

Goserelin Acetate – VitalDose® EVA Implant

Biodurable implants to enhance long-acting control of your therapeutic treatment & increase patient compliance

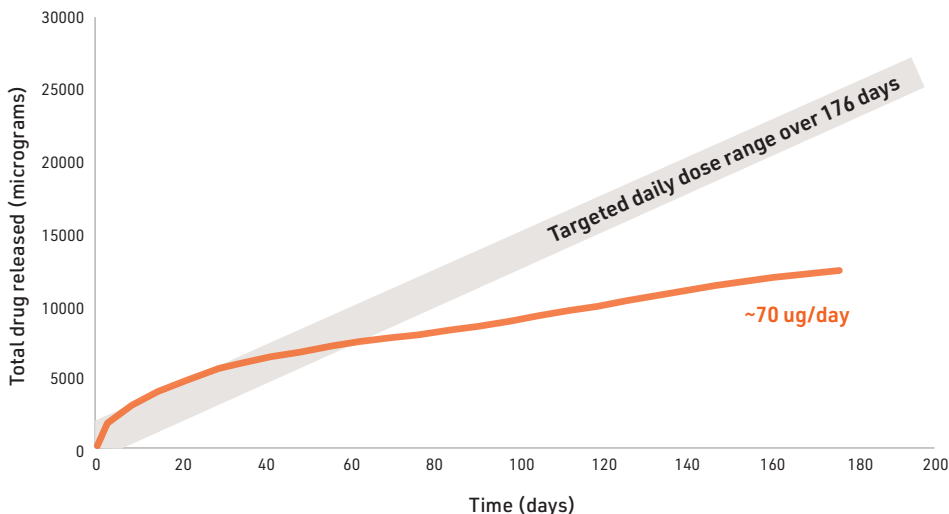
VitalDose® EVA copolymer is a technology platform for reliable controlled and sustained release performance in long-acting indications. It can be processed at low temperatures to accommodate sensitive biologics and has broad solubility characteristics for peptides and small molecules.

STUDY SUMMARY: The purpose of this study was to conduct an initial feasibility trial to demonstrate the capabilities of EVA in releasing the peptide, Goserelin Acetate. Though the intention was not to optimize the implant design to meet a target profile, adjustments to do so is achievable through additional formulation modifications. In addition, the API maintains its integrity throughout the study.

DRUG RELEASE*

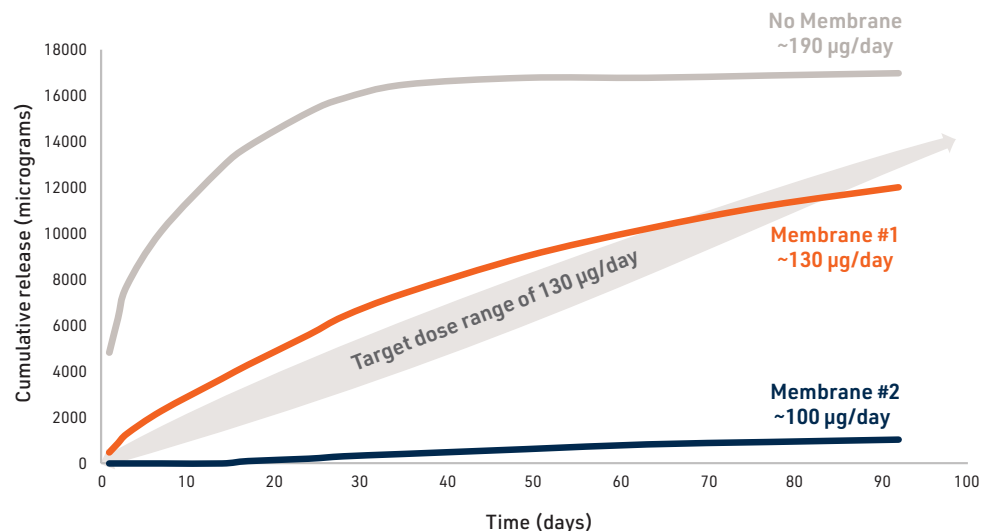
Targeting a therapeutic dose of 22.6 mg over 176 days (~130 µg/day)

Monolithic implant design



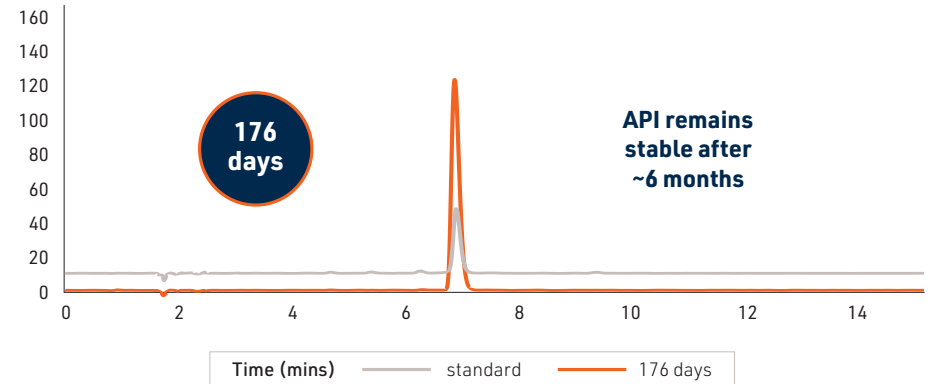
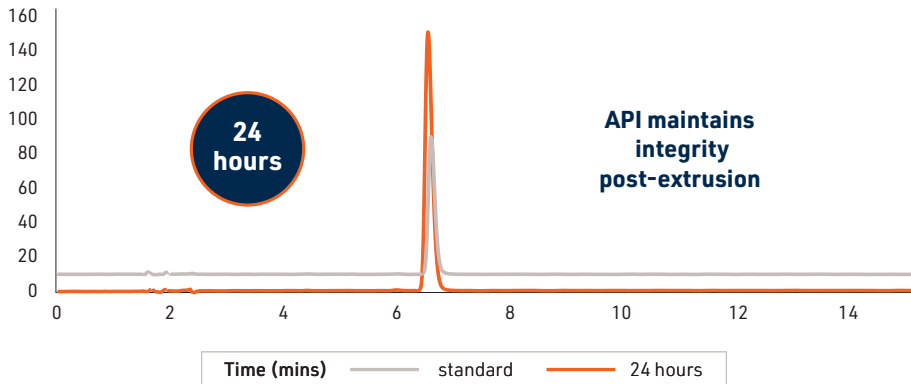
3mm D x 10mm L ● 60% Loaded (54mg of peptide)

Multilayer implant design



2mm D x 10mm L ● 60% Loaded (20mg of peptide)

API STABILITY*



Key takeaways:

- The TARGET therapeutic dose can be achieved through additional implant modifications (design, dimensions and drug loading)
- API remains stable after extrusion as well as after ~6 months of incubation at 37°C and high humidity conditions



Advantages of biodurables:

- Changes in release rate due to degradation is minimal as compared to a biodegradable polymer system
- Full control over the ability to completely disrupt therapy vs. a biodegradable polymer system

*Other study parameters:

Extrusion temperature: 60-65°C **Characterization method:** RP- HPLC **Incubation conditions:** 37°C and 100 RPM **Buffer condition for release:** 25 ml (PBS @ pH 7.4 w/ 0.02% w/v sodium azide)

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