WO6[®] Anhydrous Topical Gel

A Base for Elegant Topical Preparations With Prolonged BUDs*

PCCA # 30-5039

For a smooth, pleasing topical with a longer beyond-use date.

WO6 Anhydrous is an elegant, stable base that is suitable for a broad range of dermatological or cosmetic applications, and addresses the emerging needs of the modern compounding industry.

Over the years, compounders and regulators have paid increasing attention to beyond-use-dating criteria for compounded medications. There has been a corresponding desire for extending beyond-use dates (BUDs) to make compounds more efficient for compounders and more convenient for patients. In many specialty areas of compounding, including dermatological, there is simultaneously the need for topical bases that are light, smooth and creamy with a pleasant finish on the skin, and that can accommodate ingredients with poor aqueous stability. PCCA's W06 fulfills all of these criteria.

WO6 has water activity below 0.6 (Aw < 0.6), classifying it as an anhydrous base. This allows for prolonged BUDs by default, and it allows it to accommodate ingredients that are unstable in aqueous environments, such as hydroquinone and ascorbic acid. It is also not tacky or oily, leaving a light, silky feel on the skin that patients will appreciate.

BENEFITS FOR COMPOUNDERS

- Lower operating costs: WO6 allows for prolonged default BUDs without having to spend thousands of dollars on stability testing, and it can increase operational efficiency for compounders making anticipatory batches.
- **Broad application**: WO6 is suitable for a variety of dermatological or cosmetic applications and is capable of accommodating challenging APIs, including hydroquinone and ascorbic acid.



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BENEFITS FOR PATIENTS

- **Convenience:** It is anhydrous, which allows for a longer BUD and less-frequent prescription refills.
- Easy application: WO6 is smooth and creamy, offering a refined cosmetic feel to customized medications without a greasy or tacky residue.
- **Soft skin**: WO6 has emollient properties, moisturizing and softening the skin as it delivers APIs.

Continued on the next page

*According to standards established in the latest version of USP General Chapter 795.

USA: 800.331.2498 pccarx.com | Canada: 800.668.9453 pccarx.ca | Australia: 02.9316.1500 pccarx.com.au | UK: 0800.038.5095 pccarx.co.uk



WO6[®] Anhydrous Topical Gel

RELATED SPECIALTIES

- Dermatology
- Cosmeceuticals

FORMULATED WITHOUT

- Preservatives
- Soy
- Petrolatum/mineral oil
 Gluten

FORMULATION EXAMPLES

- PCCA Formula #13217
 Hydroquinone 4%/Tretinoin 0.05%/Fluocinolone Acetonide
 0.01% Topical Gel (WO6 Anhydrous)
- PCCA Formula #13222

Hydroquinone 6%/Kojic Acid 6%/Hydrocortisone 0.5%/ Tretinoin 0.025% Topical Gel (WO6 Anhydrous)

- PCCA Formula #14148
 Hydroquinone 8%/Kojic Acid 6%/Tranexamic Acid 3%
 Topical Gel (WO6 Anhydrous)
- PCCA Formula #13662 Hydroquinone 12%/Ascorbic Acid 4%/Kojic Acid 5% Topical Gel (PermE8/WO6 Anhydrous)
- PCCA Formula #14373
 Azelaic Acid 15%/lvermectin 1%/Metronidazole 1% Topical Gel (PermE8/WO6 Anhydrous)
- PCCA Formula #14332 Lovastatin 2%/Cholesterol Topical Gel (PermE8/WO6 Anhydrous)

For more example formulas, please visit <u>bit.ly/wo6anhydrous</u>.

FREQUENTLY ASKED QUESTIONS

Can I use WO6 for vaginal or rectal medications?

The ingredients in WO6 are safe for topical use, but studies have not been done to test its safety for intra-vaginal or intra-rectal use. Therefore, we do not recommend using it for these applications.

Can I use WO6 for topical veterinary medications?

Yes. WO6 is safe for veterinary use.

Does WO6 replace other topical bases used for dermatology or cosmetics, such as Clarifying[™] or XemaTop[™]?

No. Clarifying (PCCA #30-4845) and XemaTop (PCCA #30-4891) have unique properties that meet the compounding needs of patients with acne/problem skin and eczema/ psoriasis, respectively. Through our FormulaPlus[™] program, we have numerous XemaTop formulas with extended BUDs that are supported by stability-indicating methods. Some of these formulas have been studied in bracketed ranges, meaning that compounders can use a range of API strengths in those formulas and still assign the extended BUDs. These formulations are still our first recommendation.

Do I have to refrigerate compounds with WO6 that contain hydroquinone or ascorbic acid?

No. While oxidation is a concern for these ingredients when compounded in aqueous bases, WO6 is anhydrous. Therefore, you can store WO6-based preparations containing hydroquinone or ascorbic acid at room temperature, assuming you have not added aqueous ingredients.

What are the preferred dispensing devices for WO6 preparations?

EMP jars are the suggested dispensing device for preparations made with WO6. Airless pump dispensers are not recommended.

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.

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