ROOM TEMPERATURE STABLE PEPTIDE FORMULATIONS

solid dose injection

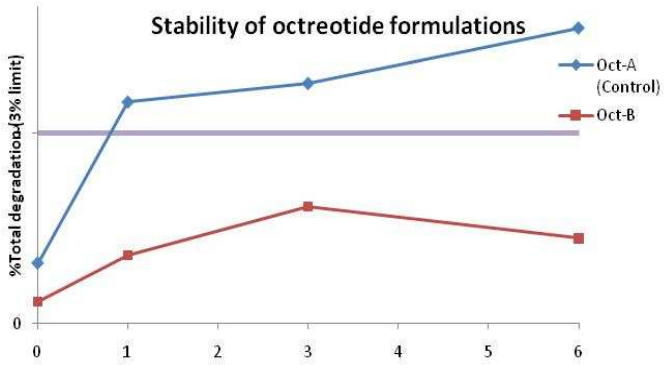
Glide Peptides

Glide SDI® (Solid Dose Injector) is an innovative, patented drug delivery system for the injection of drugs and vaccines in a solid dosage form. The Glide SDI® employs a simple spring based mechanism, which ensures the system is easy to use and cheap to manufacture.

Protein and peptide therapeutics have made significant progresses in recent years. Despite considerable effort made in the development of alternative delivery routes, parenteral administration remains the main delivery route for over 90% of protein drugs due to their poor bioavailability. Glide SDI® is ideal for protein delivery as it has the additional advantages of portability and easy self administration.

Formulation Design

Solid dosage forms are generally more stable than liquid forms because of their reduced molecular mobility. However, this is not often sufficient to achieve the stability requirement of a pharmaceutical product. A rationalised formulation design approach is adopted to screen and select suitable formulation components that can inhibit peptide degradation such as deamidation, oxidation and aggregation, and are compatible with the structural integrity of the Glide implants.



The stability profiles of two octreotide formulations (one control formulation with the Glide structural excipients only, the other combines both the structural excipients and the stabilising excipients) are shown in the figure above. The data shows that the formulation incorporating the Glide stabilising excipients is stable at 40°C, 75%RH for at least 6 months indicating room temperature stability of 18 months and beyond.



the Glide SDI

Further formulation and method optimisation has been carried out and these samples have been committed to further stability studies. The main HPLC purity profiles of one of the optimised formulations after 0, 3 and 6months storage at 40°C and the original raw material used for preparing these formulations are shown in the Table below. This data confirms the formulation design strategy is valid.

degradation profile showing main impurity profiles (%) at different retention times

Relative Retention Time	0.93/0.94	0.97	1.00	1.14	1.27
Raw material	0.52	0.16	98.63	0.00	0.41
Stabilised formulation t=0	0.54	0.16	98.46	0.01	0.42
Stabilised formulation t=3m (40°C, 75%RH)	0.46	0.13	98.34	0.05	0.46
Stabilised formulation t=6m (40°C, 75%RH)	0.38	0.12	98.55	0.06	0.45

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