



# Breaking the Myth of Exact Strength

*Co-authored with Renee Alsarraf, DVM, DACVIM, who shares her expertise and insights on why it's important for veterinarians to shift the mindset of using exact dosages to treat patients.*

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There is a misconception about exact strength in veterinary medicine. As healthcare providers, veterinarians are instinctively driven to deliver impeccable care, often aiming for a flawless execution of treatment. This can lead to apprehension when a component of patient care isn't exact. But we know that medicine is never an exact science.

When we look closely at the cGMP manufacturing process used by 503B outsourcing facilities, we realize that there is little to no difference in dosing between the 0.1 level. In fact, our patient-specific formulations don't need to be exact to be accurate and effective. The best part is that compounded standard dosages or strengths can prove to be not only safer but also more beneficial for the patients we serve.

## Why Exact Strength Doesn't Exactly Work

Requesting exact dosages only works for that particular patient at that particular weight on that particular day. And, as we all know, everyone's weight fluctuates, even animals. Consider these different patient scenarios:

- If the patient is sick, they may be losing weight.
- If the patient is on the mend, they may be gaining weight.

So, the very precise 1.22 milligram dose you request doesn't benefit the patient more than the standard 1.25 mg dose. Trying to be overly exact means the dosage is only spot-on for that particular week. You're not necessarily being exact for an extended amount of time, or for the length of their treatment.

Additionally, if you are going to stick with that exact dose, then every time the patient comes in for a re-check of bloodwork or other care, you're going to have to tweak that from say 2.6 to 2.7 milligrams, which potentially will cost your client more money and ultimately, it's not really going to make a difference.



## Potency in Practice

**Dr. Renee Alsarraf, Veterinary Oncologist**

Compared to animals, dosing in human medicine covers a much broader range. But there is also a range when it comes to animals such as dogs and cats.

Is there a difference between 1.5 mg and 1.75 mg? Definitely! But what about 1.5 mg and 1.6 mg?

Let's look at veterinary oncology – to get my patients the treatment they need, having the right strength chemotherapy drugs is important. Let's say I need to have a dog on chlorambucil and it's already available in 2.5 mg from Epicur (or stocked in our hospital pharmacy).

I might calculate it out and find that the dog needs 2.6 mgs. It doesn't make a biological or therapeutic difference to give him a 2.5 mg tablet or a 2.6 mg tablet.

Where it does make a difference, though, is in my ability to then leverage that drug stock for other patients. By stocking the standardized 2.5 mg, other dogs that need the same drug from say 2.4 to 2.6 mg can all benefit from this, plus I can keep my practice's costs down and reduce waste!

## Exact vs. Standard Dosages

When we're examining the strength of a drug, we're considering its potency, or the amount of drug needed to produce an effect, such as pain relief, lower blood pressure, or reduced anxiety. For example, a drug that relieves pain effectively in a 10-milligram dose is twice as potent as a drug that provides the same relief in 20 milligrams.

Potency can vary greatly when you treat with an 'exact' strength drug versus when you use a standard dose from a 503B outsourcing facility.

Use the chart to take a closer look at the true differences between exact and standard dosages and explore why breaking the myth of exact strength is important to raising the standard of care in veterinary medicine.

	Exact Strength	Standard Strength
<b>Formulation</b>	Compounded Capsule or Tablet	Manufactured Tablet
<b>Acceptable Potency Range</b>	Follows a <b>theoretical process</b> to obtain a 10% margin and can result in significant deviation from the expected dose.	Created from a <b>validated process</b> that typically is much more accurate (often less than 7% deviation)
<b>Development Process</b>	Manually compounded into a capsule by a technician	Manufactured by a machine
<b>Specification of Strength</b>	Greatly dependent on the training and experience of the technician making the product	Fully validated process to ensure consistency of the dosage <b>in each tablet</b> and consistency between <b>different batches of the same drug</b>
<b>Required Testing for Specification</b>	In a majority of traditionally compounded products, the potency has not been tested to ensure it is in specification.	Extensive testing is <b>required</b> to ensure the potency always falls within 10% of the strength stated on the label and retained through the shelf life and use life.

## Make 'Standard' Strength Your Standard

Standard dosages offer advantages in veterinary medicine that improve both patient care and boost the bottom line in your practice.

- 1. Pet Owner Compliance** – Standard compounded strengths make it easier for clients to care for their pets at home. They don't have to constantly get new medication when they stay with the same dose, which ultimately saves them money and simplifies treatment instructions for at-home care. Some 503B manufactured medications come in flavors for palatability, an added benefit to treatment compliance.
- 2. In-Office Stock** – Having an exact strength drug means you likely can only use it for that specific patient. However, using standard strengths allows you to build a good stock in your veterinary hospital so that you can use that same milligram dose for other patients. This reduces costs and waste because you won't have to discard unused medicine that has expired.

### Prescribe with Confidence.

The potency of 503A compounded products **is not guaranteed** and there can be wide variations in potency – but this is never true with 503B products!

Be confident your patient is getting what you are prescribing. Order a standard, validated strength from a 503B facility.

- 3. Expirations Dates** – Standardized medications from a 503B partner also use expiration dates, giving them a much longer shelf-life than Beyond-Use Dates (BUDs) used by individual patient formulations from compounding pharmacies. An expiration date indicates when the strength and/or safety of a medication can no longer be guaranteed by the manufacturer. Unlike BUDs, expiration dates can be assigned only after extensive product stability testing – which is required of 503B outsourcing facilities.
- 4. Trusted Testing** – Because of the stringent testing protocols and quality control processes 503B outsourcing facilities like Epicur must adhere to, there is significantly less variation from dosage unit to dosage unit and batch to batch. 503B manufactured drugs go through extensive stability testing to ensure they stay balanced over time, along with testing for potency, purity, sterility, and endotoxins (when applicable) to ensure traceability and FDA cGMP compliance.



### Your Pharmacy Partner Plays a Role in Potency

When it comes to patient medications no veterinary professional would disagree that quality matters. So, knowing the risks to quality when ‘exact’ strengths are manually formulated, why wouldn’t 503B pharmacy partners become the standard source?

Ultimately, the compounding pharmacy you choose is much more important than deciding between a 1.5 milligram tablet or a 1.6 milligram tablet, because that partner determines the quality of the product in terms of stability, sterility, and potency. And these qualities are what produce the ultimate benefit for your patients.

### Don't question the quality of your medications. Partner with Epicur.

Epicur® Pharma, an FDA-registered 503B outsourcing facility manufactures drugs with consistent potency, sterility, and purity from batch to batch. Reduce your risk of variability and improve patient outcomes with our manufactured medications.

View our current product lines: [epicurpharma.com/b-products](https://epicurpharma.com/b-products)

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#### About Renee Alsarraf

*Dr. Renee Alsarraf received her veterinary medical degree in 1991 from Michigan State University. While there she established the University's Pet Loss Support Group. Dr. Alsarraf completed a rotating internship and medical oncology residency in New York City at the Animal Medical Center. She worked at Memorial Sloan Kettering in a tissue culture lab. Dr. Alsarraf has performed numerous veterinary clinical trials, co-authored peer-reviewed journal articles, and has lectured both locally and on the national level. Dr. Alsarraf has created 4 different veterinary oncology practices as well as created and led 3 veterinary radiation facilities. Currently, Dr. Alsarraf works as a consultant for a national veterinary radiation therapy company and does medical oncology consults. She is an application reviewer and interviewer for MSU's Veterinary School admissions. Her debut memoir Sit, Stay, Heal: What Dogs Can Teach Us About Living Well celebrates the human-animal bond in its deepest form. She has done extensive interviews about her book on national tv, local tv, podcasts, and in-person events.*



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