BUD 360°

A comprehensive guide, covering all your bases.

MEDISCA®

There's a lot of misconceptions when it comes to beyond-use-dating.

MYTH: Potency over time studies alone are sufficient evidence for extending a BUD

FACT: Stability-indicating goes beyond potency. Potency testing was used in the past, however stability-indicating is the correct way of conducting a BUD study.

Potency refers to the concentration of the drug at a specific point in time. It only indicates how much of the medication is present in a compound.

Stability-indicating studies ensure the durability of the compound over time and separate the drug from its by-products to get a more accurate picture of the amount of medication present.

MYTH: Physical Compatibility = Chemical Stability

FACT: Just because it looks good, doesn't mean it is good.

Physical compatibility doesn't tell the whole story. Chemical stability allows to look beyond the surface of the compounded preparation.

MYTH: Pharmacists are limited to purchase materials from one compounding vendor in order to apply extended BUDs

FACT: Threatening disclaimers restricting the use of compendial grade materials, such as APIs and excipients, have been used as a marketing tactic.

Unlike bases, most actives are not proprietary or unique. An extended BUD is formula specific, and does not require the API to originate from a specific source. Pharmacies have the ability to qualify other suppliers for these products.

This is evident when looking at a USP compounded monograph where the supplier is specified for the base, but not the API.

MYTH: Bracketed studies are a requirement

FACT: They are helpful and good to have, but not a requirement for extending a BUD.

STAY INFORMED.
AVOID RISKS.

BUD QUIZ

TEST YOUR KNOWLEDGE
MEDISCA.COM/BUD/QUIZ

What are BUDs (Beyond-Use Dates)?

- The BUD is the date or time, after which a compounded preparation can no longer be used, administered or stored, and is determined from the date the preparation is compounded.

How do you establish a BUD?

- USP, NAPRA and APF have set forth guidelines for establishing beyond-use-dating of compounded preparations.
- Compounders should take into consideration the properties of the API(s), any excipients, the type of dosage form as well as container closure and storage conditions.
- Establishing the BUD of a compounded preparation should be based on concrete scientific data.
- The correct way to obtain an evidence-based extended BUD is by conducting a stability-indicating study.
- In the absence of supporting stability data, pharmacists refer to USP <795>, NAPRA or APF guidelines.

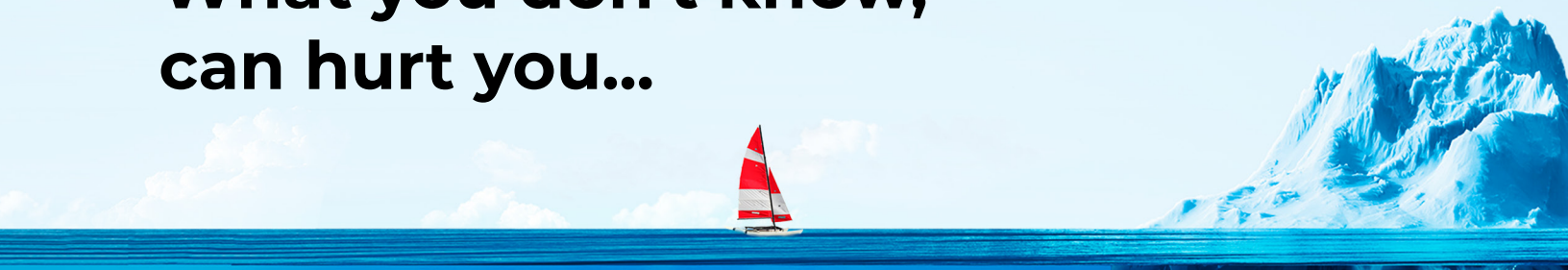
Why are BUD studies important?

- BUD studies are stability studies that help to ensure the integrity of the compounded preparation is maintained using validated, stability-indicating methods.
- They diminish potential risks that can affect patients, such as degradation of the active which can alter potency as well as **safety** due the formation of potentially dangerous by-products over time.
- A BUD study determines whether a preparation is able to maintain its strength and properties throughout its period of preparation, storage and use and to protect itself from degradation over time.
- BUD studies also allow compounders to extend the dating of compounded preparations beyond the default guidelines.
- In compliance with PCAB requirements for extending BUDs.

What are the advantages of having an extended BUD?

- **Benefit the patient by:**
  - Increasing the accessibility of medically necessary treatments (ex. patients living far from a pharmacy, vacations).
  - Reducing prescription renewal frequency and in turn reducing costs.
  - Offering more peace of mind in receiving a compounded preparation.
- **Benefit the pharmacy by:**
  - Improving pharmacy workflow.
  - Reducing costs by reducing labor (due to improved workflow), compounding larger batches and saving on shipping.
  - Providing the opportunity to prepare stock preparations.

What you don't know, can hurt you...



BUDs are much larger than they seem:

Stability-Indicating Studies are the gold standard for BUDs.

What is a stability-indicating study?

- A stability-indicating study consists of a validated, quantitative, analytical procedure used to detect how the stability of a drug changes over time.
- Stability-indicating assays can use techniques such as HPLC, MS, LC-MS/MS.
- **A stability study includes:**
  - Method development
  - Method validation
  - Forced degradation study

Forced-degradation

- Exposing the compound to extreme conditions (heat/humidity/uv radiation/acids/bases).
- Separating the drug from degradant.
- Determining quality and durability of a compounded preparation.

How do you determine you have a good stability-indicating study?

- Stability-indicating assays
- Validated methods
- Statistical analysis
- Independent & objective results
- Published and peer-reviewed (bonus!)
- Bracketed (bonus!)

What is a bracketed study?

- The study of two concentrations of a specific API or formulation in the same base, container closure system and under the same storage conditions.
- The only variable is the difference in concentration of the drug – all other factors remain consistent throughout both studies.

Oral & Topical BUD Databank

Determined Using Stability-indicating Studies

Ⓒ = Controlled substance in US and Canada

ORAL MIX	API	BUD	FORMULAS
 Product No.: 2512	Sulfamethoxazole/Trimethoprim 40/8 mg/mL	90 days at 5°C and 25°C	F 007 892v3
	Levetiracetam 50mg/mL *	90 days at 4°C and 25°C	F 006 379
	Melatonin 2.0mg/mL	90 days at 4°C and 25°C	F 006 112
	Gabapentin 100mg/mL	90 days at 25°C	F 006 620v2

ORAL MIX SF	API	BUD	FORMULAS
 Product No.: 2600	Sulfamethoxazole/Trimethoprim 0/8 mg/mL	90 days at 5°C and 25°C	F 007 893v3
	Metronidazole 50mg/mL	90 days at 4°C and 25°C	F 007 000
	Dexamethasone 1mg/mL *	90 days at 4°C and 25°C	F 006 625v3
	Gabapentin 100mg/mL	90 days at 25°C	F 006 621

VERSAPRO™ CREAM	API	BUD	FORMULAS
 Product No.: 2529	DHEA 0.2%-4%, Estradiol 0.01%-0.2%, Estriol 0.04%-0.8%, Progesterone 1%-20%, Testosterone 0.025%-0.5% (Bracketed) Ⓒ	180 days at RT and ongoing	F 008 949
	Diclofenac Sodium 1%-15% (Bracketed)	180 days at RT and ongoing	F 008 945
	Progesterone 1%-40% (Bracketed)	180 days at RT	F 008 567

HRT CREAM	API	BUD	FORMULAS
 Product No.: 0701	DHEA 0.2%-4%, Estradiol 0.01%-0.2%, Estriol 0.04%-0.8%, Progesterone 1%-20%, Testosterone 0.025%-0.5% (Bracketed) Ⓒ	180 days at RT and ongoing	F 008 948
	Hydroquione 2%-10% (Bracketed)	60 days at RT and ongoing	F 008 950
	Estriol 0.01%-10% (Bracketed)	180 days at RT	F 008 331

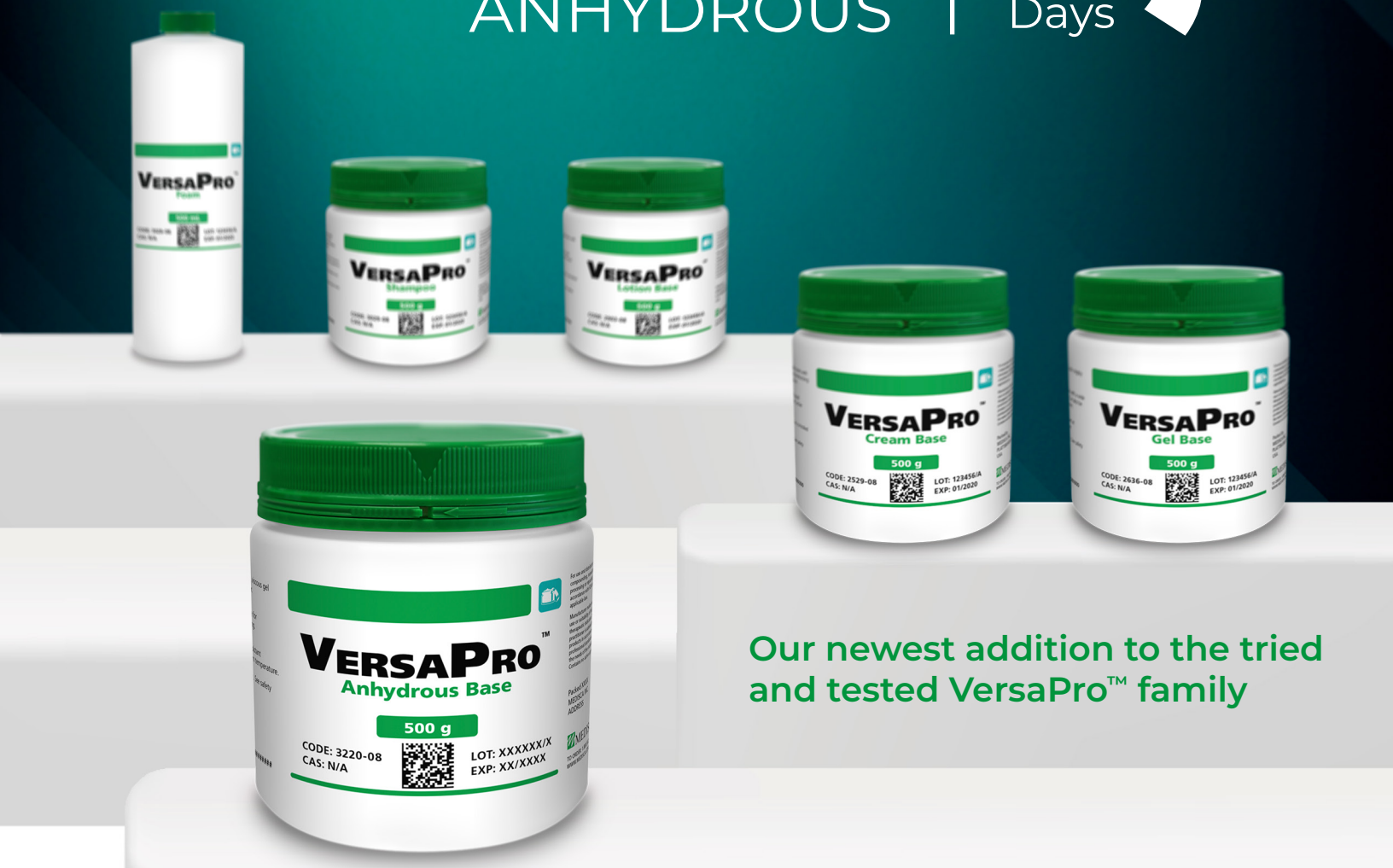
* Preparation compounded using commercial drug product (e.g., tablet, capsule, sterile powder for injection)

Explore our FULL BUD databank with 70 FREE FORMULAS

www.medisca.com/BUD

VERSAPRO™ ANHYDROUS

180° Days



Our newest addition to the tried and tested VersaPro™ family

- Specially developed to achieve a water activity below 0.6, allowing for extended **180 day default BUDs**, as per current USP <795> guidelines.
- Scientifically formulated to contain several ingredients to promote drug delivery of both lipophilic and hydrophilic APIs providing compounders the versatility they need.
- The combination of silicone and natural oils provide the ideal patient sensory experience: a soft and moisturizing texture.

Available in a variety of sizes 50, 100, 500 g and 2.5, 5 and 20 Kg

Place Your Order Today

www.medisca.com/versaproanhydrous

FOR MORE INFORMATION

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