COMPOUNDER'S INTERNATIONAL
ANALYTICAL LABORATORY
Better Quality Through Quality Testing

(303)471-8015
(800)788-9922
680 Atchison Way, Suite 100
Castle Rock, CO 80109
CompoundersLab.com
cial@compounderslab.com

2019 Testing Services & Price List

MICROBIOLOGICAL TESTS	INFORMATION	TIME REQUIRED FOR TEST	AMOUNT OF SAMPLE REQUIRED	PRICING
STERILTY TESTING (AEROBE & ANAEROBE)	Check for aerobic and anaerobic bacterial contamination. Complies with USP <797> & <71> if required number of vials are provided based upon batch size, and if Sterility Method Suitability (below) has been completed.	14 days as required by the USP We issue a preliminary report after 7 days.	2 ML Minimum for single sample. Quantity should be determined by batch size. Pooled samples* total volume must equal at least 2 ML	**$100** For multiple containers from the same lot: **$130 for 2-5 containers** **$140 for 6-10 containers** **$150 for 11+ containers**
STERILITY METHOD SUITABILITY	Verify the suitability of the sterility testing method in compliance of USP <797> & <71> Test involves inoculating 4 different bacteria, plus mold and yeast into growth media containing samples. Presence of growth demonstrates sterility test method is valid.	Takes 5 days to determine presence of microbe growth	Quantity must be 3 times the <71> batch size requirements. (10 ML Minimum) For pooled samples* the total volume must equal at least 10 ML	**$400** This test is performed concurrently with sterility testing which is needed as the control.
ENDOTOXIN	Determine level of bacterial endotoxins in compliance with USP <797> & <85> Please provide endotoxin limits or dosing requirements.	Results in 2-3 business days after sample is received or with Sterility report	2 ML Minimum required in separate container.	**$110**
FUNGI (MOLD/YEAST)	Check specifically for presence of fungal contamination. Strongly recommended for High Risk and Intrathecal injections. (Note, mold doesn't always show up in the USP sterility test)	14 days as required by the USP	Generally 2ML minimum For pooled samples* the total volume must equal at least 2ML This should be done in conjunction with a sterility test.	**$60**
ANTIMICROBIAL EFFECTIVENESS	This extensive six-step test utilizes 5 microorganisms specified by the USP to determine if the antimicrobial agent in the formulation is effective in stopping microbial growth. USP <51>	Requires ~30 days to produce results.	A minimum of 55 ML is required for the test. If a part of a multi-test study, a minimum of 50 ML per each subsequent test.	**$950**
WATER ACTIVITY (Coming Soon)	Tests for presence of water vapor which can support microbial growth. <1112>	Results in 2-3 business days after sample is received.	Generally 2ML or 2GM minimum	**To Be Determined**

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SPECIALTY TESTS	INFORMATION	TIME REQUIRED FOR TEST	AMOUNT OF SAMPLE REQUIRED	PRICING
PARTICULATES (SUBVISIBLE)	Determines the number of subvisible particles in parenterals and ophthalmics in specified ranges: ≥10μm, ≥25μm, ≥50μm. USP <788> <789> Method 1	Results are usually available within 2-3 business days.	A minimum of 4 ML in one container (syringe, vial, IV Bag, etc). Quantity of containers needs to be a statistically representative sampling of the lot and based upon past history of particulate issues.	**$100**
pH	Determines the pH of the sample to make sure it falls within desired range for safety and stability. USP <791>	Results are usually available within 2-3 business days.	A minimum of 1 ML, more is desirable.	**$50**
CONTAINER CLOSURE INTEGRITY	Tests the container integrity by dye intrusion technique to determine its ability to keep the medication safe and maintain sterility. This test can also substitute for a sterility <71> test at the end of a stability study.	Results are usually available within 2-3 business days.	A minimum of 4 filled containers (syringe, vial, pump, jar, etc).	**$150**
APPEARANCE ODOR & COLOR	Describes the sample as received and can be done periodically throughout a stability study. Can be used to document the condition of the formulation over time.	Results will be reported as samples are tested, ±2 days from dates requested (CIAL is closed on weekends and holidays)	A minimum of 5 ML or 5 GM, more is desirable.	**$50**
WATER DETERMINATION BY KARL-FISCHER	Determines the water content in an active ingredient, lyophilized product, solid, or liquid dosage form. Must be methanol soluble. (Not compatible with oily or greasy formulations). It is specific for water and should not be confused with L.O.D. Can determine % water over a range of about 1% to 100%. USP <921> Method 1a	Results are usually available within 2-3 business days.	A minimum of 0.5 GM, more is desirable.	**$150**
LOSS ON DRYING (L.O.D.)	Determines % volatile substances in an active ingredient or formulated product. This would include residual solvents as well as water. USP <731>	Results are usually available within 2-3 business days.	A minimum of 1 GM, more is desirable.	**$95**
IDENTITY BY INFRARED	Determines or confirms the identity of a single liquid or solid ingredient by producing an infrared spectral "finger print". This is then compared to a stored library of known ingredient spectra. USP <854>	Results are usually available within 2-3 business days.	A minimum of 5 MG or 0.1 mL, more is desirable	**$75**
IDENTITY BY UV/VIS	Determines identity and, in some cases of simple mixtures, can be used to quantify active ingredients using UV and Visible wavelengths of light. USP <857>	Results are usually available within 2-3 business days.	A minimum of 5 ML or 5 GM, more is desirable.	**$100**
METALS ANALYSIS	Determines amounts of single or multiple metals in an active ingredient or formulated product. Metals such as: Sodium, Potassium, Copper, Zinc, Magnesium or organometallic compounds such as Copper Gluconate can be assayed.	Results are usually available within 2-3 business days.	A minimum of 5 ML, 5 GM, or 2 capsules, more is desirable.	**$150** Per metal

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POTENCY TESTS	INFORMATION	TIME REQUIRED FOR TEST	AMOUNT OF SAMPLE REQUIRED	PRICING
POTENCY TESTING	Determine concentration of active(s) in any dosage form: capsules, gels, creams, powders, suppositories, etc. USP <621> <797>	Results usually in 5-7 business days. Please call ahead if you have a RUSH sample or a new API not listed on our API list.	Generally 5 capsules, troches, suppositories, or 5 ML for liquids & creams, or 1 GM for powders - per active. These amounts may not always be practical, call if in doubt.	**$165** Per active except those listed below or on the Potency Assay Combination list. (See last page of this document). **$190** Per active tested via Mass Spec. **$200** All Proteins & Peptides **$270** Porcine Thyroid For multiple active ingredients in the formulation, see our Potency Assay Combination price list (attached) for potentially significant savings.
POTENCY OVER TIME STABILITY	Determine potency for BUD (Beyond-Use Dating). Can be assayed at any interval for any length of time and stored at room, body temp. refrigerated, or frozen. USP <621> <797> (Also available, Stability Indicating Assays for FDA, Calif. approved stability studies. See next two rows below.)	Results at each testing interval. Lab report is in chart form which adds the new data at each time point.	Multiples of amount required for potency assay, based upon anticipated number of tests over desired time frame.	Same price as Potency Testing each time it is tested. (Contact us for attractive pricing on stability studies involving Stability Indicating Assay as required by the FDA & Calif. Also referred to as "True" Stability Studies. See next 2 rows below.)
STABILITY INDICATING METHOD DEVELOPMENT	Determine BUD per official FDA , Calif. and potential new <795> & <797> requirements. Involves forcibly degrading the sample using heat, light, acids, bases, and oxidizing agents and developing a validated method which proves that potential breakdown products will not interfere with the active ingredients during the stability study being requested. (See below) USP <621> <797>	Time required for method development depends on complexity of the sample and current workload. It is best to plan ahead and pay the $2,000 deposit quickly so work can be scheduled.	Typically need about 100 ML or 100 GM of sample. Please contact us to get exact quantity.	**Starting at $9,500** Price depends upon complexity of formulation. **Please contact us to discuss and receive a quote before sending samples.** (Please note that a $2,000 deposit is required before testing can begin)
STABILITY STUDY USING STABILITY INDICATING METHOD	Following development of the Stability Indicating Method, the Stability Study will use that method to periodically test the concentration of active(s) to establish the best BUD. This can be done for any dosage form. USP <621> <797>	Results will be reported as the samples are tested, ±3 days from dates requested. (CIAL is closed on weekends and holidays)	Depends on sample, number of actives in the formulation, and time points requested. Please contact us to get exact quantity.	Please contact us to discuss and receive a quote before sending samples.
ACCELERATED STABILITY TESTING	Accelerate stability testing by a factor of approx. 2 to 3 fold. CIAL has an elevated temperature and humidity chamber to help accelerate the testing of your room temperature samples.	Results will be reported as the samples are tested, ±3 days from dates requested. (CIAL is closed on weekends and holidays)	Depends on sample, number of actives in the formulation, and time points requested, but generally the same as Potency Testing (above). Please contact us to get exact quantity.	**$235** Per active ingredient, per time point. **$260** Per active ingredient, per time point when tested via Mass Spectrometer
API POWDER POTENCY & IDENTITY	Determine potency and identity of the pure active ingredient.	Results usually in 5 - 7 business days.	Generally 1 GM. For very expensive ingredients we can often test with as little as 25 MG - 100 MG shipped in a No. 3 capsule shell.	**$300**
UNIFORMITY OF DOSAGE UNITS	Tests for consistency of each dosage unit. <905>	Results usually in 5 business days.	Test requires a minimum of 30 dosage units.	**Price will vary depending upon type of formulation and number of active ingredients. Please call for quote.**

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POTENCY ASSAY COMBINATIONS
COMPLETE LIST OF MULTIPLE ACTIVE INGREDIENT FORMULATIONS

- Betamethasone Acetate / Betamethasone Sodium Phosphate
- Dexamethasone / Dexamethasone Acetate / Dexamethasone Sodium Phosphate
- DHEA / Estrone / Estradiol / Estriol / Progesterone / Pregnenolone / Testosterone
- Ketamine / Medetomidine
- Levothyroxine Sodium (T4) / Liothyronine (T3)
- Papaverine HCl / Phentolamine Mesylate
- Testosterone Cypionate / Testosterone Decanoate / Testosterone Enanthate / Testosterone Isocaproate / Testosterone Propionate

NEW!
SPECIAL POTENCY ASSAYS REQUIRING MASS SPECTROMETER CAPABILITIES

Because of their very low concentrations, difficulty to detect, or difficulty to analyze for a number of reasons, the following actives may require the use of a mass spectrometer in tandem with our UHPLC instruments. Because such instruments are very involved to operate, the analysis costs are greater, therefore assays of these compounds will be charged at a rate of $180.

- Amantadine HCl
- Cabergoline
- Calcitriol
- Choline Chloride
- Calcium Gluconate
- Cacodylate Sodium
- Dimethyl Glycine
- Etidronate Disodium
- Gentamicin
- Galactosamine
- Glucosamine
- N-Acetyl Glucosamine
- N-Acetyl-D-Glucosamine
- Glycerophosphocholine
- Inositol
- Kanamycin Sulfate
- Methenamine Mandate
- Neomycin
- RG3 Ginsenoside
- Topiramate
- Proline
- Zoledronic Acid
- Any active whose concentration is 10 MCG or lower may need to be assayed in this way.

***Vitamin B12 preparations with multiple ingredients (More than 4) may be subject to this pricing. Please contact CIAL to confirm the pricing.**

PRICING OF POTENCY ASSAY COMBINATIONS

If you wish to have potency assay performed on formulations which have multiple active ingredients, we may be able to test them all together using the same method. On the left is **The Complete** list of those multiple ingredient combinations that we can assay together. When we are able to test them in combination, it can result in considerable savings.

Because we care about your success, we price active ingredient combinations in a way that will give you a very attractive price compared to other laboratories. For example, consider the commonly prescribed BHRT combination: DHEA / Estrone / Estradiol / Estriol / Progesterone / Testosterone) or any combination of these within the group). We price the first active at the full price of $165, but each of the others at only $95.

First example: 6 Active Ingredients that can be assayed together:

		Our Pricing	Competitive Labs
First Active:	DHEA	$165	$180
Second Active:	Estriol	$ 95	$180
Third Active:	Estradiol	$ 95	$180
Fourth Active:	Estrone	$ 95	$180
Fifth Active:	Progesterone	$ 95	$180
Sixth Active:	Testosterone	$ 95	$180
Total Charge:		$640	$1,080

That's a $440 savings!

Second Example (Tri-est): 3 Active Ingredients that can be assayed together

		Our Pricing	Competitive Labs
First Active:	Estriol	$165	$180
Second Active:	Estradiol	$ 95	$180
Third Active:	Estrone	$ 95	$180
Total Charge:		$355	$540

That's a $185 savings compared to other labs!

Third Example (T3/T4): 2 Active Ingredients that can be assayed together

		Our Pricing	Competitive Labs
First Active:	T3	$165	$180
Second Active:	T4	$ 95	$180
Total Charge:		$260	$360

That's a $100 savings!

Fourth Example (Tri-mix): 2 Active Ingredients that can be assayed together and one which must be assayed in a second procedure:

		Our Pricing	Competitive Labs
First Active:	Papaverine	$165	$180
Second Active:	Phentolamine	$ 95	$180
Third Active:	Prostaglandin	$165	$180
Total Charge:		$425	$540

That's a $115 savings!

Fifth Example (Mass Spec): 2 Active Ingredients that can be assayed together using UHPLC and one which must be assayed via the mass spectrometer:

		Our Pricing
First Active:	Ketamine	$165
Second Active:	Medetomidine	$ 95
Third Active:	Amantadine HCl	$190
Total Charge:		$450

RUSH CHARGES

Potency Rush Charge Per Sample

2-3 days: $50 **Same Day: $100**

Advanced notice required. Must arrive before 11AM

PAYMENT FOR TESTING SERVICES

Payment via check or credit card can be made when samples are sent for testing.

Payment is due when test results are released and can be paid via credit card or Purchase Order/ Invoice.

If payment is not received within 45 days after reports are released, a late charge of 10% will be added to the total amount.