LoxOral®

Patent Pending Technology

Excipient Powder Base for Use in Oral Capsule Formulations

PCCA # **30-4774**

PCCA EXCLUSIVE

One base that does it all.

LoxOral gives you more bang for your base. It's an all-in-one excipient base that can be used in oral capsule formulations with many types of active pharmaceutical ingredients (APIs), including hygroscopic, static prone and poorly soluble drugs.

LoxOral is much more than a filler — it's an innovative capsule excipient base that delivers powerful benefits for you and your patients.

BENEFITS

- **Saves time**: Easily mixes with many types of APIs and allows powders to fall more easily and faster into the capsules than when using alternate fillers such as lactose or microcrystalline cellulose.

  When comparing the time to fill 100 capsules in a capsule machine:
  - Microcrystalline Cellulose as the excipient filler took 8 minutes 28 seconds
  - LoxOral as the excipient filler took 2 minutes 45 seconds

  When comparing the time to fill 100 capsules with ingredients to make progesterone 50 mg slow release capsules size #1:
  - Microcrystalline Cellulose as the excipient filler with Methocel E4M took 9 minutes 22 seconds
  - LoxOral as the excipient filler with Methocel E4M took 5 minutes 34 seconds
- **Reduces static**: Some APIs such as progesterone are known to be quite static-prone. LoxOral helps reduce static and clumping and improves flowability.
- **Even distribution**: Well-defined, uniform particle size creates improved distribution of the API within the base.

We packed 100 capsules* using a machine — here's how long it took:

LoxOral

00:02:45

— vs —

Microcrystalline Cellulose (PH-105)

00:08:28

"We compound a lot of progesterone slow-release capsules, and LoxOral has helped reduce the static, making our process faster. It also allows our medications to be lactose-free, so we can serve a wider variety of patients."

Darrin Berlin, BSPharm
President of Dispensaries Ltd. in Edmonton, AB

**Conducted by PCCA Consulting with tight pack using just the filler (no APIs)*

- **Improved dissolution**: Enhances the release of many types of APIs — including poorly soluble drugs — potentially leading to improved absorption.
- **Optimal stability**: Low hygroscopicity resists moisture and promotes stability, even for moisture-sensitive APIs.

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RELATED SPECIALTIES

- Family Practice
- Internal Medicine
- OB/Gyn
- Veterinary Medicine
- Hormone Replacement Therapy (HRT)

FORMULATED WITHOUT

- Gluten
- Casein
- Sodium lauryl sulfate (SLS)
- Lactose
- Soy
- Corn
- Dye
- Magnesium stearate

NUTRITIONAL INFORMATION

Based on testing, each 100 Gm of LoxOral provides: 399 Calories; 91.89 Gm Carbohydrates; 3.45 Gm Fat; <0.01 Gm Protein

FORMULATION EXAMPLES

- **PCCA Formula #12508**
  Ketotifen 1 mg Capsules Size #3 (LoxOral)
- **PCCA Formula #12965**
  Minoxidil 0.25 mg Capsules Size #3 (LoxOral)
- **PCCA Formula #10797**
  Progesterone 100 mg Slow Release Capsules Size #1 (LoxOral)
- **PCCA Formula #11297**
  Estriol/Estradiol [80%/20%] 2 mg/Progesterone 100 mg Slow Release Capsules Size #1 (LoxOral)
- **PCCA Formula #10811**
  Dehydroepiandrosterone 25 mg Slow Release Capsules Size #1 (LoxOral)
- **PCCA Formula #12586**
  Naltrexone HCl 1.5 mg Capsules Size #3 (LoxOral)
- **PCCA Formula #12584**
  Naltrexone HCl 4.5 mg Capsules Size #3 (LoxOral)
- **PCCA Formula #11558**
  Cisapride 5 mg Capsules Size #3 (LoxOral) (Vet)
- **PCCA Formula #10963**
  Betahistine Dihydrochloride 16 mg Capsules Size #1 (LoxOral)
- **PCCA Formula #10821**
  Thyroid 60 mg Capsules Size #3 (LoxOral)

Continued on the next page

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FREQUENTLY ASKED QUESTIONS

How is LoxOral different from what else is on the market?
LoxOral is the only excipient base needed for most 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 similarly?
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.

Where can pack stats be obtained?
On the Members-Only Website > Resources > Formula Tools. Select the Capsule Calculator and enter in your preferred ingredients' lot numbers to have access to the latest available packing statistics. Alternatively, you can also search by the ingredient names or part numbers then select the appropriate lot numbers.

Is it an immediate-release or modified-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 slow release capsule.

Can powder mixing be done with LoxOral in the PCCA RAM mixer?
Yes, but due to the complexity of PCCA LoxOral, the low setting should be used (unless otherwise directed on a PCCA formula) to reduce clumping of the base on the lid or within the jar.

Can LoxOral be used in pregnant or nursing women?
Yes.

Can LoxOral be used in animals?
Yes.

Can LoxOral be used in rectal or vaginal capsules?
Yes.

CONTROLLED STUDIES

1. Technical Report: Comparison of Dissolution Properties of Piroxicam Using Microcrystalline Cellulose and a New Excipient (LoxOral)
2. Technical Report: Improvement of Dissolution Properties of Ketoconazole Using a New Excipient (LoxOral) in Comparison with Microcrystalline Cellulose
3. Technical Report: Effect of LoxOral and Lactose on *In Vitro* Dissolution Studies of Progesterone Sustained Release Capsules
4. Technical Report: Effect of Particle Size on the Bioaccessibility of Progesterone from LoxOral in an *In Vitro* Dynamic Gastrointestinal System

To see all of our LoxOral studies in depth, search PCCA Document #98670 on the Members-Only Website.

PLEASE NOTE

Always make sure you have checked the PCCA formula database and are following the most up-to-date version of a formula, as changes are continually made to existing formulations to provide the highest quality. The formulas and/or statements listed are provided for educational purposes only. They are compounding ideas that have commonly been requested by physicians and have not been evaluated by the Food and Drug Administration. Formulas and/or material listed are not to be interpreted as a promise, guarantee, or claim of therapeutic efficacy or safety. The information contained herein is not intended to replace or substitute for conventional medical care or encourage its abandonment. Every patient is unique, and formulas should be adjusted to meet their individual needs.