

Customized Solutions

CASE STUDY



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Pediatrics

Cold chain throughout dispensing, mixing, packaging, storage and shipping to extend the stability of the product, all designed/engineered by CoreRx specifically for this product.

A Biotech company partnered with CoreRx for Phase 2 development and GMP manufacturing of an oral solution



THE CHALLENGES

- ↻ API required very high daily dose for patients.
- ↻ Stability was challenging for both neat API and drug product.
- ↻ Patients have taste aversions and trouble swallowing.



THE SOLUTION

- ↻ CoreRx formulated a high dose suspension product at 200mg/ml for Rett's Syndrome patients.
- ↻ The easy to swallow suspension had a satisfactory taste and adequate shelf life.
- ↻ The product requires cold chain (5°C) throughout dispensing, mixing, packaging, storage and shipping to extend the stability of the product, all designed/engineered by CoreRx specifically for this product.



THE RESULTS

- ↻ CoreRx completed registration batches and validation activities.
- ↻ Client completed commercial Quality audit and plans to commercialize the product at CoreRx.
- ↻ Commercial approval is targeted for end 2022, product volumes are expected to be about 60 batches/year.
- ↻ Infrastructure enhancements at CoreRx include an expanded walk-in refrigerator, stability chambers and various pieces of manufacturing equipment required for cold chain.