



2018 Testing Services & Price

	INFORMATION	TIME REQUIRED FOR TEST	AMOUNT OF SAMPLE REQUIRED	PRICING																		
POTENCY TESTING	Check concentration of active(s) in any dosage form: capsules, gels, creams, powders, suppositories, etc. USP <621> & <797>	Results usually in 5-7 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 5ML for liquids / creams, 1GM for powders. These amounts are not always practical, call if in doubt.	\$150 Per active except those listed on the Potency Assay Combination price sheet Porcine Thyroid: \$230 (Requires 28 hour enzymatic digestion) For multiple active ingredients in the formulation, see our Potency Assay Combination price sheet (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. (Also available, Stability Indicating Assays for FDA approved stability studies.) USP <621> & <797>	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. (Also referred to as "True" Stability Studies)																		
API POWDER	Testing of the pure active ingredient to determine potency and verify identity.	Results usually in 5 - 7 days.	Generally 1GM. For very expensive ingredients we can often test with as little as 25MG - 100MG in a No. 3 capsule.	\$300																		
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 to verify growth will occur.	Takes 5 days to determine presence of microbe growth	10ML Minimum single sample. Quantity must meet <71> batch size requirements. For pooled samples* the total volume must equal at least 10ML	\$400 This test is run concurrently with sterility testing, which is needed as the control.																		
STERILITY TESTING	Check for aerobic and anaerobic bacterial contamination in compliance of USP <797> & <71>	14 days as required by the USP We issue a preliminary report after 7 days.	For single sample 2-5ML. Quantity will be determined by batch size. Pooled samples* total volume must equal at least 2ML.	\$100																		
FUNGI (MOLD/YEAST)	Check specifically for fungi in compliance of USP <797> & <71>. (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 run in conjunction with a sterility test.	\$60																		
ENDOTOXIN	Determine presence of bacterial endotoxins in compliance of USP <797> & <85>	Results in 2-3 days after sample is received.	Quantity will be determined by batch size. For pooled samples* the total volume must equal at least 2ML. For single sample 2-5ML	\$110																		
PACKAGE PRICES	<p>Our standard prices are among the most attractive available. These packages are priced to encourage more complete, and more frequent testing for your protection.</p> <table border="0"> <thead> <tr> <th>Test Package</th> <th>Price of Package</th> </tr> </thead> <tbody> <tr> <td>A. Potency, sterility, fungal, and endotoxin:</td> <td>\$390 (\$30 savings)</td> </tr> <tr> <td>B. Potency, sterility, and endotoxin:</td> <td>\$335 (\$25 savings)</td> </tr> <tr> <td>C. Potency, sterility, and fungal:</td> <td>\$290 (\$20 savings)</td> </tr> <tr> <td>D. Potency and endotoxin:</td> <td>\$240 (\$20 savings)</td> </tr> <tr> <td>E. Potency and sterility:</td> <td>\$235 (\$15 savings)</td> </tr> <tr> <td>F. Sterility, fungal, and endotoxin:</td> <td>\$255 (\$15 savings)</td> </tr> <tr> <td>G. Sterility, and endotoxin:</td> <td>\$200 (\$10 savings)</td> </tr> <tr> <td>H. Sterility, and fungal:</td> <td>\$150 (\$10 savings)</td> </tr> </tbody> </table> <p>Package prices assume 1 active ingredient; additional actives will increase price accordingly. (See pricing above and Combo pricing)</p>				Test Package	Price of Package	A. Potency, sterility, fungal, and endotoxin:	\$390 (\$30 savings)	B. Potency, sterility, and endotoxin:	\$335 (\$25 savings)	C. Potency, sterility, and fungal:	\$290 (\$20 savings)	D. Potency and endotoxin:	\$240 (\$20 savings)	E. Potency and sterility:	\$235 (\$15 savings)	F. Sterility, fungal, and endotoxin:	\$255 (\$15 savings)	G. Sterility, and endotoxin:	\$200 (\$10 savings)	H. Sterility, and fungal:	\$150 (\$10 savings)
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<p>Potency Rush Charge (2-3 days) \$50 Same Day Potency Rush Charge: \$100 - Advanced notice required, must arrive before 11AM *Pooled Samples and/or Reconstituted Samples: \$35 additional charge</p>																						



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STABILITY INDICATING METHOD DEVELOPMENT	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.	Method development depends on complexity of the sample. This will usually be completed in approximately 3 weeks.	Typically need about 100ML or 100GM of sample. Please contact us to get exact amounts.	Starting at \$9,000 Price depends upon complexity of formulation. For multiple active ingredients in the formulation, we make every effort to create a single method which will test for all of the actives. (*Please note that a \$2,000 deposit is required in advance)
STABILITY STUDY USING STABILITY INDICATING METHOD	Following development of the Stability Indicating Method, the Stability Study will 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, ±2 days from dates requested. (CIAL is closed on weekends and holidays)	Depends on sample, number of actives in the formulation, and time points requested.	\$150 Per active ingredient, per time point.
ACCELERATED TESTING	Accelerate your testing by a factor of 2 to 3. CIAL has a constant temperature and humidity chamber to help accelerate the testing of your room temperature samples.	Results will be reported as the samples are tested, ±2 days from dates requested. (CIAL is closed on weekends and holidays)	Depends on sample, number of actives in the formulation, and time points requested.	\$220 Per active ingredient, per time point.
PARTICULATES	Determines the number of sub-visible particles in parenterals and ophthalmics, in ranges: ≥10µm, ≥25µm, ≥50µm. USP <788> <789>	Results are usually available within 2-3 days.	A minimum of 1 container (syringe, vial, IV Bag, etc). Quantity of containers needs to be a statistically representative sampling of the lot.	\$100 Per container
pH	Measures 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 days.	A minimum of 1ML, more is desirable.	\$50 Per test
CONTAINER ENCLOSURE INTEGRITY	Tests the container integrity 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 days.	A minimum of 4 filled containers (syringe, vial, pump, jar, etc).	\$150 Per test
APPEARANCE AND ODOR	Describes the sample as received as well as periodically throughout a stability study. This can be used to document the condition of the formulation over time.	Results will be reported as the samples are tested, ±2 days from dates requested (CIAL is closed on weekends and holidays)	A minimum of 5ML or 5GM, more is desirable.	\$50 Per time point
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 55ML is required for the test. If a part of a multi-test study, a minimum of 50ML per each subsequent test.	\$950 Per test



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Potency Assay Combinations Complete List of Multiple Active Ingredient Formulations	Pricing of Potency Assay Combinations																																																																																	
<ul style="list-style-type: none"> • Amoxicillin / Clavulanate • 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 • Ticercillin Clavulanate 	<p>If you wish to have potency assay performed on formulations which have multiple active ingredients, we may be able to run them all together on the same method. On the left is THE COMPLETE list of those multiple ingredient combinations that we can run together. When we are able to run them in combination, it can save you a lot of money.</p> <p>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, 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 \$150, but each of the others at only \$75each.</p> <p>First example: 6 Active Ingredients that can be assayed together:</p> <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 30%;"></th> <th style="text-align: center; border-bottom: 1px solid black;">Our Pricing</th> <th style="text-align: center; border-bottom: 1px solid black;">Competitive Labs</th> </tr> </thead> <tbody> <tr> <td>First Active: DHEA</td> <td style="text-align: center;">\$150</td> <td style="text-align: center;">\$170</td> </tr> <tr> <td>Second Active: Estriol</td> <td style="text-align: center;">\$ 75</td> <td style="text-align: center;">\$170</td> </tr> <tr> <td>Third Active: Estradiol</td> <td style="text-align: center;">\$ 75</td> <td style="text-align: center;">\$170</td> </tr> <tr> <td>Fourth Active: Estrone</td> <td style="text-align: center;">\$ 75</td> <td style="text-align: center;">\$170</td> </tr> <tr> <td>Fifth Active: Progesterone</td> <td style="text-align: center;">\$ 75</td> <td style="text-align: center;">\$170</td> </tr> <tr> <td>Sixth Active: Testosterone</td> <td style="text-align: center; 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<p>Because of their very low concentrations, difficulty to detect, or difficulty to analyze for a number of reasons, the following actives <u>may</u> 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 <u>will</u> be charged at a rate of \$180.</p> <ul style="list-style-type: none"> • 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 10MCG or lower may need to be assayed in this way. <p>*Vitamin B12 preparations with multiple ingredients (More than 4) may be subject to this pricing. Please contact CIAL to confirm the pricing.</p>																																																																																		