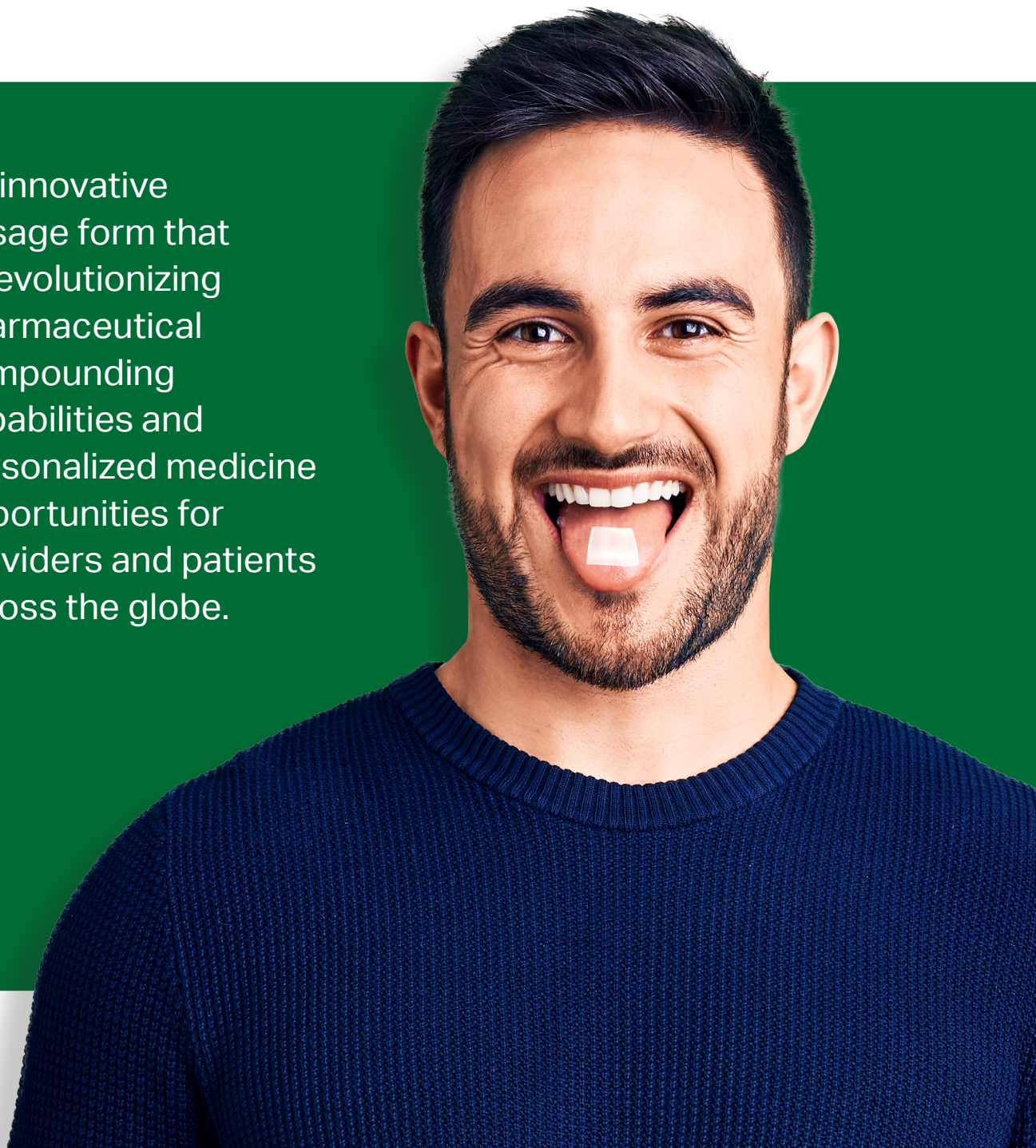




NovaFilm[™]

Oral Transmucosal Films

An innovative dosage form that is revolutionizing pharmaceutical compounding capabilities and personalized medicine opportunities for providers and patients across the globe.



Challenges That May Resonate With You

Trouble Swallowing

9% of school-aged children cannot swallow a tablet or pill ¹.

30-60% of geriatric patients in nursing homes have symptoms of dysphagia ².

First-Pass Metabolism

Many drugs have a low or a large range in oral bioavailability due to extensive gut and first-pass metabolism.

Examples include **sildenafil** with an oral bioavailability of 38-41% ³ and **naltrexone** with a large oral bioavailability range of 5-40% ⁴.

Need for Rapid Onset

Certain drugs require or are preferred to have rapid onset of action. **Ondansetron**, for example, may be an ideal candidate for rapid onset ⁵. **Phosphodiesterase (PDE) inhibitors** may be another, where we see that standard oral dosage forms are recommended to be taken approximately 1 hour before intercourse ⁶.

Heat Labile Actives

Certain active ingredients are heat labile, such as **oxytocin** ⁷, potentially making them unsuitable for certain compounding processes that require high temperature, as is the case with rapid dissolve tablets (RDTs) and troches.

Patient Non-Adherence

It is estimated that 50% of patients do not adhere to prescribed therapy. Many factors impact compliance including individual preferences ⁸.

Longer Beyond-Use Dating

According to USP <795> for non-sterile compounding, aqueous dosage forms with a water activity ≥ 0.6 , must receive a shorter beyond-use date (BUD) in the absence of stability data. Shorter BUDs can mean for more frequent refills, which can impact patient adherence among more.

1. McPherson, T.B. et al. Patient-centered Care as Value-added Service by Compounding Pharmacies. *International Journal of Pharmaceutical Compounding*. Vol.17, No.4, Jul/Aug, 2013, 339-343.

2. Azer, S.A., Kanugula, K., & Kshirsagar, R.K. (2023). Dysphagia. *NIH - National Library of Medicine. StatPearls*. Retrieved from: Laliberte, F. et al. (2011).

3. Gupta M., Kovar A., Meibohm B. (2005). The clinical pharmacokinetics of phosphodiesterase-5 inhibitors for erectile dysfunction. *J. Clin. Pharmacol.* 45 987-1003. doi: 10.1177/0091270005276847.

4. Tolijan, K. & Vrooman, B. (2018). Low-dose naltrexone (LDN) – Review of therapeutic utilization. *Medical Sciences*, 82. doi: 10.3390/medsci6040082.

5. Griddine, A. & Bush, J.S. (2023). Ondansetron. *StatPearls*. Retrieved from: <https://www.ncbi.nlm.nih.gov/books/NBK499839/>

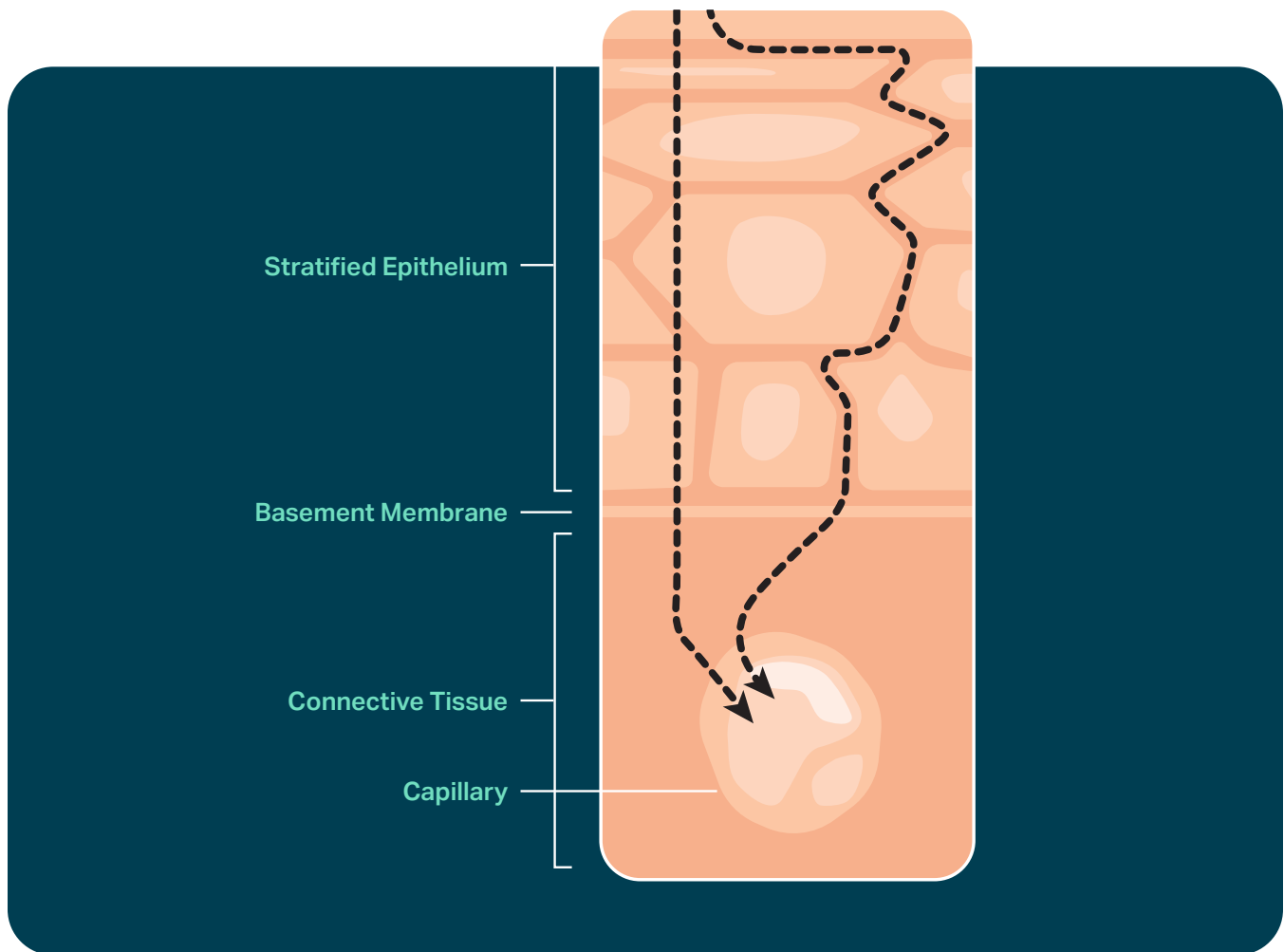
6. De Toni, L., et al. (2018). Sublingual administration of sildenafil oro-dispersible film: New profiles of drug tolerability and pharmacokinetics for PDE5 inhibitors. *Frontiers in Pharmacology*, 59. doi: 10.3389/fphar.2018.00059.

7. Zhu, C. et al. (2018). Heat-stable sublingual oxytocin tablets as a potential needle-free approach for preventing postpartum hemorrhage in low-resource settings. *Drug Delivery and Translational Research*, 8, 853-856.

8. Laba, T.L., Brien, J., & Jan, S. (2012). Understanding rational non-adherence to medications. A discrete choice experiment in a community sample in Australia. *BMC Family Practice*, 61.

Could Oral Mucosal Delivery Be The **Solution**?

- High membrane permeability and good systemic bioavailability due to its thin membrane structure, high vascularization, and high blood flow ¹.
- Large surface area and ease of application for absorption ².
- An alternative to oral routes of delivery, which, for certain drugs, can be associated with insufficient bioavailability due to first-pass metabolism, enzymes, and stomach pH ³. Also an alternative for patients that have difficulty swallowing or chewing.
- Alternative to parenteral routes of delivery.



1. Hussain MW, Kushwaha P, Rahman MA, Akhtar J. Development and Evaluation of Fast Dissolving Film for Oro-Buccal Drug Delivery of Chlorpromazine. Indian Journal of Pharmaceutical Education and Research. 2017;51:S539–S547.
2. Ghodake PP, Karande MK, Osmani RA, Bhosale RR, Harkare RB, Kale BB. Mouth dissolving films: Innovative vehicle for oral drug delivery. International Journal of Pharma Research & Review. 2013;2:41–4.
3. Sevinc Ozakar, R. & Ozakar, E. (2021). Current overview of oral thin films. Turkish Journal of Pharmaceutical Sciences.

Oral Mucosal Dosage Forms & Delivery Systems



Dosage Form Troches

Definition Also referred to as a lozenge, troches are a solid oral dosage form that is designed to dissolve or disintegrate in the mouth. Typically intended to provide local action in the oral cavity or throat, but can also provide systemic effect after dissolution or swallowing¹.

Rapid Dissolve Tablets

Also referred to as oral disintegrating tablets, rapid dissolve tablets (RDTs) are a solid dosage form intended to disintegrate quickly within the mouth to provide dispersion before patient swallows the resulting slurry where the substance is intended for gastrointestinal (GI) delivery¹.

Oral Transmucosal Films

Oral Transmucosal Films (OTFs) are thin sheets that are placed in the oral cavity and formulated to facilitate absorption through the proximal mucosal membranes (buccal or sublingual) avoiding first-pass metabolism or degradation in the GI tract, providing a quick onset of action¹.

Suggested Use Longer disintegration for local action in mouth and throat before swallowing (GI absorption)

Fast disintegration, with some mucosal absorption before swallowing (GI absorption)

Rapid disintegration time combined with mucoadhesion for absorption across the proximal mucosa

Delivery System Medisca Troche Base

Base Description Water-soluble blend of polyethylene glycols. Sugar-free and naturally sweetened options.

Medisca Medi-RDT™ Base

Sugar-free, finely granulated powder blend for compounding oral disintegrating tablets.

Medisca NovaFilm™ Gel Base

Versatile concentrated mucoadhesive gel base containing all natural polymers.

Free of Preservatives, Dyes, Sugar, Lactose, and Gluten

✓

✓

Contains preservatives

Water Activity <0.6 (180 BUD)

<0.6 (180 BUD)

<0.6 when dried (180 BUD)

Disintegrating Time >15 minutes

93 seconds

60 seconds

Permeation

In-vitro study comparing the permeation of low-dose naltrexone between troches, RDTs, and OTFs²

Carrying Capacity Max ~ 400 mg per troche when using 0.9 mL mold

Max ~ 200 mg per tablet when using 750 mg mold

Max ~ 50 mg per film when using 1 mL mold

1. United States Pharmacopeia (USP). 2021. General Chapter USP <1151> Pharmaceutical Dosage Forms.

2. 1.De Toni, L., et al. (2018). Sublingual administration of sildenafil oro-dispersible film: New profiles of drug tolerability and pharmacokinetics for PDE5 inhibitors. *Frontiers in Pharmacology*, 59. doi: 10.3389/fphar.2018.00059.

Introducing NovaFilm™

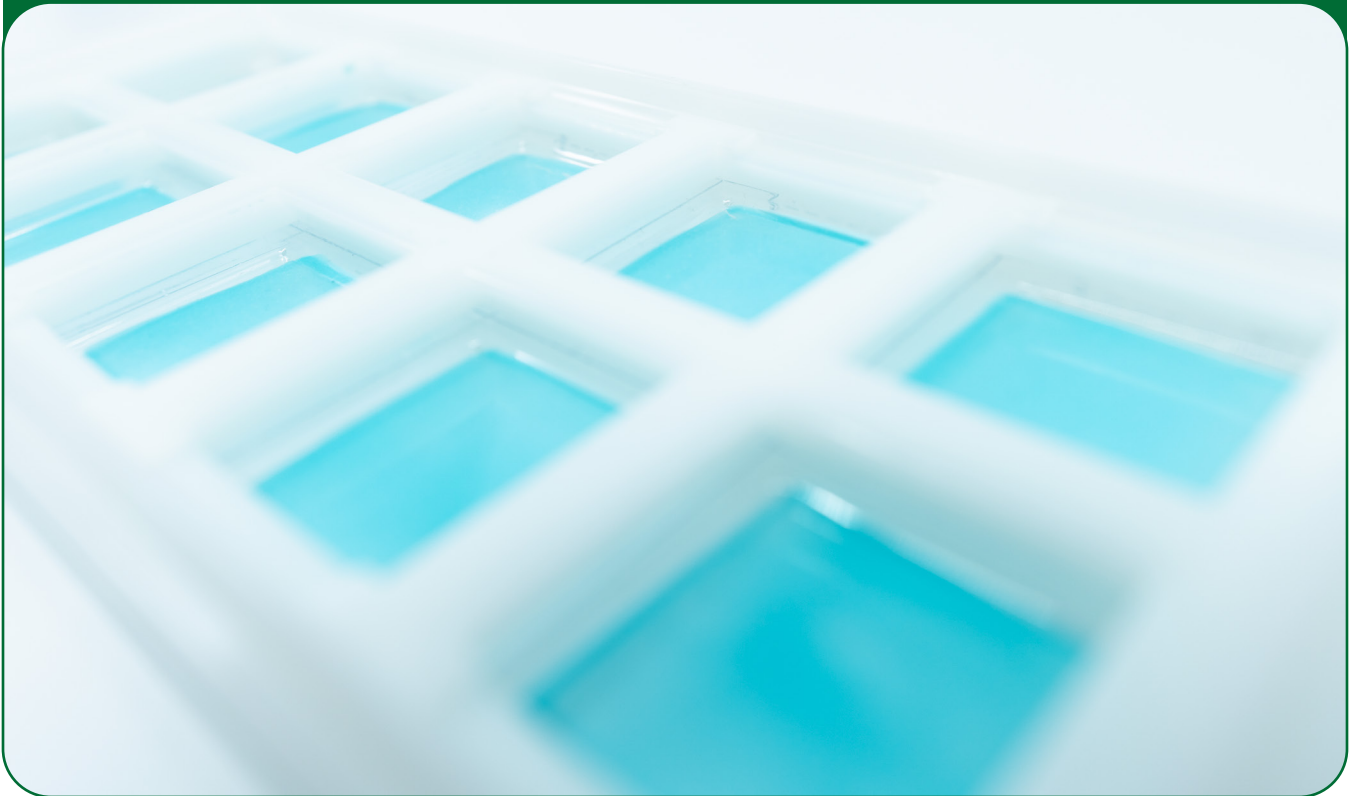
Oral Transmucosal Films

Colliding the power of NovaFilm Gel Base with a cutting-edge molding process, Medisca has not only expanded the capacity of NovaFilm from versatile gel to the oral transmucosal film (Patent Pending) – but has introduced for the first time to compounding markets around the world, this innovative dosage form and revolutionary opportunity for personalized medicine.



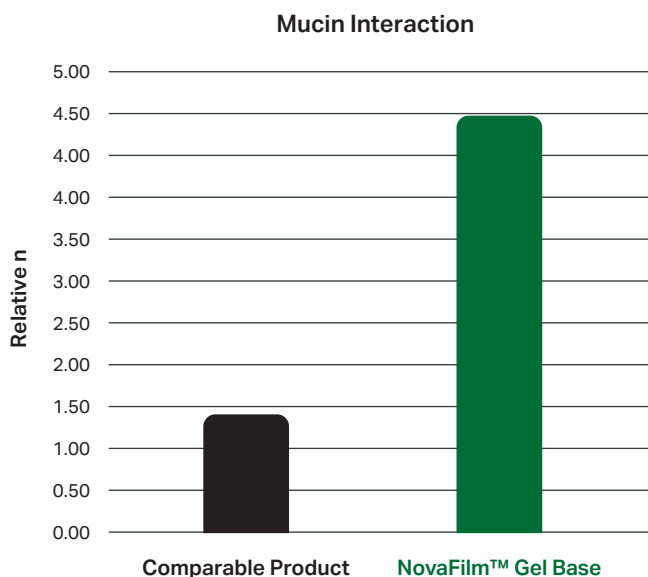
Scan QR Code to Learn More

Product No.: 5498-01



The Base

NovaFilm Gel Base is a concentrated mucoadhesive vehicle consisting of all natural polymers for delivery of active ingredients to mucosal membranes, including oral, nasal, rectal, and vaginal tissues – with demonstrated superior mucoadhesive results relative to comparable products according to in-vitro testing¹.



3x more mucin interaction to help prolong contact time with mucosa

4x more resistance to stress so it can maintain its shape with mucosa

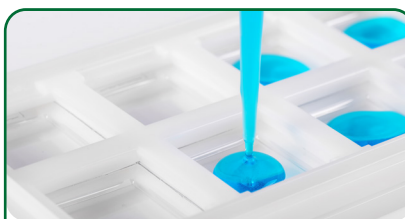
2x the adhesive bond to mucosal surfaces, easily forming a bond even with brief contact

The Molding Process



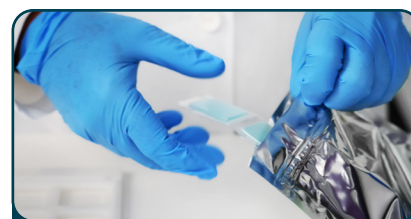
Step 1

Combine active ingredient into the NovaFilm Gel using the Medisca MAZ[®] Mixer or the Luer-Lock Syringe for syringe-to-syringe mixing.



Step 2

Fill the Blister Molds using the Medisca Transfer Pipette with 50 mL loading capacity and 1 mL metered dispensing capability.



Step 3

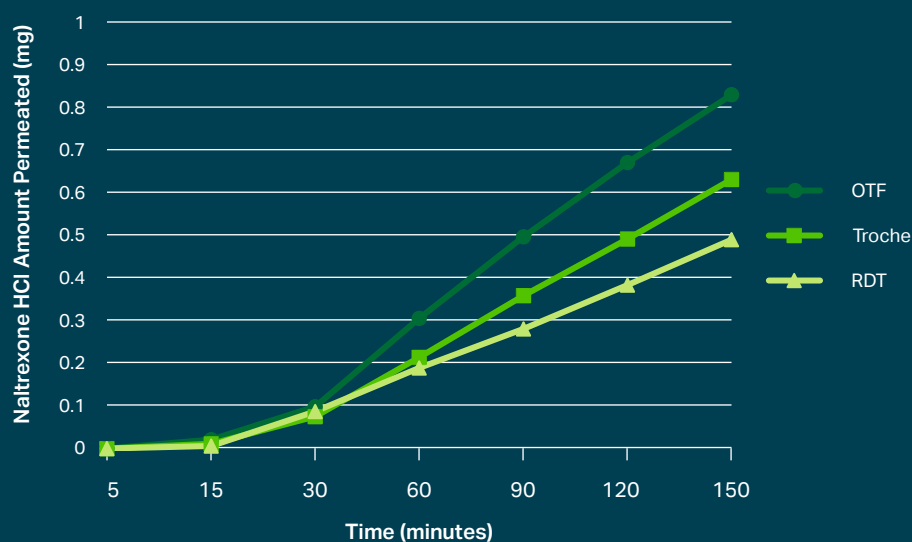
Dry the films by baking the preparation in a convection oven or air dry over night, creating a final anhydrous film with a water activity < 0.6.

1. Medisca Research & Development. (2020). NovaFilm™ rheological and clinical evaluation of a novel concentrated mucoadhesive gel base. A Medisca Technical Report.

The Absorption Potential

To evaluate the permeation profile of OTFs, an in-vitro experiment was conducted using a human-derived epithelial cell model that exhibits in vivo-like morphological and growth characteristics ¹. Naltrexone hydrochloride 4.5 mg OTFs were compounded using NovaFilm Gel Base and evaluated alongside compounded naltrexone hydrochloride 4.5 mg troches and compounded naltrexone hydrochloride 4.5 mg rapid dissolve tablets. The intact dosages were placed directly in the receptor medium in contact with the cells. Permeation aliquots were collected at predetermined time points and evaluated using a validated HPLC method.

Based on the permeation-time curve, the NovaFilm OTF demonstrated the fastest permeation rate and highest permeation percentage among the three tested dosages.



Featured Formulas

F 009 668 Sildenafil 22 mg Oral Transmucosal Films (Solid Suspension, 30 Films) (MAZ)

F 009 669 Progesterone 40 mg Oral Transmucosal Films (Solid Suspension, 30 Films) (MAZ)

F 009 674 Naltrexone Hydrochloride 4.5 mg Oral Transmucosal Films (Solid Suspension, 30 Films) (MAZ)

F 009 712 Oxytocin 40 IU Oral Transmucosal Films (Solid Suspension, 30 Films) (MAZ)

The formulas referenced herein are for information purposes only. Any use thereof should be verified by a licensed pharmacist and based on a duly licensed prescriber's prescription.

1. Epioral and epigingival in vitro 3D tissues. MatTek Life Sciences. (2023, May 12). <https://www.mattek.com/mattekproduct/epioral-epigingival/>

OTFs: An **Innovative Solution** To Your Challenges

Avoid Swallowing

No swallowing or water required with oral transmucosal films (OTFs).

Limit First-Pass Metabolism

Defined by rapid disintegration and mucoadhesion, first-pass metabolism is significantly reduced with OTFs. This may be ideal for drugs that have poor or a large range in oral bioavailability, such as sildenafil¹ and naltrexone².

Achieve Rapid Onset

In-vitro permeation testing reveals that NovaFilm OTFs demonstrate a faster permeation rate and higher permeation percentage relative to troches and rapid dissolve tablets³, which may be desired for therapeutic plans requiring rapid onset, as may be the case with drugs like PDE inhibitors⁴ and ondansetron⁵.

Solution for Heat Labile Actives

With the option to air dry preparations overnight, NovaFilm OTFs are an ideal transmucosal dosage form for active ingredients that are heat labile, such as oxytocin⁶.

Patient Non-Adherence

Personal preference is a huge consideration for achieving the best patient adherence. Thin oral transmucosal films are discrete and durable.

Longer Therapeutic Durations

With a default beyond-use date (BUD) limit of 180 days, NovaFilm OTFs are ideal for longer therapeutic plans that require extended dating.

1. Gupta M, Kovar A, Meibohm B. (2005). The clinical pharmacokinetics of phosphodiesterase-5 inhibitors for erectile dysfunction. *J. Clin. Pharmacol.* 45 987–1003. doi: 10.1177/0091270005276847.
2. 1.Tolijan, K. & Vrooman, B. (2018). Low-dose naltrexone (LDN) – Review of therapeutic utilization. *Medical Sciences*, 82. doi: 10.3390/medsci6040082.
3. Medisca. (2023). Assessment of the absorption potential of naltrexone 4.5 mg OTF, Troche, and RDT using a human-derived tissue model.
4. 1.De Toni, L., et al. (2018). Sublingual administration of sildenafil oro-dispersible film: New profiles of drug tolerability and pharmacokinetics for PDE5 inhibitors. *Frontiers in Pharmacology*, 59. doi: 10.3389/fphar.2018.00059.
5. 1.Griddine, A. & Bush, J.S. (2023). Ondansetron. *StatPearls*. Retrieved from: <https://www.ncbi.nlm.nih.gov/books/NBK499839/>
6. 1.Zhu, C. et al. (2018). Heat-stable sublingual oxytocin tablets as a potential needle-free approach for preventing postpartum hemorrhage in low-resource settings. *Drug Delivery and Translational Research*, 8, 853-856.



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compounding pharmacy today!**

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