



# **Phosveda® (Calcium Succinate) Capsules**

A New Phosphate Binder  
presented by BioLink Life Sciences, Inc.



# Calcium Succinate Capsules



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- NDA deemed “approvable” but now “on hold” because FDA inspector could not complete inspection at former contract manufacturer
- Efficacy: Demonstrated bioequivalence to calcium acetate through *in vitro* bioequivalence studies authorized by the FDA
- Safety: Relying on the safety of calcium (as calcium acetate)

# Calcium Succinate Capsules: Description

- New oral phosphate binder

Active ingredient is calcium (as calcium succinate)

Dry powder formulation in HPMC capsule

Dissolves within 30 minutes to provide ionized calcium for phosphate binding

Stable for years at room temperature or when exposed to elevated temperatures

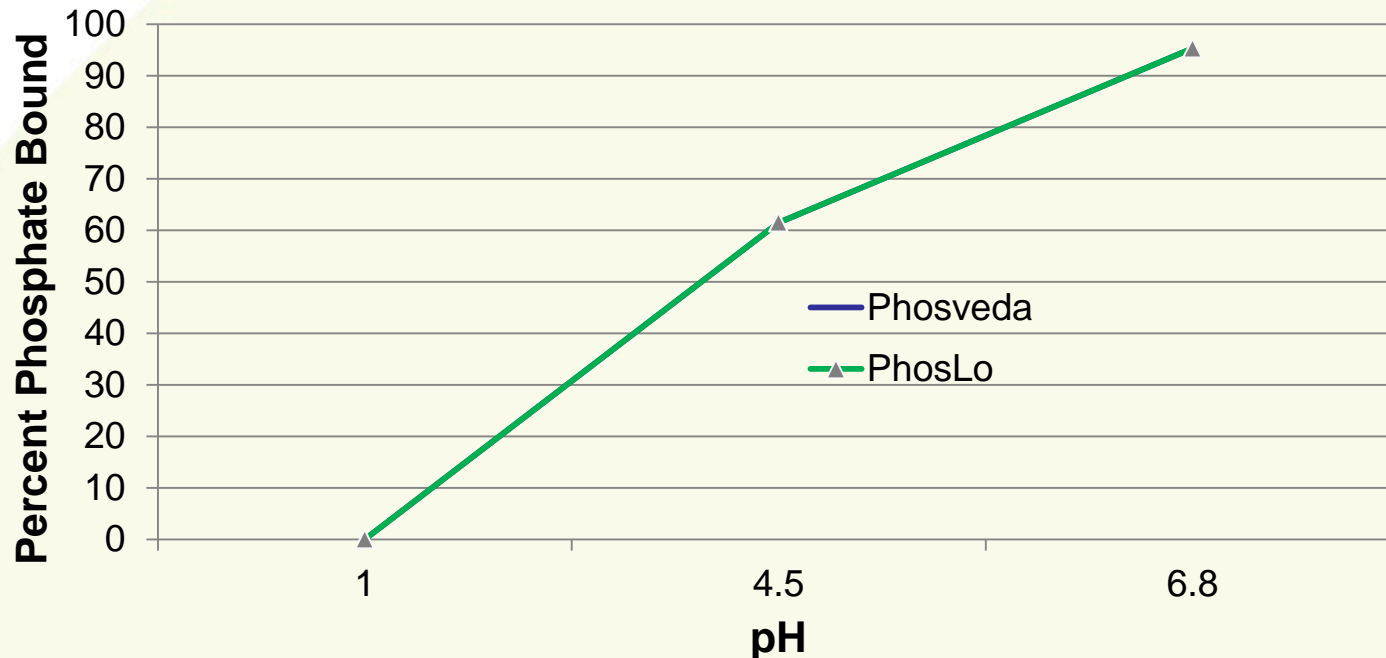
# Indications

- PhosLo® Gelcaps are oral phosphate binders indicated for the reduction of serum phosphorus in patients with end stage renal disease (ESRD).
- Calcium Succinate Capsules are oral phosphate binders that will be indicated for the reduction of serum phosphorus in patients with ESRD.

# Mechanism of Action

- The active pharmaceutical ingredient in both PhosLo gelcaps and Calcium Succinate Capsules is calcium.
- Phosphate binders that exert their action via calcium do so by forming insoluble calcium phosphate precipitates in the gastrointestinal tract and are eliminated via the feces.

# Calcium Succinate Capsules: Efficacy vs. PhosLo® Gelcaps (*in vitro study*)



Note: The data points for Phosveda and PhosLo are identical at each pH. As a result, a single line defines phosphate binding.

# Calcium Succinate Capsules: Safety

BioLink is relying on FDA's finding of safety and effectiveness for the Reference Listed Drug PhosLo<sup>®</sup> gelcaps (calcium acetate, NDA 201160) to support the nonclinical safety and efficacy of Calcium Succinate Capsules.



# Calcium Succinate Capsules: Summary

- Active Ingredient is calcium.
- Capsule dissolves rapidly and is stable during storage (no crosslinking)
- Patient tolerability significantly improved
- “Vinegar breath” eliminated
- Side effects expected to be similar to those of calcium acetate
- NDA can be reactivated for FDA review when new manufacturer completes validation batch production.