

# COMPOUNDING FOR **HORMONE RESTORATION THERAPY**



# INTRODUCTION



No longer are the days where women are treated simply with estrogen therapy for their menopausal symptoms. Treatment has become more complex and all encompassing. Patients want relief of more than simply hot flashes; they want to address concerns with decreased libido, vaginal dryness, weight fluctuations, memory loss, sleep disturbances, menstrual irregularities and muscle mass depletion, just to name a few. However, hormone restoration therapy (HRT) doesn't only apply to women; men often experience hormone imbalances, and subsequent symptoms, which are sometimes referred to as "Andropause". HRT and corresponding lab monitoring should be considered in all males experiencing such symptoms. Along with addressing imbalances and dominance issues with sex hormones, the thyroid and adrenals have to be considered as well.

Some of the most common challenges prescribers seem to face when dealing with HRT on a daily basis include:

- **What is the best way to approach treatment?**
- **How can prescribers effectively treat and control HRT in such a way that gives their patients the safest and most effective dosing and delivery method possible?**

In approaching treatment for HRT, it is crucial to remember the following key elements:

- **To Restore:** By incrementally adding the minimum amounts of any hormone required in an attempt to reduce or eliminate symptomatology, replenish deficiencies or prevent the onset of age-related diseases.
- **To Balance:** By restoring the correct amount of one hormone, always taking into account its impact and further need for other hormones, and always considering the overall homeostatic mechanism.
- **To Pattern:** By determining the need for cyclic versus continuous dosing. Avoid off-setting naturally occurring rhythms, by replacing deficiencies and bringing balance to the overall homeostatic mechanism.
- **To Adjust:** By regularly monitoring subjective symptoms and performing objective tests on hormone levels to minimize dosing, while striving to achieve the best possible therapeutic outcome. Be cognizant of your ever moving target and when treatment should end.
- **To Minimize:** By applying the minimum amount of hormones necessary to achieve the maximum therapeutic outcome, never neglecting the potential for long-term side effects.



Ⓢ = Controlled Substance

After the correct approach to HRT for a patient is determined, the next step becomes treatment. Commercially available products are limited to fixed doses of conjugated estrogens and progestins/progesterone, as well as Testosterone Ⓢ therapy, primarily intended for males. More often than not, the correct delivery method or hormone needed, such as DHEA Ⓢ and Pregnenolone, is commercially unavailable. Not all patients are alike, so how can we provide treatment that is best suited for them? The simplest and most applicable solution is the prescribing of compounded medications. Compounded medications allow for customization for the individual patient. This allows prescribers to follow all of the key elements of treating HRT without compromise.

- **Dosing:** Lowest effective dose can be prescribed for that patient, without having to worry about the fixed dosing increments set by commercial products.
- **Delivery method:** Compounded preparations allow for the option of several dosage forms that will be best suited for the patient's symptoms and preference, such as capsules, troches, lozenges, creams, injections, suppositories and vaginal applicators.
- **Convenience:** Multiple hormones can be combined into one preparation for a patient, to minimize multiple medications having to be administered.
- **Compliance:** Since compounded prescriptions allow for total customization for the individual patient, bases and excipients can be changed to meet allergy or sensitivity issues, not to mention that patients can choose flavours of their choice for products, such as lozenges and troches, where commercial products do not allow for these accommodations. Also, by providing the correct dose and delivery method most convenient and applicable to the patient, this helps to increase patient compliance for successful HRT.

# COMMON FEMALE SYMPTOMS ASSOCIATED WITH HORMONE IMBALANCES



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HORMONE SYMPTOMS	INCREASED HORMONE LEVELS ↑	DECREASED HORMONE LEVELS ↓	FLUCTUATING HORMONE LEVELS ↑↓
Acne	DHEA Ⓢ, Testosterone Ⓢ	Estrogen	Progesterone
Anxiety	DHEA Ⓢ, Cortisol, Testosterone Ⓢ		Progesterone
Apathy	Estrogen	DHEA Ⓢ, Cortisol, Testosterone Ⓢ	
Breast Tenderness	Estrogen	Thyroid	Progesterone
Concentration (Decreased)	Cortisol	DHEA Ⓢ, Estrogen, Progesterone, Thyroid	
Depression	Cortisol	DHEA Ⓢ, Progesterone, Testosterone Ⓢ, Thyroid	Estrogen
Dry Eyes		Estrogen, Thyroid	
Dry Skin and Hair		DHEA Ⓢ, Estrogen, Testosterone Ⓢ, Thyroid	
Fatigue		Cortisol, DHEA Ⓢ, Estrogen, Testosterone Ⓢ, Thyroid	
Fibrocystic Breast	Estrogen	Progesterone, Thyroid	
Fluid Retention	Estrogen, Cortisol		Progesterone
Foggy Mind	Progesterone	Estrogen, Testosterone Ⓢ, Thyroid	
Hair Growth (Body and Face)	Insulin	Estrogen, Progesterone	Testosterone Ⓢ
Hair Loss	DHEA Ⓢ, Testosterone Ⓢ	Estrogen, Thyroid	
Headaches		Testosterone Ⓢ, Thyroid	Estrogen, Progesterone
Hot Flashes	Insulin	Estrogen, Progesterone, Thyroid	
Irritability	DHEA Ⓢ, Cortisol, Estrogen, Testosterone Ⓢ	Progesterone	
Joint Pains		Cortisol, Estrogen, Testosterone Ⓢ, Thyroid	
Memory Problems	Cortisol	DHEA Ⓢ, Estrogen, Testosterone Ⓢ	
Mood Swings	Cortisol, Testosterone Ⓢ		Estrogen, Progesterone
Night Sweats		Estrogen, Progesterone, Thyroid	
Painful Intercourse		Estrogen, Progesterone, Testosterone Ⓢ	
Salt Cravings		Cortisol, DHEA Ⓢ	
Sex Drive (Decreased)	Cortisol	DHEA Ⓢ, Progesterone, Testosterone Ⓢ, Thyroid	Estrogen
Sexual Sensation (Decreased)		DHEA Ⓢ, Estrogen, Progesterone, Testosterone Ⓢ	
Sleep Disturbances	Cortisol	Estrogen	Progesterone
Sweet Cravings	Insulin	Cortisol, Progesterone	
Thinning of Skin	Cortisol	DHEA Ⓢ, Estrogen, Testosterone Ⓢ, Thyroid	
Urinary Incontinence	Estrogen, Progesterone, Testosterone Ⓢ		
Vaginal Dryness	Estrogen, Progesterone, Testosterone Ⓢ		
Weight Gain	Cortisol, DHEA Ⓢ, Estrogen, Insulin, Testosterone Ⓢ	Thyroid	Progesterone



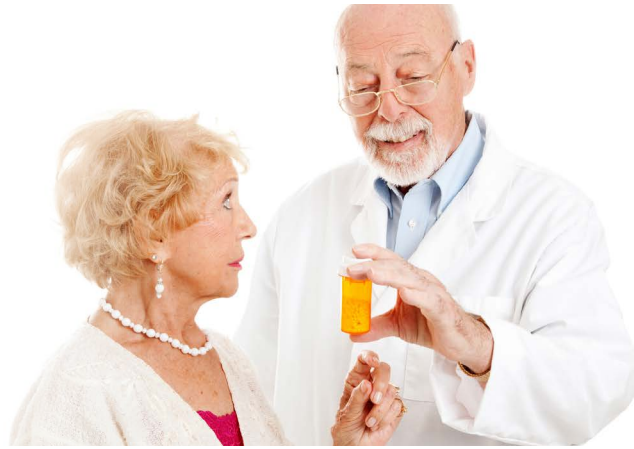
# COMMON MALE SYMPTOMS ASSOCIATED WITH HORMONE IMBALANCES



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HORMONE SYMPTOMS	INCREASED HORMONE LEVELS ↑	DECREASED HORMONE LEVELS ↓
Anxiety	DHEA Ⓢ, Estrogen	
Apathy	Estrogen	DHEA Ⓢ, Testosterone Ⓢ
Burned Out Feeling	Estrogen	DHEA Ⓢ, Testosterone Ⓢ, Thyroid
Bone Loss	Estrogen	Testosterone Ⓢ
Cold Extremities		Estrogen, Testosterone Ⓢ, Thyroid
Concentration (Decreased)	Testosterone Ⓢ	Estrogen, Thyroid
Confusion	Estrogen	Thyroid
Constipation	Insulin	Thyroid
Depression		Thyroid
Fatigue		DHEA Ⓢ, Testosterone Ⓢ, Thyroid
Fluid Retention	Estrogen	Thyroid
Hair Loss		Testosterone Ⓢ
Headaches		Thyroid
Joint Pains		DHEA Ⓢ, Testosterone Ⓢ, Thyroid
Morning Erections (Decreased)	Estrogen	DHEA Ⓢ, Testosterone Ⓢ
Muscle Mass (Decreased)		DHEA Ⓢ, Testosterone Ⓢ
Muscle Pain		DHEA Ⓢ, Testosterone Ⓢ, Thyroid
Night Sweats		Thyroid
Salt Cravings		DHEA Ⓢ
Sex Drive (Decreased)	Estrogen	DHEA Ⓢ, Testosterone Ⓢ
Sweet Cravings	Insulin	
Sleep Disturbances		Thyroid
Urinary Retention	Estrogen	Testosterone Ⓢ
Urinary Urgency	Estrogen	Testosterone Ⓢ
Weight Gain	Insulin	Thyroid

# ORAL CAPSULE FORMULATIONS



Ⓢ = Controlled Substance

FORMULA #	FORMULA TITLE	DESCRIPTION	IDEAL DISPENSER	MEDISCA BASE
F 004 657v2	Estradiol 1mg Oral Capsules (Powder Blend, 100 x Size #3 Capsules)	Hormone Restoration Therapy (HRT)	Light-resistant vials	CapsuBlend™-H
F 005 501	Estradiol 0.2mg, Estriol 0.8mg Oral Capsules (Powder Blend, 100 x Size #1 Capsules)	Hormone Restoration Therapy (HRT)	Light-resistant vials	CapsuBlend™-H
F 004 941	Progesterone 25mg Oral Capsules (Powder Blend, 100 x Size #4 Capsules)	Hormone Restoration Therapy (HRT)	Light-resistant vials	CapsuBlend™-P
F 005 533	Progesterone 100mg Oral Capsules (Powder Blend, 100 x Size #2 Capsules)	Hormone Restoration Therapy (HRT)	Light-resistant vials	CapsuBlend™-P
F 001 686v5	Liothyronine 7.5µg Oral Capsules (Powder Blend, 100 x Size #3 Capsules)	Hypothyroid	Light-resistant vials	CapsuBlend™-S
F 000 921v6	Liothyronine 25µg Oral Capsules (Powder blend, 100 x Size #3 Capsules)	Hypothyroid	Light-resistant vials	CapsuBlend™-S
F 004 248v2	Thyroid 65mg Oral Capsules (Powder Blend, 100 x Size #1 Capsules)	Hypothyroid	Light-resistant vials	CapsuBlend™-S
F 005 747v2	Anastrozole 0.1mg Oral Capsules (Powder Blend, 100 x Size #4 Capsules)	Hypogonadism prevention/ treatment in men undergoing exogenous testosterone Ⓢ therapy.	Light-resistant vials	CapsuBlend™-S
F 006 130	Hydrocortisone 5mg Oral Capsules (Powder Blend, 100 x Size #3 Capsules)	Treatment of adrenal fatigue.	Light-resistant vials	CapsuBlend™-P
F 001 567v4	Clomiphene Citrate 50mg Oral Capsules (Powder Blend, 100 x Size #1 Capsules)	Hypogonadism prevention/ treatment in men undergoing exogenous testosterone Ⓢ therapy.	Light-resistant vials	CapsuBlend™-S

# ORAL TROCHE FORMULATIONS



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FORMULA #	FORMULA TITLE	DESCRIPTION	IDEAL DISPENSER	MEDISCA BASE
F 001 629v2	Progesterone 25mg Oral Troches (Solid Suspension, 30 Troches)	Hormone Restoration Therapy (HRT)	Troche mold with sleeve	Troche Base
F 001 384v2	Progesterone 200mg Oral Troches (Solid Suspension, 30 Troches)	Hormone Restoration Therapy (HRT)	Troche mold with sleeve	Troche Base
F 003 719v2	Progesterone 100mg, Testosterone 0.5mg Ⓢ Oral Troches (Solid Suspension, 30 x 0.9mL Troches)	Hormone Restoration Therapy (HRT)	Troche mold with sleeve	Troche Base
F 002 004v2	Oxytocin 10 IU Oral Troches (Solid Suspension, 30 x 0.9mL Troches)	Increasing sex drive and sensation.	Troche mold with sleeve	Troche Base
F 005 037v2	Dehydroepiandrosterone 50mg Ⓢ Oral Troches (Solid Suspension, 150 x 0.9mL Troches)	Hormone Restoration Therapy (HRT)	Troche mold with sleeve	Troche Base
F 001 730v2	Estradiol 0.25mg, Estriol 1mg Oral Troches (Solid Suspension, 60 Troches)	Hormone Restoration Therapy (HRT)	Troche mold with sleeve	Troche Base
F 003 850v2	Estradiol 1mg, Progesterone 175mg, Testosterone 1.25mg Ⓢ Oral Troches (Solid Suspension, 100 x 0.9mL Troches)	Hormone Restoration Therapy (HRT)	Troche mold with sleeve	Troche Base

# RAPID-DISSOLVE TABLET FORMULATIONS

FORMULA #	FORMULA TITLE	DESCRIPTION	IDEAL DISPENSER	MEDISCA BASE
F 005 468v3	Progesterone 100mg Oral Rapid-Dissolve Tablets (Solid Suspension, 96 x 750mg [0.93mL] Tablets)	Hormone Restoration Therapy (HRT)	Medi-RDT Blister Pack	Medi-RDT Base
F 005 469v2	Progesterone 200mg Oral Rapid-Dissolve Tablets (Solid Suspension, 96 x 750mg [0.93mL] Tablets)	Hormone Restoration Therapy (HRT)	Medi-RDT Blister Pack	Medi-RDT Base
F 005 470v2	Testosterone 20mg Ⓢ Oral Rapid-Dissolve Tablets (Solid Suspension, 96 x 750mg [0.93mL] Tablets)	Hormone Restoration Therapy (HRT)	Medi-RDT Blister Pack	Medi-RDT Base
F 005 471v2	Dehydroepiandrosterone 50mg Ⓢ Oral Rapid-Dissolve Tablets (Solid Suspension, 96 x 750mg [0.93mL] Tablets)	Hormone Restoration Therapy (HRT)	Medi-RDT Blister Pack	Medi-RDT Base
F 005 475v2	Estradiol 0.4mg, Estriol 1.6mg Oral Rapid-Dissolve Tablets (Solid Suspension, 96 x 750mg [0.93mL] Tablets)	Hormone Restoration Therapy (HRT)	Medi-RDT Blister Pack	Medi-RDT Base
F 005 472v2	Melatonin 5mg Oral Rapid-Dissolve Tablets (Solid Suspension, 96 x 750mg [0.93mL] Tablets)	Sleep Disturbances/ Insomnia	Medi-RDT Blister Pack	Medi-RDT Base

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# TOPICAL CREAM FORMULATIONS

Extended BUDs available online at [www.medisca.net](http://www.medisca.net)

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FORMULA #	FORMULA TITLE	DESCRIPTION	IDEAL DISPENSER	MEDISCA BASE
F 001 528v3	Progesterone 20% Topical Cream (Emulsion, 20g)	Hormone Restoration Therapy (HRT)	MD™ Dispenser Jar or Pump, Topi-Click	HRT Cream Base
F 003 307v2	Progesterone 30mg/g, Testosterone 4mg/g Ⓢ Topical Cream (Emulsion, 30g)	Hormone Restoration Therapy (HRT)	MD™ Dispenser Jar or Pump, Topi-Click	HRT Cream Base
F 005 386	Dehydroepiandrosterone 25mg/mL Ⓢ, Testosterone 12.5mg/mL Ⓢ Topical Cream (Emulsion, 30mL)	Hormone Restoration Therapy (HRT)	MD™ Dispenser Jar or Pump, Topi-Click	HRT Cream Base
F 002 048v4	Estradiol 5mg/g, Progesterone 10mg/g Topical Cream (Emulsion, 20g)	Hormone Restoration Therapy (HRT)	MD™ Dispenser Jar or Pump, Topi-Click	HRT Cream Base
F 003 097v3	Estradiol 1mg/mL, Estriol 4mg/mL Topical Cream (Emulsion, 5mL)	Hormone Restoration Therapy (HRT)	MD™ Dispenser Jar or Pump, Topi-Click	HRT Cream Base
F 001 208v3	Estradiol 0.05mg/mL, Estriol 0.05mg/mL Topical Cream (Emulsion, 100mL)	Hormone Restoration Therapy (HRT)	MD™ Dispenser Jar or Pump, Topi-Click	HRT Cream Base
F 003 979v2	Estradiol 0.1mg/g, Progesterone 20mg/g, Testosterone 2mg/g Ⓢ Topical Cream (Emulsion, 30g)	Hormone Restoration Therapy (HRT)	MD™ Dispenser Jar or Pump, Topi-Click	HRT Cream Base
F 004 029v3	Estradiol 1mg/g, Estriol 4mg/g, Progesterone 40mg/g Topical Cream (Emulsion, 100g)	Hormone Restoration Therapy (HRT)	MD™ Dispenser Jar or Pump, Topi-Click	VersaPro™ Cream Base
F 004 455v2	Estradiol 0.2mg/mL, Progesterone 20mg/mL Topical Cream (Emulsion, 100mL)	Hormone Restoration Therapy (HRT)	MD™ Dispenser Jar or Pump, Topi-Click	VersaPro™ Cream Base
F 004 546	Progesterone 100mg/mL Topical Cream (Emulsion, 24mL)	Hormone Restoration Therapy (HRT)	MD™ Dispenser Jar or Pump, Topi-Click	VersaPro™ Cream Base
F 004 779	Dehydroepiandrosterone 5% Ⓢ, Testosterone 13.33% Ⓢ Topical Cream (Emulsion, 100mL)	Hormone Restoration Therapy (HRT)	MD™ Dispenser Jar or Pump, Topi-Click	VersaPro™ Cream Base
F 004 540v4	Testosterone 10mg/mL Ⓢ Topical Cream (Emulsion, 100mL)	Hormone Restoration Therapy (HRT)	MD™ Dispenser Jar or Pump, Topi-Click	VersaPro™ Cream Base
F 004 588	Estradiol 0.4mg/mL, Estriol 1.6mg/mL, Testosterone 2mg/mL Ⓢ Topical Cream (Emulsion, 24mL)	Hormone Restoration Therapy (HRT)	MD™ Dispenser Jar or Pump, Topi-Click	VersaPro™ Cream Base
F 004 585v2	Progesterone 187.5mg/mL, Testosterone 5mg/mL Ⓢ Topical Cream (Emulsion, 100mL)	Hormone Restoration Therapy (HRT)	MD™ Dispenser Jar or Pump, Topi-Click	VersaPro™ Cream Base



# TOPICAL GEL FORMULATIONS



Ⓢ = Controlled Substance

FORMULA #	FORMULA TITLE	DESCRIPTION	IDEAL DISPENSER	MEDISCA BASE
F 001 478v2	Testosterone 50mg/mL Ⓢ Topical Gel (Suspension, 25mL)	Hormone Restoration Therapy (HRT)	MD™ Dispenser Jar or Pump, Topi-Click	HRT Gel Base
F 003 036v3	Estradiol 2mg/0.1mL Topical Gel (Suspension, 5mL)	Hormone Restoration Therapy (HRT)	MD™ Dispenser Jar or Pump, Topi-Click	HRT Gel Base
F 005 142v3	Chrysin 15mg/mL, Testosterone 125mg/mL Ⓢ Topical Gel (Suspension, 30mL)	Hormone Restoration Therapy (HRT)	MD™ Dispenser Jar or Pump, Topi-Click	HRT Gel Base
F 001 257v2	Estradiol 0.25mg/g, Estriol 1.0mg/g Topical Gel (Suspension, 60g)	Hormone Restoration Therapy (HRT)	MD™ Dispenser Jar or Pump, Topi-Click	HRT Gel Base
F 002 440v3	Testosterone 0.5% Ⓢ Topical Gel (Emulsion, 100g)	Hormone Restoration Therapy (HRT)	MD™ Dispenser Jar or Pump, Topi-Click	HRT Gel Base
F 005 034	Testosterone 10mg/mL Ⓢ Topical Gel (Suspension, 150mL)	Hormone Restoration Therapy (HRT)	MD™ Dispenser Jar or Pump, Topi-Click	VersaPro™ Gel Base
F 004 903v2	Testosterone 10% Ⓢ Topical Gel (Suspension, 100g)	Hormone Restoration Therapy (HRT)	MD™ Dispenser Jar or Pump, Topi-Click	VersaPro™ Gel Base
F 004 904	Progesterone 15% Topical Gel (Suspension, 100g)	Hormone Restoration Therapy (HRT)	MD™ Dispenser Jar or Pump, Topi-Click	VersaPro™ Gel Base

# VAGINAL SUPPOSITORY FORMULATIONS

FORMULA #	FORMULA TITLE	DESCRIPTION	IDEAL DISPENSER	MEDISCA BASE
F 004 864	Progesterone 50mg Suppositories (Solid Suspension, 100 x 2.4mL Suppositories)	Hormone Restoration Therapy (HRT)	Light-resistant container	SPG Supposi Base™
F 004 865	Progesterone 100mg Suppositories (Solid Suspension, 100 x 2.4mL Suppositories)	Hormone Restoration Therapy (HRT)	Light-resistant container	SPG Supposi-Base™
F 004 866	Progesterone 200mg Suppositories (Solid Suspension, 100 x 2.4mL Suppositories)	Hormone Restoration Therapy (HRT)	Light-resistant container	SPG Supposi-Base™
F 005 065	Estradiol 2mg, Progesterone 100mg Vaginal Suppositories (Solid Suspension, 100 x 2.0mL Suppositories)	Hormone Restoration Therapy (HRT)	Light-resistant container	SPG Supposi-Base™
F 004 432v3	Boric Acid 600mg Vaginal Suppositories (Solid Suspension, 30 x 1.9g [1.775mL] Suppositories)	Treatment of vaginal disturbances such as those due to pH imbalances, yeast or bacterial infections.	Light-resistant container	SPG Supposi-Base™

# VAGINAL CREAM FORMULATIONS

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FORMULA #	FORMULA TITLE	DESCRIPTION	IDEAL DISPENSER	MEDISCA BASE
F 002 573v2	Estradiol 0.05mg/mL Vaginal Cream (Emulsion, 8mL)	Hormone Restoration Therapy (HRT) for Vaginal Symptoms	MD™ Dispenser Jar, Vaginal Applicators	HRT Cream Base
F 003 592v2	Estriol 3mg/g Vaginal Cream (Emulsion, 30g)	Hormone Restoration Therapy (HRT) for Vaginal Symptoms	MD™ Dispenser Jar, Vaginal Applicators	HRT Cream Base
F 004 468	Estradiol 0.01%, Testosterone 0.1% Ⓢ Vaginal Cream (Emulsion, 100g)	Hormone Restoration Therapy (HRT) for Vaginal Symptoms	MD™ Dispenser Jar, Vaginal Applicators	HRT Cream Base
F 001 300v3	Estradiol 0.15mg/0.1mL, Estriol 0.15mg/0.1mL Vaginal Cream (Emulsion, 40mL)	Hormone Restoration Therapy (HRT) for Vaginal Symptoms	MD™ Dispenser Jar, Vaginal Applicators	HRT Cream Base
F 002 461v3	Estradiol 0.625mg/mL Vaginal Cream (Emulsion, 4mL)	Hormone Restoration Therapy (HRT) for Vaginal Symptoms	MD™ Dispenser Jar, Vaginal Applicators	HRT Cream Base
F 000 875v2	Testosterone 1% Ⓢ Vaginal Cream (Emulsion, 30mL)	Hormone Restoration Therapy (HRT) for Vaginal Symptoms	MD™ Dispenser Jar, Vaginal Applicators	VersaPro™ Cream Base
F 000 876v2	Estriol 0.5% Vaginal Cream (Emulsion, 30mL)	Hormone Restoration Therapy (HRT) for Vaginal Symptoms	MD™ Dispenser Jar, Vaginal Applicators	VersaPro™ Cream Base
F 000 786v2	Progesterone 1% Vaginal Cream (Emulsion, 100mL)	Hormone Restoration Therapy (HRT) for Vaginal Symptoms	MD™ Dispenser Jar, Vaginal Applicators	VersaPro™ Cream Base
F 001 991v4	Estriol 3mg/5mL Vaginal Cream (Emulsion, 25mL)	Hormone Restoration Therapy (HRT) for Vaginal Symptoms	MD™ Dispenser Jar, Vaginal Applicators	VersaPro™ Cream Base
F 001 591v4	Progesterone 30mg/5mL, Testosterone 2mg/5mL Ⓢ Vaginal Cream (Emulsion, 140mL)	Hormone Restoration Therapy (HRT) for Vaginal Symptoms	MD™ Dispenser Jar, Vaginal Applicators	VersaPro™ Cream Base

# VAGINAL CAPSULE FORMULATION

FORMULA #	FORMULA TITLE	DESCRIPTION	IDEAL DISPENSER	MEDISCA BASE
F 004 860v2	Boric Acid 600mg Vaginal Capsules (Powder Blend, 100 x Size #00 Capsules)	Treatment of vaginal disturbances such as those due to pH imbalances, yeast or bacterial infections.	Light-resistant vials	N/A

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# RDT KIT



**RAPID  
DISSOLVE TABLET**

## **COMPREHENSIVE RDT KIT**



Now is the time to take your compounding practice to the next level by offering your patients MEDISCA'S new Rapid Dissolve Tablet. Our innovative RDT Kit contains everything you need to get started and help you accommodate to your customer needs and expand your competitive edge.

## **QUICK JUST BECAME *FASTER!***

*"The new RDT mold worked wonderfully! It is easier to fill, clean and it bakes for ½ the time of the others we have tried. In addition, the switch over was made without hassle, there was no need to change our current formula. We are very pleased with the results and excited that we have been able to reduce the compounding time."*

MATTHEW BERNSTEIN, R.P.H., HM COMPOUNDING

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Encapsulation  
Made Easy

## BASES

## CAPSUBLEND® EXCIPIENTS



Proven to be the most versatile of dosage forms for over a century, capsules have always played an important role in drug delivery for pharmaceutical applications. However, their preparation has not always been evident and can most often be time consuming. To minimize the headache of excipient selection and blend preparation, while ensuring a higher level of efficacy, MEDISCA has designed a unique line of products: **CapsuBlend® Excipients**. Based on the Biopharmaceutical Classification System (1995), which categorizes drugs mainly according to their solubility amongst other properties, **CapsuBlend® Excipients** represent a conceptual breakthrough for the compounding industry. Our customized, ready-to-use formulations for poorly soluble, highly soluble, or hygroscopic drugs act as the perfect fillers for immediate-release capsules.

*Want to know how **CapsuBlend® Excipients** are more effective? Check out MEDISCA's article published in the International Journal of Pharmaceutical Compounding (Sept/Oct 2013) to find out! Study is available on [medisca.com](http://medisca.com)*

## FEATURES & BENEFITS

- ENHANCED DRUG DISSOLUTION
- IMPROVED CHEMICAL STABILITY
- INCREASED EFFICIENCY
- REDUCED STATIC OF ACTIVES
- LACTOSE-FREE

*" I really enjoy compounding with MEDISCA's **CapsuBlend®** products. They render the final mixture much more homogenous and aesthetically pleasing. Also, to ensure that these products do in fact dissolve more quickly, I conducted comparative tests using other excipients from a competitor. Results showed that **CapsuBlend®** dissolved faster, while the competitor's formed a paste. "*

**JEANNINE MATTE, R.Ph. – Owner Pharmacist**



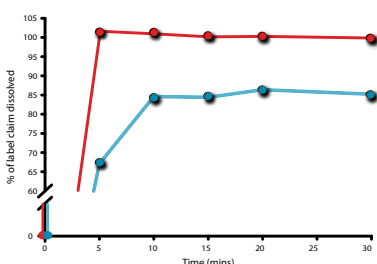


## From a dissolution point of view...

To demonstrate the importance of excipient selection and drug compatibility, MEDISCA partnered up with Pharmatest Laboratories, a Pharmaceutical testing laboratory with 25+ years of experience in providing analytical services. A comparative study was established between MEDISCA's **CapsuBlend® Excipients** and Lactose Monohydrate, a widely preferred non-specific excipient. Although commonly used, Lactose is known to provide poor powder blend flowability and to interact negatively with various drug actives.

### THE RESULT : Enhanced USP – compliant drug dissolution profiles with CapsuBlend®

Comparative drug release profiles of Levocarnitine 250mg capsules in **CapsuBlend®-H** versus Lactose Monohydrate



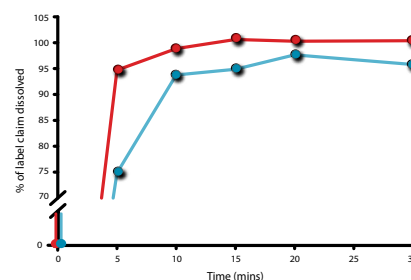
**CapsuBlend®-H resists moisture sorption and provides the stability needed for proper efficacy**

**CapsuBlend®-H** offered a statistically significantly greater dissolution of Levocarnitine when compared to capsules filled with Lactose Monohydrate with  $p < 0.05$ . Due to chemical incompatibility and instability between Lactose and Levocarnitine, capsules with Lactose showed a low dissolution efficiency.

**CapsuBlend®-P enhances dissolution by improving solubility**

This unique premixed blend promotes a faster drug dissolution by improving the solubility of poorly soluble actives such as Theophylline. **CapsuBlend®-P** enabled a superior dissolution of Theophylline when compared to capsules filled with Lactose Monohydrate with  $p < 0.05$ .

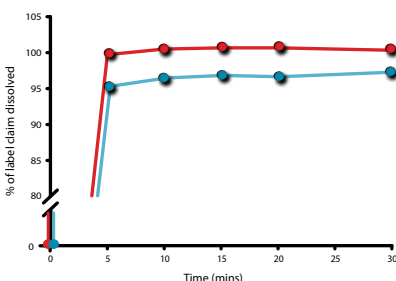
Comparative drug release profiles of Theophylline 100mg capsules in **CapsuBlend®-P** versus Lactose Monohydrate



**CapsuBlend®-S provides desired disintegration without impeding dissolution**

MEDISCA's premixed blend for soluble drugs allowed for an improved dissolution of Metronidazole when compared to the capsules compounded with Lactose Monohydrate as a filler. The difference in performance is statistically significant with  $p < 0.05$ .

Comparative drug release profiles of Metronidazole 250mg capsules in **CapsuBlend®-S** versus Lactose Monohydrate





Ⓢ = Controlled Substances

Ⓝ = Narcotics

# CAPSUBLEND™ Excipients

## Compatibility List

<b>CAPSUBLEND™ -H</b> For Hygroscopic Soluble Actives	<b>CAPSUBLEND™ -P</b> For Poorly Soluble Actives	<b>CAPSUBLEND™ -S</b> For Highly Soluble Actives
Betahistine HCl Cyanocobalamin Diclofenac Sodium Estradiol Lecithin Levocarnitine Levothyroxine Na Metformin HCl Naltrexone HCl Phentermine HCl Ⓢ Pilocarpine HCl Potassium Citrate Penicillamine Praziquantel Ranitidine HCl Tetracycline HCl	7-Keto-DHEA Ⓢ Carbamazepine Cisapride Cyclosporine A Dehydroepiandrosterone (DHEA) Ⓢ Flurbiprofen Glipizide Griseofulvin Haloperidol Ibuprofen Itraconazole Melatonin Medroxyprogesterone Mercaptopurine Methoxsalen Progesterone Pyrantel Pamoate Sulfadiazine Spironolactone Tamoxifen Theophylline Tinidazole Trilostane Ursodiol Zaleplon	Amiloride Amitriptyline HCl Ascorbic Acid Atenolol Atropine Captopril Cimetidine Ciprofloxacin HCl Clonidine HCl Cyclophosphamide Diltiazem HCl Enalapril Maleate Finasteride Fluconazole Fluoxetine HCl Folic Acid Guaifenesin Hydrocodone Bitartrate Ⓝ Ketamine HCl Ⓝ Levofloxacin Hemihydrate Liothyronine Na Meclizine Metoclopramide HCl Metoprolol Tartate Metronidazole Papaverine HCl Procarbazine HCl Promethazine HCl Propranolol HCl Oxycodone Ⓝ Quinine Reserpine Succimer (DMSA) Thyroid Tramadol HCl Tranexamic Acid

This classification accounts for all Biopharmaceutical Classification System (BCS) properties including drug solubility and permeability. High solubility is defined when the highest dose strength is soluble in 250mL or less of aqueous media over a pH range of 1 – 7.5 at 37°C or 98.6°F and high permeability is defined as more than 90% of the dose absorbed. For more details, you may contact one of our Technical Support Services representatives.

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# Where Quality Meets Dual Route Efficiency



## BASES

## SPG SUPPOSI-BASE™



Having difficulties breaking apart your current suppository base? Do you often find yourself waiting a long time for it to melt? The MEDISCA **SPG Supposi-Base™** is your solution! This amphiphilic base enhances the solubility and bioavailability of drug actives in a quick and simplified manner without the need for mold lubrication. Composed of Saturated Polyglycolysed Glycerides of strictly vegetable and petrochemical origin, the **SPG Supposi-Base™** pure white pellets bring together quality & efficiency in rectal and vaginal suppository compounding.

### FEATURES & BENEFITS

<b>APPEARANCE</b>	Pure white soft pellets
<b>FUNCTIONS</b>	Enables solubilization and absorption enhancement of drug actives in rectal and vaginal suppositories without the need for mold lubrication. Exhibits excellent mold release characteristics.
<b>INTENDED USE</b>	Efficient pharmaceutical compounding of rectal and vaginal suppositories
<b>MELTING RANGE</b>	35 to 37°C (95 to 98.6°F)
<b>DENSITY</b>	On average 0.963g/mL at 40°C
<b>SOLUBILITIES AT 20°C</b>	<ul style="list-style-type: none"> <li>– Insoluble in Ethanol 96 and Mineral Oils</li> <li>– Freely soluble in Chloroform and Methylene Chloride</li> <li>– Dispersible in Water</li> </ul>
<b>PELLET WEIGHT</b>	115 to 145mg
<b>SAFETY ASSESSEMENT</b>	Very low to no irritation profile*

DISCLAIMER : \*May result in burning sensation in some uses when combined with certain active ingredients. For prescription compounding. MEDISCA makes no representation and takes no responsibility for the clinical or therapeutic use of this product with or without active ingredients. The pharmacist is hereby advised to use this product in accordance with a licensed prescriber's prescription. MEDISCA cannot be held liable to any person or entity concerning claims, loss or damages caused by or alleged to be caused by the use or misuse of the information contained in this suggested product information sheet.



## BASES

## HRT CREAM BASE



MEDISCA's **HRT Cream Base** is a scientifically advanced oil-in-water emulsion developed for use as a topical or vaginal delivery system for hormones. Primarily used for women, this versatile base can also be used for men. **HRT Cream Base** exhibits great moisturizing and penetration enhancing capabilities; it is highly absorbent and is specially designed with an emollient to help soften skin.

### FEATURES & BENEFITS


<b>SCIENTIFIC DATA</b>	Validated Beyond-Use-Dates (BUDs) available
<b>API COMPATIBILITY</b>	For lipophilic drugs only
<b>APPEARANCE</b>	<ul style="list-style-type: none"> <li>– Smooth white cream. Non-greasy, non-sticky and non-scented</li> <li>– Free of alcohol, petrolatum and oil</li> </ul>
<b>INTENDED USE</b>	<ul style="list-style-type: none"> <li>– Pharmaceutical : Suitable vehicle for hormones</li> <li>– Cosmetic : Can be used as a standalone cosmetic moisturizer containing Vitamin E and Aloe Vera</li> <li>– Compatible with Hydroquinone, Retinoic Acid, Tretinoin</li> </ul>
<b>TOLERANCE TO SALT FORMS OF APIs</b>	Very low
<b>APPLICATION ON MUCOUS MEMBRANE</b>	Yes
<b>HEAT SENSITIVITY</b>	Stable at 45°C (113°F)
<b>PRESERVATIVE EFFECTIVENESS</b>	Passes USP microbial challenge test <51>

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**IN VITRO SKIN STUDIES  
AND BUD RESULTS**

**VERSAPRO™  
CREAM BASE**



 With its great carrying capacity and excellent emollient characteristics, MEDISCA's **VersaPro™ Cream Base** is ideal for both pharmaceutical and cosmetic purposes. Its versatility relates in part to its increased pH stability and excellent compatibility with a wide range of active pharmaceutical ingredients. This unique oil-in-water emulsion is non-greasy, non-irritant and paraben-free. **VersaPro™** is a highly moisturizing cream formulated with excellent penetrating properties.

**FEATURES & BENEFITS**

<b>SCIENTIFIC DATA</b>	<ul style="list-style-type: none"> <li>– Increased permeation of Progesterone through the skin (<i>DPSI, January 2010</i>)</li> <li>– Validated Beyond-Use-Dates (BUDs) Available</li> <li>– Scientifically Classified as an All-Day Moisturizer</li> </ul>
<b>API COMPATIBILITY</b>	For lipophilic and hydrophilic drugs (hormones, analgesics, etc.)
<b>APPEARANCE</b>	White, smooth, versatile cream
<b>INTENDED USE</b>	<ul style="list-style-type: none"> <li>– Pharmaceutical : Highly penetrating transdermal delivery vehicle</li> <li>– Cosmetic : Non-comedogenic moisturizer containing Vitamin E and Aloe Vera</li> </ul>
<b>pH STABILITY</b>	pH 2 to 12
<b>TOLERANCE TO API BASE &amp; SALT FORMS</b>	Excellent
<b>APPLICATION TO MUCOUS MEMBRANES</b>	Yes
<b>HEAT SENSITIVITY</b>	Stable at 45°C (113°F)
<b>PRESERVATIVE EFFECTIVENESS</b>	Passes USP microbial challenge test <51>



## In vitro skin studies on MEDISCA formulations

### SUPERIOR PERFORMANCE OF VERSAPRO™ COMPARED TO COMPETITOR'S CREAM BASE

## INTRODUCTION

Realizing the critical role of drug penetration and skin retention involved in transdermal applications, MEDISCA has taken a unique approach towards formulation development by testing and comparing its products to today's leading cream bases. To achieve this goal, MEDISCA partnered up with Dow Pharmaceutical Sciences Inc. (DPSI), a topical product development company with 25+ years of experience interpreting *in vitro* data. DPSI specifically studied the *in vitro* percutaneous absorption of (<sup>14</sup>C)-Progesterone from nine transdermal delivery vehicles, including MEDISCA's own VersaPro™ Cream Base. The study was conducted by using the Bronaugh flow-through diffusion cell method (see Figure 1) and human excised skin from a single Caucasian female donor following elective abdominal surgery. In fact, results from *in vitro* studies using this particular tissue preparation are typically less variable and more reproducible than *in vitro* studies using human cadaver skin preparations.



Figure 1. Bronaugh Flow-Through Cells. 2010 DPSI. Available at [www.dowpharmascl.com](http://www.dowpharmascl.com)

## METHODS

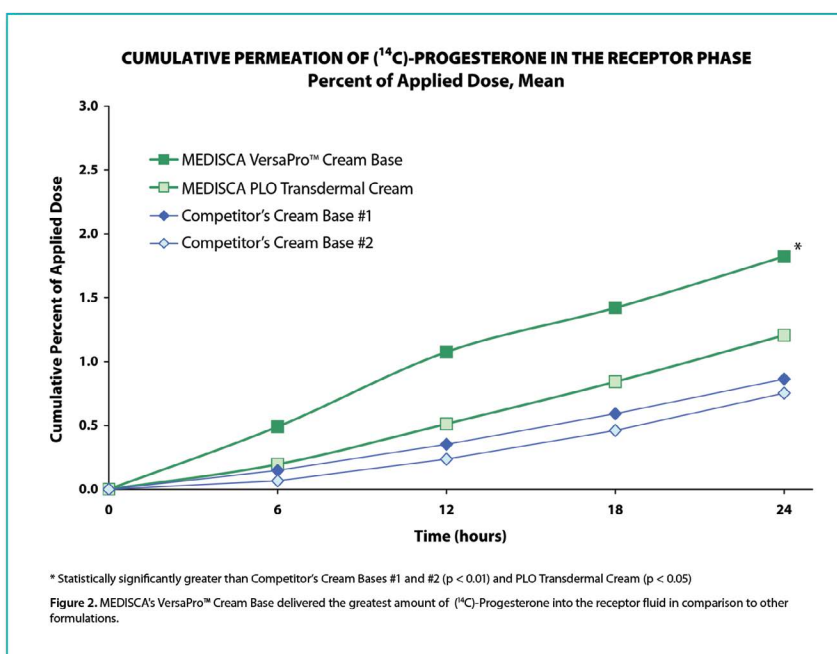
All formulations evaluated in this study were equally spiked with sufficient (<sup>14</sup>C)-Progesterone to achieve a nominal formulation dose of 1.0μCi/3.2mg per diffusion cell, which corresponds to a topical application of 5mg formulation per cm<sup>2</sup> of tissue. This clinically relevant dose was dispensed onto dermatomed skin tissue (0.028 ± 0.004 inches), and was left undisturbed for a 24-hour exposure period. The 54 flow-through diffusion cells were maintained at a constant temperature of 32°C by use of recirculating water baths. Fresh receptor phase buffered solution was continuously pumped under the tissue at a flow rate of 1.0mL/hr and collected in 6-hour intervals. Over the 24-hour period, the amount of (<sup>14</sup>C)-Progesterone residing in the receptor phase samples was quantified using liquid scintillation analyzing techniques to determine the cumulative permeation of (<sup>14</sup>C)-Progesterone.

## RESULTS

Following a 24-hour period, MEDISCA's VersaPro™ Cream Base delivered significantly more (<sup>14</sup>C)-Progesterone relative to the Competitor's Cream Bases and PLO Transdermal Cream (1.82% of the applied dose).

In addition, VersaPro™ Cream Base displayed a more rapid rate of (<sup>14</sup>C)-Progesterone delivery over the exposure period.

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 MD Syringe	5mL, 10mL	0.15mL	+/-2%
 MD Jar	50mL	0.5mL	+/-10%
 MD Pump	30mL, 50mL, 80mL, 100mL, 150mL, 200mL, <b>new</b> 240mL	Actuator A: 0.5mL Actuator B: 1.0mL <b>new</b> Actuator C: 1.5mL	+/-5%

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