Get more bang for your base with LoxOral. It’s the only excipient capsule base that can be used in any type of oral capsule formulation, and with any type of active ingredient.

**BENEFITS**

LoxOral is so much more than a filler – it’s an innovative capsule excipient base that delivers powerful benefits:

**Improved dissolution:** Enhances the release of all types of active pharmaceutical ingredients (APIs), including poorly soluble drugs, potentially leading to improved absorption

**Even distribution:** Well-defined, uniform particle size creates improved distribution of the API within the base

**Optimal stability:** Low hygroscopicity resists moisture and promotes stability, even for moisture-sensitive APIs

**Ease of use:** Reduces static associated with some APIs, such as progesterone, and helps reduce clumping and improve flowability

**Additional benefits:**
- A great choice for a capsule excipient (or suitable capsule filler) for patients with allergens or special dietary needs
- **LoxOral contains no:**
  - Gluten
  - Casein
  - Sodium lauryl sulfate (SLS)
  - Lactose
  - Soy
  - Corn
  - Dye
  - Magnesium stearate
- Contains isomalt, an ingredient shown to have potential prebiotic effects
Proven Results

**IMPROVED DISSOLUTION**

Studies demonstrated a higher dissolution rate of APIs that utilized LoxOral as the excipient base compared to those that used microcrystalline cellulose (shown in below graphs). An increase in dissolution rate has potential to provide a more rapid onset and increased bioavailability. *Note: Piroxicam and ketoconazole were used in the testing due to their prior validated methodologies.*

**SUSTAINED-RELEASE USE**

A comparative study was done using both LoxOral and lactose monohydrate along with Methocel E4M as excipients in formulations for progesterone sustained-release capsules. The study showed a satisfactory and comparable dissolution profile for both progesterone formulations, proving the reliable substitution of LoxOral in sustained-release preparations. PCCA LoxOral base provides various advantages over lactose, especially for lipophilic compounds such as progesterone. These advantages are due to the excellent flowability, reduced static and improved stability from the low hygroscopicity of LoxOral.

Dissolution profiles of piroxicam and ketoconazole (drugs chosen for testing purposes only) from capsules containing different excipients, LoxOral and microcrystalline cellulose (MCC).

Dissolution profiles of progesterone from capsules containing different excipients, LoxOral and Lactose Monohydrate combined with Methocel E4M.

See PCCA Document #98670 “LoxOral™ Studies Booklet” for full details on all the testing performed.

LoxOral has been tested according to USP General Chapter <1059> Excipient Performance.
FORMULATION EXAMPLES

**PCCA Formula #10811**
Dehydroepiandrosterone 25 mg SR Capsules Size #1 (LoxOral™)

**PCCA Formula #10807**
Domperidone 10 mg Capsules Size #1 (LoxOral™)

**PCCA Formula #10809**
Ergotamine Tartrate 1 mg/Caffeine 100 mg Capsules Size #1 (LoxOral™)

**PCCA Formula #10824**
Estradiol 10%/LoxOral™ Trituration

**PCCA Formula #10822**
Estriol 10%/Estradiol 10%/LoxOral™ Trituration

**PCCA Formula #10823**
Estriol 10%/LoxOral™ Trituration

**PCCA Formula #10785**
Estriol/Estradiol [50%/50%] 1 mg SR Capsules Size #1 (LoxOral™)

**PCCA Formula #10789**
Estriol/Estradiol [80%/20%] 1.25 mg SR Capsules Size #1 (LoxOral™)

**PCCA Formula #10782**
Estriol/Estradiol [80%/20%] 1.25 mg/Progesterone 100 mg SR Capsules Size #1 (LoxOral™)

**PCCA Formula #10779**
Estriol/Estradiol [80%/20%] 2.5 mg/Progesterone 100 mg SR Capsules Size #1 (LoxOral™)

**PCCA Formula #10820**
Levothyroxine Sodium (T4) 100 micrograms SR Capsules Size #1 (PCCA Dilution) (LoxOral™)

**PCCA Formula #10817**
Levothyroxine Sodium (T4) 150 micrograms/Liothyronine (T3) 37.5 micrograms Capsules Size #1 (PCCA Dilution) (LoxOral™)

**PCCA Formula #10815**
Liothyronine (T3) 7.5 micrograms SR Capsules Size #1 (PCCA Dilution) (LoxOral™)

**PCCA Formula #10805**
Naltrexone HCl 0.5 mg Capsules Size #1 (LoxOral™)

**PCCA Formula #10810**
Nystatin 500,000 Units Capsules Size #3 (LoxOral™)

**PCCA Formula #10825**
Piroxicam 3.5 mg Capsules Size #3 (LoxOral™)

**PCCA Formula #10800**
Progesterone 50 mg SR Capsules Size #1 (LoxOral™)

**PCCA Formula #10797**
Progesterone 100 mg SR Capsules Size #1 (LoxOral™)

**PCCA Formula #10795**
Progesterone 200 mg Capsules Size #1 (LoxOral™)

**PCCA Formula #10821**
Thyroid 60 mg Capsules Size #3 (LoxOral™)

Other strengths and capsule sizes are also available.
LoxOral™ FAQs

**How is this product different from what is currently on the market?**

PCCA LoxOral is the only excipient base needed for all types of APIs used in capsule formulations. This all-in-one base acts not only as a filler, but also improves dissolution, flowability and stability of the preparation. Plus, LoxOral is free of sodium lauryl sulfate, a common irritant that is found in other products on the market.

**Are there other PCCA products that perform a similar function?**

Common capsule fillers are lactose or microcrystalline cellulose. These agents act only as capsule fillers and lack the additional benefits that LoxOral provides, such as improving dissolution and flowability, reducing static and promoting stability.

**Is LoxOral an immediate-release or sustained-release filler?**

LoxOral is an immediate-release excipient base; however, it can easily be combined with Methocel E4M (40% in a size #1 capsule or larger is recommended) to create a sustained-release capsule.

**Is LoxOral safe for pregnant or nursing women?**

Yes.

**Can LoxOral be used in animals?**

Yes.

**Is it safe to use rectally or vaginally?**

Yes.

**What is the carb count of LoxOral?**

Testing was done with the following results:

Each 100 gm of LoxOral provides:

- 399 Calories
- 91.89 gm Carbohydrates
- 3.45 gm Fat
- <0.01 gm Protein

**How does LoxOral show potential for prebiotic effects?**

LoxOral contains an ingredient (isomalt) that has shown potential prebiotic effects. Studies referenced below show that isomalt may contribute to a healthy luminal environment of the colonic mucosa.

- Human studies have also been conducted to determine the effect of IMOs on the colonic microflora. Kohmoto et al. (1988).