



Veterinary Dosing Guide:

“Standard” Validated vs “Exact On-Demand” Dosages





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Veterinary medicine requires a great deal from the prescribing veterinarian—there are imperfect choices, as most veterinary drugs are off-label human medicines; limited formulations; practical cost considerations; and communication barriers with patients who, at times, can't be reasoned with.

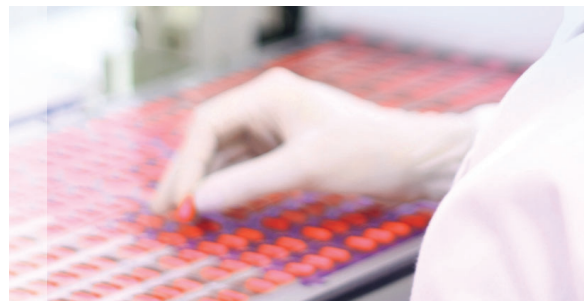
Defining Exact Dose vs. Standard Dose

In this industry, we frequently receive calls requesting, for example, a 3.125 mg dosage of a drug (exact on-demand dosage) when we have a 3 mg tablet readily available (standard validated dosage). 3.125 mg of a drug would be manually made into a capsule by a trained technician, while the 3 mg tablet is pressed by a machine utilizing a fully validated process to ensure consistency of the dosage in each tablet and also consistency between different batches of the same drug. In addition, the tablet has been tested to ensure the potency is within specification. However, in the manual process, the accuracy of achieving an exact 3.125 mg dosage greatly depends on the training and experience of the technician that is making the product and, in a majority of the products, the potency has not been tested to ensure it is in specification.

Formulation	Manufacturing Process	Dosage
 Capsule	503B compounded by human	Exact on Demand*
 Tablet	503B compounded by machine	Standard*

*See figure 2

If you had to make a choice between an “exact” dose vs a “standard” dose compounded, what rationale do you use to decide what dose is acceptable? For medications with a narrow therapeutic range in the blood, for example, thyroid or anti-seizure medications, dosage variations can have a significant impact on outcomes and can make it difficult to ascertain whether suboptimal



responses are due to the medication, side effects, or the condition itself.

Epicur® Pharma, a 503B outsourcing facility, provides a range of “standard” dosages that are subject to extensive research, testing, and development to provide medication that is:

1. specifically tested and/or
2. has a high assurance to be always within 10% of the strength stated on the label and retain that strength through the shelf life and use life.

Knowing this, does that change your rationale?

When an “exact” dose is requested for 3.125 mg, and the pharmacy has 3 mg and 3.5 mg and 2.75 mg, compounding on-demand the “exact” dose rarely would be subject to the same testing—if at all—as a “standard” dosage. Thus, the “exact” dose follows a **theoretical process** to obtain the 10% margin and can result in significant deviation from the expected 3.125 mg dose. Knowing this, would you rather use the standard dosage from a **validated process** that typically is much more accurate (often less than 7% deviation) or the “exact” dose that may be further from the expected 3.125 mg than a 3 mg or 2.75 mg dose?

Note that since on-demand medications can't be tested for potency because it's destructive, costly, and adds weeks to delivery time, recent testing data has shown wild variation in many cases. It's always an unvalidated process.

Exact (on-demand)	Standard 1 (validated)	Standard 2 (validated)	Standard 3 (validated)
3.125	3	2.75	3.5

0.8	2.5	2.4	2.2	2.8
0.81	2.53125	2.43	2.2275	2.835
0.82	2.5625	2.46	2.255	2.87
0.83	2.59375	2.49	2.2825	2.905
0.84	2.625	2.52	2.31	2.94
0.85	2.65625	2.55	2.3375	2.975
0.86	2.6875	2.58	2.365	3.01
0.87	2.71875	2.61	2.3925	3.045
0.88	2.75	2.64	2.42	3.08
0.89	2.78125	2.67	2.4475	3.115
0.9	2.8125	2.7	2.475	3.15
0.91	2.84375	2.73	2.5025	3.185
0.92	2.875	2.76	2.53	3.22
0.93	2.90625	2.79	2.5575	3.255
0.94	2.9375	2.82	2.585	3.29
0.95	2.96875	2.85	2.6125	3.325
0.96	3	2.88	2.64	3.36
0.97	3.03125	2.91	2.6675	3.395
0.98	3.0625	2.94	2.695	3.43
0.99	3.09375	2.97	2.7225	3.465
1	3.125	3	2.75	3.5
1.01	3.15625	3.03	2.7775	3.535
1.02	3.1875	3.06	2.805	3.57
1.03	3.21875	3.09	2.8325	3.605
1.04	3.25	3.12	2.86	3.64
1.05	3.28125	3.15	2.8875	3.675
1.06	3.3125	3.18	2.915	3.71
1.07	3.34375	3.21	2.9425	3.745
1.08	3.375	3.24	2.97	3.78
1.09	3.40625	3.27	2.9975	3.815
1.1	3.4375	3.3	3.025	3.85
1.11	3.46875	3.33	3.0525	3.885
1.12	3.5	3.36	3.08	3.92
1.13	3.53125	3.39	3.1075	3.955
1.14	3.5625	3.42	3.135	3.99
1.15	3.59375	3.45	3.1625	4.025
1.16	3.625	3.48	3.19	4.06
1.17	3.65625	3.51	3.2175	4.095
1.18	3.6875	3.54	3.245	4.13
1.19	3.71875	3.57	3.2725	4.165
1.2	3.75	3.6	3.3	4.2

Examining Exact Dose

Let's break down exact dosages. In the chart to the left, you'll note the "exact" dose of 3.125 mg produces an actual dosage range anywhere from **2.8125-3.4375 mg** following the compounding allowance of +/- 10%! That's not exactly exact.

Since the process is not validated, more typically it would be somewhere around 2.5 mg–3.75 mg. Using standard validated dosages, the range is significantly reduced for a 3 mg dose to **2.79-3.21 mg** which **contains** the 3.125 mg dose possibility but has significantly less variation from dosage unit to dosage unit and batch to batch.

With the standard validated dosage, your patients will use a more uniform dose and should have a more uniform response vs varying **1.25 mg** on a 3.125 mg "exact" dose.



Is this variability acceptable in your practice when evaluating outcomes in your patients? Can you tell the difference between patient decline or side effects vs dosage fluctuations out of your control?

As 503B facilities like Epicur® Pharma expand product lines, more medications and dosage choices will be available to reduce your risk of variability and improve patient outcomes. New formulations will also help to improve compliance, with animal-specific flavorings like savory chicken oil-based suspensions for dogs and cats and sweeter profiles for ferrets and birds. View our current product lines: epicurpharma.com/b-products/