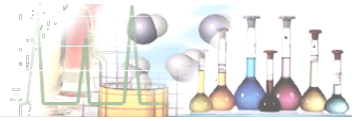
COMPOUNDER'S INTERNATIONAL
ANALYTICAL LABORATORY
Better Quality Through Quality Testing



(303)471-8015
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2021 Testing Services & Price List

MICROBIOLOGICAL TESTS & TEST CODES	INFORMATION	TIME REQUIRED FOR TEST	AMOUNT OF SAMPLE REQUIRED	PRICING
STERILTY TESTING (STE)	Test for microbial contamination of sterile product. Complies with USP <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 Preliminary report provided after 7 days.	2 ML minimum. Quantity should be determined by container volume and batch size. <71>. Please indicate number of vials to be pooled.	**$110** For multiple containers from the same lot: **$140 for 2-5 containers** **$150 for 6-10 containers** **$160 for 11+ containers**
STERILITY METHOD SUITABILITY (SMS)	Verify the suitability of the sterility testing method. Test involves inoculating 6 different microorganisms into growth media containing samples. Presence of growth demonstrates sterility test method is valid. USP <71>	Results usually in 7 to 14 business days	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	**$450**
ENDOTOXIN (END)	Determines level of bacterial endotoxin. Please provide endotoxin limits or dosing requirements. USP <85>	Results usually in 2-3 business days.	2 ML Minimum required in separate container.	**$115**
FUNGI (MOLD/YEAST) (FUN)	Check specifically for presence of fungal contamination. For High Risk and Intrathecal injections.	14 days	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 (AET)	This extensive test utilizes 5 microorganisms as specified by the USP to determine if the antimicrobial agent in the formulation is effective. USP <51>	Due to required test length, final report usually in 35 to 45 days	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 (WA)	Tests for susceptibility of microbial growth and for possible hydrolytic breakdown of active ingredients. USP <1112>	Results usually in 5-7 business days.	Generally 5ML or 5GM minimum.	**$95**
VISIBLE PARTICULATES (VP)	Checks for presence of visible particulates in sterile parenteral solutions by visualizing against a black and white background. This is particularly useful during stability studies of sterile products. USP <790>	Results usually in 2-3 business days.	A minimum of one container.	**$10 per container**
MICROSCOPIC EXAMINATION OF UNKNOWN SUBSTANCE (MEX)	Under high magnification of up to 12,500X this service can be ordered to investigate unknown substances, such as microscopic particles to determine their identity and possible source.	Results usually in 2-3 business days.	A minimum of one container.	**$110**
MICROBIAL ENUMERATION OF NONSTERILE PRODUCTS (ME)	Determines the total viable aerobic microbial count present per ML or per GM of product. USP <61>	Results usually in 7-10 business days.	A minimum of 10 GM or 10 ML or 1% of the batch size, is required for the test.	**$100**
TEST FOR SPECIFIED MICROORGANISMS IN NONSTERILE PRODUCTS (SM)	Checks for presence of certain specified bacteria and fungi present in a product. This test accompanies the Microbial Enumeration test above. USP <62>	Results usually in 2 weeks. This test is not performed in-house.	Sample is obtained from the results of Microbial Enumeration test (above).	**$ 85/microbe**

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SPECIALTY TESTS	INFORMATION	TIME REQUIRED FOR TEST	AMOUNT OF SAMPLE REQUIRED	PRICING
PARTICULATES (SUBVISIBLE) (PRT)	Determines the number of subvisible particles in parenterals and ophthalmics in specified ranges: ≥10μm, ≥25μm, ≥50μm. USP <788> <789> Method 1	Results usually in 5-7 business days.	A total minimum of 25 ML is required. Quantity of containers should be statistically representative.	**$120**
pH (PH)	Determines the pH of the sample to make sure it falls within desired range for safety and stability. USP <791>	Results usually in 5-7 business days.	A minimum of 1 ML, more is desirable.	**$60**
CONTAINER CLOSURE INTEGRITY (CCI)	Tests the container integrity by dye intrusion technique to determine its ability to keep the medication safe and maintain sterility. USP <381>	Results usually in 5-7 business days.	A minimum of 4 filled containers (syringe, vial, pump, jar, etc).	**$150**
APPEARANCE ODOR & COLOR (AOC)	Describes the sample as received and can be checked periodically throughout a stability study. Can be used to document the condition of the formulation over time.	Results usually in 5-7 business days.	A minimum of 5 ML or 5 GM, more is desirable.	**$60**
WATER DETERMINATION BY KARL-FISCHER (WAT)	Determines the water content in an API, 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. USP <921> Method 1a	Results usually in 5-7 business days.	A minimum of 1 GM, more is desirable.	**$165**
LOSS ON DRYING (LOD)	Determines total % of volatile substances in an active ingredient or formulated product. This would include residual solvents as well as water. USP <731>	Results usually in 5-7 business days.	A minimum of 1 GM, more is desirable.	**$95**
IDENTITY BY INFRARED (IR)	Determines or confirms the identity of a single liquid or solid API by producing an infrared spectral "finger print". This is then compared to a stored library of known ingredient spectra. USP <197A> <854>	Results usually in 5-7 business days.	A minimum of 5 MG or 0.1 mL, more is desirable	**$80**
IDENTITY BY UV/VIS (UV)	Determines API identity according to USP monograph using UV and Visible wavelengths of light. USP <857>	Results usually in 5-7 business days.	A minimum of 5 ML or 5 GM, more is desirable.	**$100**
METALS ANALYSIS (MET)	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. Likewise, toxic metals such as Lead, Arsenic, Cadmium and Mercury levels can be determined. USP <730>	Results usually in 5-7 business days.	A minimum of 5 ML, 5 GM, or 2 capsules, more is desirable.	**$175** Per Metal / Element
VISCOSITY (VIS)	Determines the ability of a fluid formulation or other substance to cling to a surface such as the skin, throat or eye. USP <912>	Results usually in 5-7 business days.	A minimum of 20 ML or 20 GM, more is desirable.	**$105**
SPECIFIC GRAVITY (SPG)	Determines the density of a fluid formulation or other substance such as a cream. Allows conversion between weight and volume for formulation calculations. USP <841>	Results usually in 5-7 business days.	A minimum of 6 ML for liquids, 25 ML for creams/semi-solids, more is desirable.	**$75**
MELTING POINT (MP)	The melting point or melting range of an API is often used for identification as well as to check for purity according to the USP monograph. USP <741>	Results usually in 5-7 business days.	A minimum of 1 GM, more is desirable.	**$150**
RESIDUE ON IGNITION / SULFATED ASH (ASH)	Determines the total level of inorganic impurities in an API according to the USP monograph. This test involves heating the sample in a furnace to burn off all organic substances, leaving only inorganic ash. USP <281>	Results usually in 5-7 business days.	A minimum of 2 GM, more is desirable.	**$250**
CHEMICAL IDENTIFICATION (CID)	Verifies the presence of a chemical substance in an API by means of a chemical reaction. Examples: Chloride, Sodium, Acetate, Citrate, etc. USP <191>	Results usually in 5-7 business days.	A minimum of 50 mg, more is desirable.	**Generally $80 to $100**
ABSORBANCE OF SOLUTION / ABSORPTIVITY (ABS)	Determines the quantity of a UV active ingredient in a formulation containing a single active ingredient. USP <857>	Results usually in 5-7 business days.	A minimum of 100 mg, more is desirable.	**$165**
OPTICAL ROTATION (OR)	Tests for purity and identity of optically active (chiral) APIs. Examples: Levo or Dextro rotary actives (L-Carnitine) USP <781S>	Results usually in 3-5 business days.	A minimum of 1 GM, more is desirable.	**$95**
CRYSTALINITY (CRY)	Characterizes compliance of crystalline APIs under polarized light, according to the individual monograph. USP <695>	Results usually in 3-5 business days.	A minimum of 10 mg, more is desirable.	**$75**

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POTENCY TESTS	INFORMATION	TIME REQUIRED FOR TEST	AMOUNT OF SAMPLE REQUIRED	PRICING
POTENCY TESTING VIA UHPLC OR MASS SPECTROSCOPY (POT)	Determine concentration of active(s) in any dosage form: capsules, gels, creams, powders, suppositories, etc. USP <621> <795> <797>	Results usually in 5-7 business days. Please call ahead if you have a RUSH sample or a new API not found on our web site 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 tested via UHPLC **$200** Per active tested via Mass Spec. **$225** All Proteins & Peptides **$285** Desiccated Thyroid For multiple active ingredients in the formulation, see our Potency Assay Combination price list (attached) for potentially significant savings.
POTENCY OVER TIME STABILITY (POS)	Determine potency for Beyond-Use Dating (BUD) in states where this method is allowed. Can be assayed at any interval for any length of time and stored at room, body temp. refrigerated, or frozen. USP <621> <795> <797> (Also available, Stability Indicating Assays for FDA, Calif. approved stability studies. See next two rows below.)	Results will be reported as the samples are tested, ±3 days from dates requested. (No testing is performed on weekends or holidays) 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 USP, FDA & Calif. Also referred to as "True" Stability Studies. See next 2 rows below.)
STABILITY INDICATING ASSAY METHOD DEVELOPMENT -Phase 1- (SID)	Determine BUD per USP, FDA, & Calif. 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> <795>	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 and also 50 ML or GM placebo. 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 INDICATING ASSAY STABILITY STUDY -Phase 2- (SIA)	Following development and validation of the Stability Indicating Method (above), 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><795>	Results will be reported as the samples are tested, ±3 days from dates requested. (No testing is performed on weekends or holidays)	Depends on sample, number of actives in the formulation, number of different tests to be performed, and time points requested. Please contact us to get exact quantity.	**Please contact us to discuss and receive a quote before sending samples.**
CONTROLLED ROOM TEMPERATURE & HUMIDITY STABILITY TESTING (CRT)	Beyond standard room temperature, CIAL has controlled temperature and humidity chambers (25ºC/60% R.H.) to meet FDA, ICH requirements.	Results will be reported as the samples are tested, ±3 days from dates requested. (No testing is performed on weekends or holidays)	Depends on sample, number of actives in the formulation, and time points requested. Please contact us to get exact quantity.	Add **$30 storage fee**, for each time point, to normal price.
ACCELERATED STABILITY TESTING (ACC)	Accelerate stability testing by a factor of approx. 2 to 3 fold. CIAL has an elevated temperature and humidity chamber (40ºC/75% R.H.) to accelerate the testing of your room temperature samples. Note: This test will provide approximate idea of stability but does not replace normal stability testing	Results will be reported as the samples are tested, ±3 days from dates requested. (No testing is performed on weekends or holidays)	Depends on sample, number of actives in the formulation, and time points requested. Please contact us to get exact quantity.	Add **$70 storage fee**, for each time point, to normal price.
MINIMUM FILL (MF)	Ensures that the labeled amount of product in a container confirms to the labeled amount. Test applies to creams, lotions, ointments, pastes, etc. USP <755>	Results usually in 5 - 7 business days.	Test requires 10 filled containers.	**$250**
UNIFORMITY OF DOSAGE UNITS (UDU)	Tests for consistency of each dosage unit. USP <905>	Results usually in 5 - 7 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.
CLEANING VALIDATION (CLV)	Tests for residue of active ingredient(s) remaining on compounding surfaces after cleaning procedure. USP <800>	Results usually in 5 - 7 business days.	Test requires a swab for each surface tested, plus 4 blank swabs. Contact us for procedure.	**$330** To check for interference and recovery from blank swabs. (Isn't needed if done on test below) Plus **$165** For each test swab to be tested.
SURFACE RECOVERY VALIDATION (SRV)	Tests for recovery of active ingredient from various surfaces in compounding lab prior to performing the cleaning validation procedure. USP <800>	Results usually in 5 - 7 business days.	Test requires a swab for each surface tested, plus 4 blank swabs. Contact us for procedure.	**$330** To check for interference and recovery from swabs. (Isn't needed if done on test above) Plus **$165** For each surface test swab tested.
IDENTITY BY UHPLC RETENTION TIME (IRT)	Generally performed along with the test for potency via UHPLC, this test verifies the identity of an API by determining if the retention and UV spectrum of the sample matches that of the reference standard. Performed per USP monograph.	Results usually in 5 - 7 business days.	Same as potency test sample requirements.	**$60**

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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

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 $200. (See the API List on our web site at *www.compounderslab.com* for more information on how each is tested).

- Amantadine HCl
- Cabergoline
- Calcitriol
- Choline Chloride
- Calcium Gluconate
- Cacodylate Sodium
- Dimethyl Glycine
- Gentamicin
- Galactosamine
- Glucosamine
- N-Acetyl Glucosamine
- N-Acetyl-D-Glucosamine
- Glycerophosphocholine
- Inositol
- Kanamycin Sulfate
- Methenamine Mandate
- Methionine
- Neomycin
- Niacinamide (in a B-Complex)
- 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 / 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 $110.

First example: 5 Active Ingredients that can be assayed together:

		Our Pricing	Competitive Labs
First Active:	DHEA	$165	$180
Second Active:	Estriol	$110	$180
Third Active:	Estradiol	$110	$180
Fourth Active:	Progesterone	$110	$180
Fifth Active:	Testosterone	$110	$180
Total Charge:		$605	$900

That's a $295 savings compared to other labs!

Second Example: 3 Active Ingredients that can be assayed together

		Our Pricing	Competitive Labs
First Active:	Estriol	$165	$180
Second Active:	Estradiol	$110	$180
Third Active:	Progesterone	$110	$180
Total Charge:		$385	$540

That's a $155 savings!

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

		Our Pricing	Competitive Labs
First Active:	T3	$165	$180
Second Active:	T4	$110	$180
Total Charge:		$275	$360

That's a $85 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	$110	$180
Third Active:	Prostaglandin	$165	$180
Total Charge:		$440	$540

That's a $100 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	$110
Third Active:	Amantadine HCl	$200
Total Charge:		$475

RUSH CHARGES

Potency Rush Charge Per Sample

2-3 days: 30% additional **Same Day (24 hr.): 75% additional**

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.
If payment is not received within 180 days after reports are released, an additional 25% charge will be added to the total amount.

CIAL has a policy of not charging for the majority of reference standards or specialty items needed to perform various tests. Periodically, we are requested to test a sample or active which is very expensive and/or rarely seen. In such cases we will contact the customer and request help to share in the cost.