is proven to be a game changer to produce highly pure Semaglutide API with consistent yield.



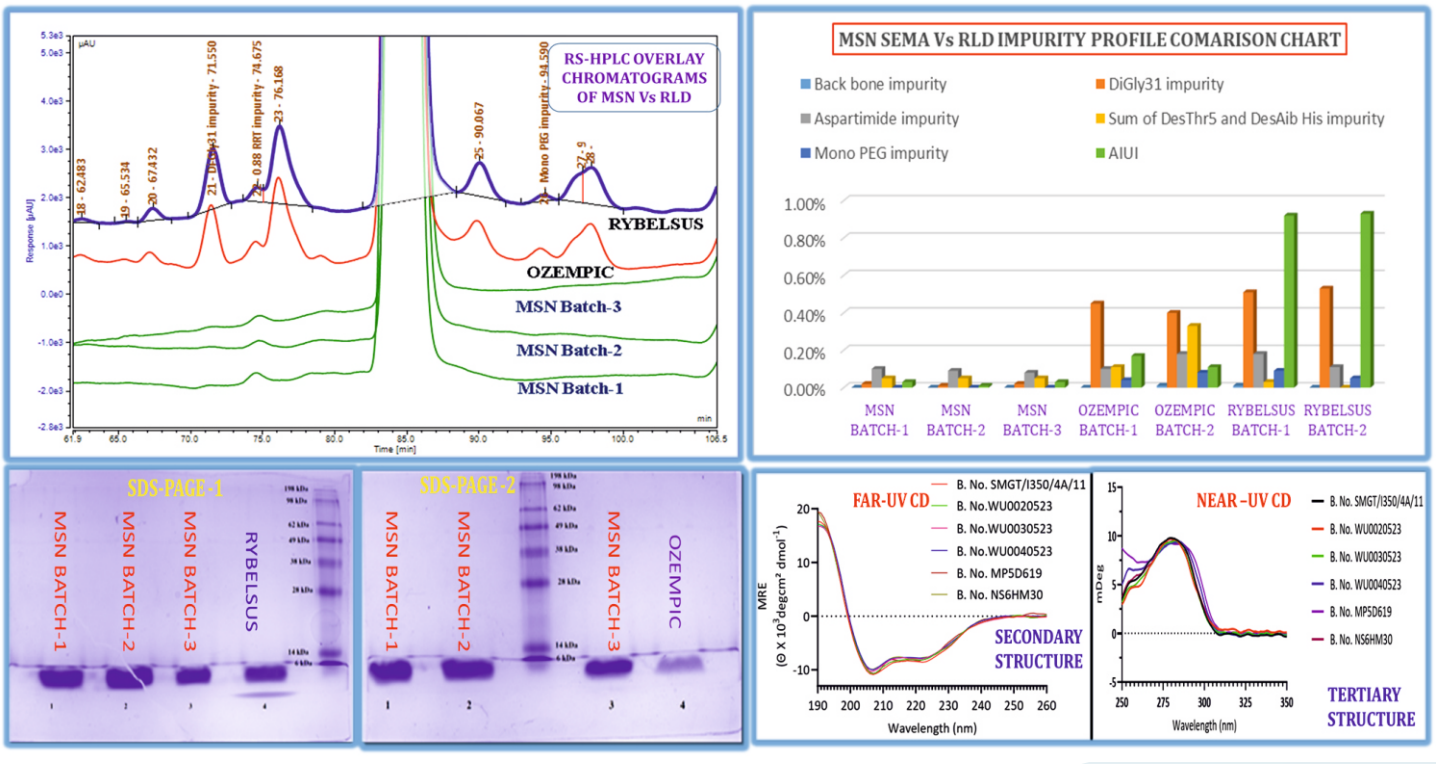
Advantages of the technology of MSN-SEMAGLUTIDE:

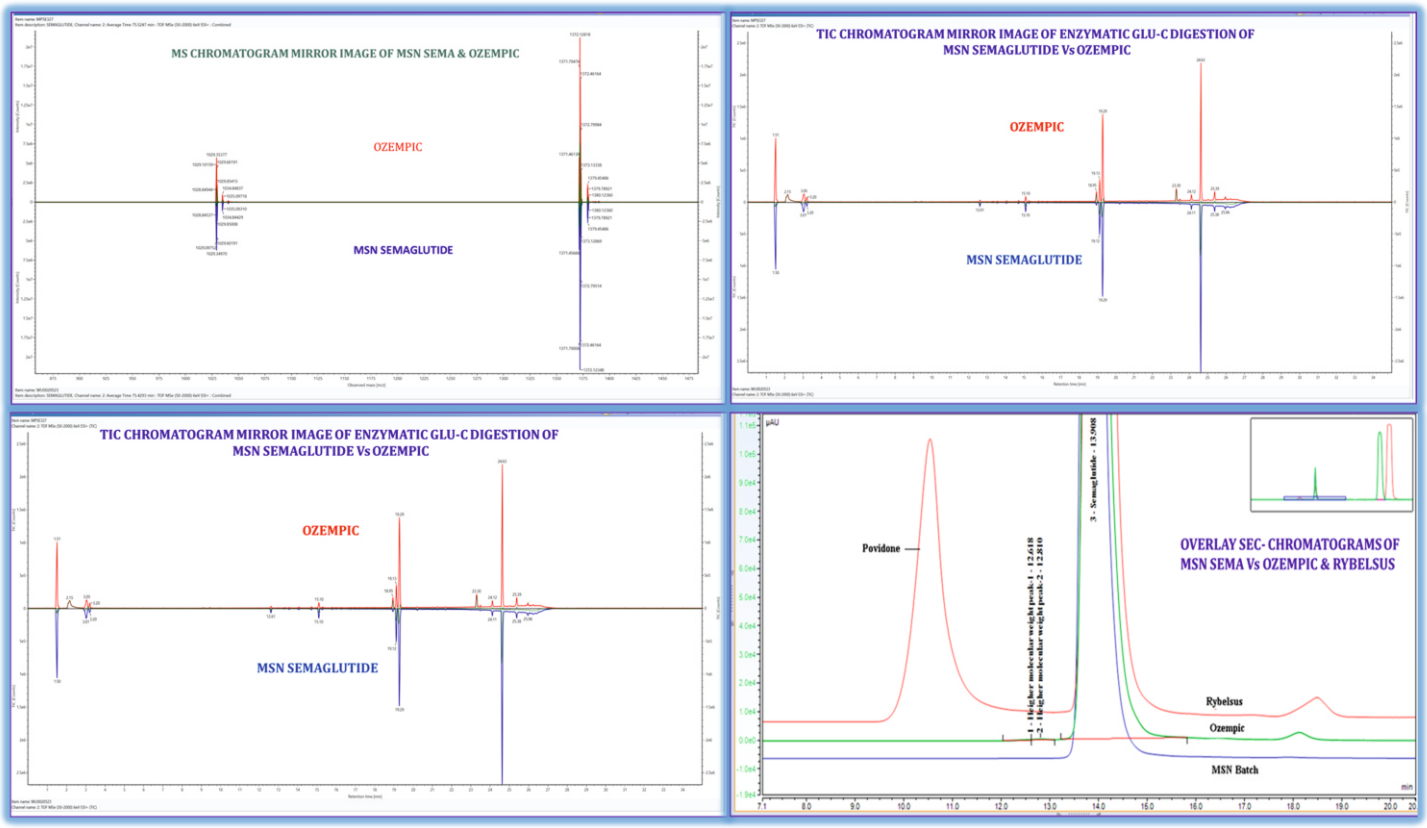
- USDMF filed in September-2023.
- Patent protection sought for the technology.
- Extensive sameness study - comparison of Primary, Secondary, Tertiary structures including Bio-Assay with RLD proved similarity.
- Technology of MSN-Semaglutide possesses all parameters in compliance with USFDA guidelines.
- Purity of MSN-Semaglutide is greater than RLD in terms of all known and unknown impurities.
- API is also tested for absence of Genotoxic, Nitrosamine and Elemental impurities.
- Multiple orthogonal techniques used for the characterization of API and sameness package is established in accordance with FDA guidelines.
- Multiple customers are satisfied with the quality of MSN-Semaglutide API.

Supply Chain Management and Manufacturing:

- State of the art manufacturing facility equipped with world class synthesizers and purification techniques to manufacture the peptides is the capability of MSN.
- Raw materials are procured from reliable GMP compliant sources and also from In-house manufacturing facilities.
- Multi kilogram level production capacity is available.
- MSN QC/QA department is capable to test and release all CQAs.

Glimpse of Multiple Orthogonal Techniques Proving Sameness of MSN SEMAGLUTIDE With The RLD - OZEMPIC & RYBELSUS





EXECUTIVE SUMMARY

MSN-SEMAGLUTIDE is highly pure and similar to RLD in terms of physicochemical properties and bio-assay. GMP material can be manufactured and supplied in multi-Kilogram level to customers with regulatory compliance.

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