

# COMPOUNDING FOR DERMATOLOGICAL CONDITIONS





## INTRODUCTION



Treating dermatological conditions in the past seemed to be a long and trying process for both prescribers and patients. Often times, multiple drug therapies were employed and rendered undesirable side effects such as dry, thin, red, peeling and irritated skin. This proved to be very discouraging to patients as they do not want to be bothered with side effects that can be worse than the condition itself. With the recent resurgence of compounding services, prescribers and pharmacists have worked together to find simplified treatment regimens that lead to an increase in patient compliance, by addressing concerns most commonly encountered during treatment with commercial products. Some of the most popular dermatological conditions that have been successfully treated by compounded preparations include, but are not limited to:

- Acne
- Pruritus, such as eczema and psoriasis
- Hair Loss

- Callus and Wart Remover
- Corrective Cosmetic

- Topical Fungus and Rashes
- Anti-Aging

The Advantages of Compounding Dermatological Preparations include:

#### **Dosing**

The therapeutic effective dose can be prescribed without having to worry about the fixed dosing increments set by commercial products.

#### **Topical Composition**

Compounded preparations of several topical compositions, such as creams, lotions, ointments and solutions, allow for the patient, pharmacist and prescriber to determine what will be best suited for both therapeutic effect and patient preference.

#### Convenience

Multiple drugs can be combined into one preparation for the patient to minimize the administration of multiple medications.

#### Compliance

Since compounded prescriptions allow for total customization for the individual patient, bases and excipients can be changed to meet allergy or sensitivity issues and to minimize harsh side effects. Also, by providing the most effective dose, the topical composition most convenient and applicable to the patient, this helps to increase patient compliance for successful treatment of their dermatological concerns.



# **ACNE**



FORMULA #	FORMULA TITLE	DESCRIPTION	MEDISCA BASE
F 006 042	Aloe Vera 0.2%, Tea Tree Oil 5% Topical Cream (Emulsion, 100g)	Moisturizing Acne Control Cream	VersaPro <sup>™</sup> Cream Base
F 005 882	Clindamycin Hydrochloride 2.26%, Hydrocortisone 1%, Salicylic Acid 3% Topical Cream (Emulsion, 30g)	Moisturizing Acne Rosacea Cream	VersaPro™ Cream Base
F 005 883	Salicylic Acid 5%, Spironolactone 5% Topical Cream (Emulsion, 100g)	Moisturizing Hormonal Acne Cream	VersaPro™ Cream Base
F 005 884v2	Sulfur 6% Topical Cream (Emulsion, 100g)	Nighttime Acne Treatment	VersaPro™ Cream Base
F 005 885	Erythromycin 4.0%, Zinc Sulfate 1.056% Topical Cream (Emulsion, 100g)	Treatment for acne and bacterial infections.	VersaPro™ Cream Base

# **PRURITUS**

FORMULA #	FORMULA TITLE	DESCRIPTION	MEDISCA BASE
F 005 886	Coal Tar Solution 10%, Salicylic Acid 10% Topical Ointment (Emulsion, 30g)	Treatment for various types of psoriasis.	Ointment Base (Emulsifying)
F 005 887v2	Betamethasone Dipropionate 0.064%, Calcipotriol 0.005% Topical Cream (Emulsion, 100g)	Treatment for various types of psoriasis.	VersaPro™ Cream Base
F 004 030v3	Hydrocortisone 2% Topical Cream (Emulsion, 100g)	Treatment for mild atopic dermatitis (eczema).	VersaPro™ Cream Base
F 005 888v2	Tacrolimus 0.15% Topical Cream (Emulsion, 100g)	Treatment for moderate to severe atopic dermatitis (eczema).	VersaPro™ Cream Base
F 003 559v2	Coal Tar Solution 10%, Salicylic Acid 2%, Sulfur 4%, Urea 20% Topical Ointment (Emulsion, 120g)	Treatment for various types of psoriasis.	Ointment Base (Emulsifying)
F 005 204	Fluocinolone Acetonide 0.05%, Ketoconazole 2%, Salicylic Acid 6% Topical Shampoo (Suspension, 60mL)	Shampoo treatment for dandruff and scalp psoriasis.	N/A

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FORMULA #	FORMULA TITLE	DESCRIPTION	MEDISCA BASE
F 003 093v2	Betamethasone Sodium Phosphate 0.132%, Finasteride 0.5%, Minoxidil 8% Scalp Lotion (Suspension, 100g)	Treatment for hair loss; ideal for bald areas.	Mediderm™ (Cream Base)
F 005 993v2	Minoxidil 5%, Progesterone 0.025%, Spironolactone 3% Topical Liquid (Solution, 60mL)	Treatment for female pattern baldness.	N/A
F 001 919v3	Minoxidil 3%, Tretinoin 0.025% Topical Liquid (Solution, 60mL)	Treatment of bald areas or maintenance for areas of hair regrowth.	N/A
F 003 527v2	Finasteride 0.1%, Minoxidil 5% Topical Liquid (Solution, 100mL)	Treatment of bald areas or maintenance for areas of hair regrowth.	N/A
F 005 212	Minoxidil 5% Topical Liquid (Solution, 100mL)	Treatment of bald areas or maintenance for areas of hair regrowth.	N/A
F 003 526v2	Finasteride 0.1% Topical Liquid (Solution, 60mL)	Treatment of bald areas or maintenance for areas of hair regrowth.	N/A

# **COSMETIC**

FORMULA #	FORMULA TITLE	DESCRIPTION	MEDISCA BASE
F 001 701v3	Ascorbic Acid 0.01%, Dexamethasone 0.1%, Hydroquinone 5%, Tretinoin 0.1% Topical Cream (Emulsion, 50mL)	Skin brightener, spot and pigment corrector cream.	HRT Cream Base
F 004 544	Lactic Acid 14%, Resorcinol 14%, Salicylic Acid 14% Topical Liquid (Solution, 100mL)	Chemical peel for in-office prescriber administration (aka Jessner's Solution).	N/A

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# CALLUS AND WART REMOVER



FORMULA #	FORMULA TITLE	DESCRIPTION	MEDISCA BASE
F 001 675v2	Podophyllum 5%, Salicylic Acid 5%, Trichloroacetic Acid 5% Topical Liquid (Suspension, 15mL)	Treatment for various types of warts.	N/A
F 004 516	Acyclovir 5%, Lidocaine 2%, Lysine Hydrochloride 0.75% Topical Lip Balm (Solid Suspension, 20g)	Treatment for cold sores and fever blisters.	N/A
F 002 371v2	Salicylic Acid 3%, Urea 20% Topical Lotion (Emulsion, 100g)	Corn or Callus Remover	Mediderm <sup>™</sup> (Cream Base)
F 002 032	5-Fluorouracil 2%, Salicylic Acid 20% Topical Liquid (Suspension, 100mL)	Treatment for various types of warts, such as plantar warts.	N/A
F 002 489	L-Lysine Hydrochloride 6.25% Topical Lip Balm (Solid Suspension, 10g)	Prevention and/or treatment for cold sores/fever blisters.	N/A
F 002 508v2	Acetic Acid 10%, Lactic Acid 10%, Salicylic Acid 10% Topical Liquid (Solution, 10g)	Treatment solution for warts.	N/A

# **TOPICAL FUNGUS/RASH**

FORMULA #	FORMULA TITLE	DESCRIPTION	MEDISCA BASE
F 005 889v2	Cholestyramine 10%, Nystatin 10%, Zinc Oxide 10% Topical Ointment (Suspension, 90g)	Treatment for diaper rash.	OleaBase™ Plasticized
F 005 890v2	Benzoic Acid 6%, Salicylic Acid 3% Topical Ointment (Emulsion, 30g)	Topical treatment for fungal rashes, such as athlete's foot (Whitfield's Ointment).	OleaBase™ Plasticized
F 000 451	Ciclopirox Olamine 8% Topical Nail Lacquer Liquid (Solution, 6.6mL)	Treatment for onychomycosis on fingernails and/or toenails.	N/A
F 004 560	Fluconazole 2%, Salicylic Acid 6% Topical Shampoo (Suspension, 120mL)	Treatment of scalp ringworm.	N/A
F 005 891	Clotrimazole 10%, Urea 20% Topical Ointment (Emulsion, 30g)	Treatment of fungal infections, such as dry and scaly athlete's foot.	OleaBase™ Plasticized
F 005 892	Betamethasone Valerate 0.05%, Miconazole Nitrate 2%, Mupirocin 1% Topical Ointment (Suspension, 30g)	All-purpose nipple ointment for breast feeding.	OleaBase™ Plasticized

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### **ANTI-AGING**



FORMULA #	FORMULA TITLE	DESCRIPTION	MEDISCA BASE
F 005 895	Estriol 0.3%, Progesterone 2%, Retinoic Acid 0.1% Topical Cream (Emulsion, 100g)	Treatment for fine lines, wrinkles and thinning of facial skin.	VersaPro™ Cream Base
F 005 896v2	Ascorbic Acid 3%, Hydroquinone 5%, Kojic Acid 5%, Tretinoin 0.05% Topical Gel (Suspension, 100g)	Exfoliating skin brightener, pigment corrector and wrinkle cream.	VersaPro™ Gel Base
F 005 897v2	Coenzyme Q10 1%, Lipoic Acid 5%, Vitamin E Acetate 5% Topical Cream (Emulsion, 60g)	Antioxidant cream that also reduces fine lines and wrinkles from photo-aged skin.	VersaPro™ Cream Base
F 005 994	Estriol 0.05%, Vitamin E Acetate 200IU/g Topical Cream (Emulsion, 30g)	Anti-aging and anti-oxidant cream to improve skin moisture, elasticity and firmness.	VersaPro™ Cream Base
F 005 898v2	Coenzyme Q10 1% Topical Cream (Emulsion, 100g)	Reduction of fine lines and wrinkles from photo-aged skin.	VersaPro™ Cream Base
F 005 922v2	Dimethylaminoethanol Bitartrate 5% Topical Liquid (Solution, 100mL)	Prevents sagginess and increases skin firmness on face and hands.	N/A

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

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#### **IN VITRO SKIN STUDIES** AND BUD RESULTS

# **VERSAPRO**<sup>™</sup> **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**

SCIENTIFIC DATA	<ul> <li>Increased permeation of Progesterone through the skin (DPSI, January 2010)</li> <li>Validated Beyond-Use-Dates (BUDs) Available</li> <li>Scientifically Classified as an All-Day Moisturizer</li> </ul>
API COMPATIBILITY	For lipophilic and hydrophilic drugs (hormones, analgesics, etc.)
APPEARANCE	White, smooth, versatile cream
INTENDED USE	<ul> <li>Pharmaceutical: Highly penetrating transdermal delivery vehicle</li> <li>Cosmetic: Non-comedogenic moisturizer containing Vitamin E and Aloe Vera</li> </ul>
pH STABILITY	pH 2 to 12
TOLERANCE TO API BASE & SALT FORMS	Excellent
APPLICATION TO MUCOUS MEMBRANES	Yes
HEAT SENSITIVITY	Stable at 45°C (113°F)
PRESERVATIVE EFFECTIVENESS	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 (14C)-Progesterone from nine transdermal delivery vehicles, including MEDISCA's own VersaPro<sup>TM</sup> 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 <a href="https://www.dowpharmasci.com">www.dowpharmasci.com</a>

#### **METHODS**

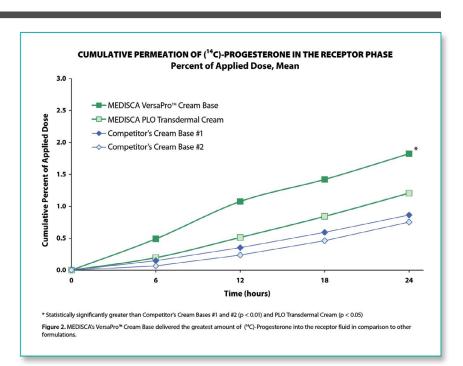
All formulations evaluated in this study were equally spiked with sufficient ( $^{14}$ C)-Progesterone to achieve a nominal formulation dose of  $1.0\mu$ Ci/3.2mg per diffusion cell, which corresponds to a topical application of 5mg formulation per cm² of tissue. This clinically relevant dose was dispensed onto dermatomed skin tissue ( $0.028 \pm 0.004$  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 1.0 mL/hr and collected in 6-hour intervals. Over the 24-hour period, the amount of ( $^{14}$ C)-Progesterone residing in the receptor phase samples was quantified using liquid scintillation analyzing techniques to determine the cumulative permeation of ( $^{14}$ C)-Progesterone.

#### **RESULTS**

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

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

DISCLAIMER: For prescription compounding. MEDISCA makes no representations 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 damage caused by, or alleged to be caused by the use or misuse of the information contained in this suggested product information sheet. The results indicated herein are based upon an independent laboratory study (at DPSI) of comparative skin penetration via percutaneous absorption using excised human skin obtained from elective surgery. No claims or representations are made concerning the uses or advantages of these formulations in the therapeutic setting. Their uses are at the sole discretion and professional judgement of the health care practitioner.





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