



2020 Testing Services & Price List

MICROBIOLOGICAL TESTS	INFORMATION	TIME REQUIRED FOR TEST	AMOUNT OF SAMPLE REQUIRED	PRICING
STERILITY TESTING (AEROBE & ANAEROBE)	<p>Check for aerobic and anaerobic bacterial contamination.</p> <p>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.</p>	<p>14 days as required by the USP We issue a preliminary report after 7 days.</p>	<p>2 ML Minimum for single sample. Quantity should be determined by batch size.</p> <p>Pooled samples* total volume must equal at least 2 ML</p>	<p>\$100</p> <p>For multiple containers from the same lot: \$130 for 2-5 containers \$140 for 6-10 containers \$150 for 11+ containers</p>
STERILITY METHOD SUITABILITY	<p>Verify the suitability of the sterility testing method in compliance of USP <797> & <71></p> <p>Test involves inoculating 4 different bacteria, plus mold and yeast into growth media containing samples. Presence of growth demonstrates sterility test method is valid.</p>	<p>Takes 5 days to determine presence of microbe growth</p>	<p>Quantity must be 3 times the <71> batch size requirements. (10 ML Minimum)</p> <p>For pooled samples* the total volume must equal at least 10 ML</p>	<p>\$400</p> <p>This test is performed concurrently with sterility testing which is needed as the control.</p>
ENDOTOXIN	<p>Determine level of bacterial endotoxins in compliance with USP <797> & <85></p> <p>Please provide endotoxin limits or dosing requirements.</p>	<p>Results in 2-3 business days after sample is received or with Sterility report</p>	<p>2 ML Minimum required in separate container.</p>	<p>\$110</p>
FUNGI (MOLD/YEAST)	<p>Check specifically for presence of fungal contamination.</p> <p>Strongly recommended for High Risk and Intrathecal injections. (Note, mold doesn't always show up in the USP sterility test)</p>	<p>14 days as required by the USP</p>	<p>Generally 2ML minimum</p> <p>For pooled samples* the total volume must equal at least 2ML This should be done in conjunction with a sterility test.</p>	<p>\$60</p>
ANTIMICROBIAL EFFECTIVENESS	<p>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></p>	<p>Requires ~30 days to produce results.</p>	<p>A minimum of 55 ML is required for the test.</p> <p>If a part of a multi-test study, a minimum of 50 ML per each subsequent test.</p>	<p>\$950</p>
WATER ACTIVITY	<p>Tests for presence of water vapor which can support microbial growth and contribute to hydrolytic breakdown of active ingredients. <1112></p>	<p>Results usually in 5 - 7 business days</p>	<p>Generally 5ML or 5GM minimum</p>	<p>\$95</p>



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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 usually in 5 - 7 business days.	A minimum of 25 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.	\$110
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 container, more is desirable.	\$60
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. USP <381>	Results usually in 5 - 7 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 usually in 5 - 7 business days.	A minimum of 5 ML or 5 GM, more is desirable.	\$60
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 usually in 5 - 7 business days.	A minimum of 0.5 GM, more is desirable.	\$165
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 usually in 5 - 7 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 usually in 5 - 7 business days.	A minimum of 5 MG or 0.1 mL, more is desirable	\$80
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 usually in 5 - 7 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 by ICP-OES. 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
VISCOSITY	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.	\$95
SPECIFIC GRAVITY	Determines the density of a fluid formulation or other substance such as a cream. Allows conversion between weight and volume. 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



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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 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 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 USP, FDA, & Calif. requirements. This will be required in the new December, 2019 <795>. 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. Please contact us to get exact quantity.	Please contact us to discuss and receive a quote before sending samples.
STABILITY STUDY USING STABILITY INDICATING METHOD	Following development 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. (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 - 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	Tests for residue of active ingredient remaining on compounding surfaces after cleaning procedure.	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	Tests for recovery of active ingredient from various surfaces in compounding lab prior to performing the cleaning validation procedure.	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.



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POTENCY ASSAY COMBINATIONS COMPLETE LIST OF MULTIPLE ACTIVE INGREDIENT FORMULATIONS	PRICING OF POTENCY ASSAY COMBINATIONS																																																																																	
<p style="text-align: center;">NEW! SPECIAL POTENCY ASSAYS REQUIRING MASS SPECTROMETER CAPABILITIES</p>	<p>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.</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, 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.</p> <p>First example: 6 Active Ingredients that can be assayed together:</p> <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th></th> <th style="text-align: center;"><u>Our Pricing</u></th> <th style="text-align: center;"><u>Competitive Labs</u></th> </tr> </thead> <tbody> <tr> <td>First Active: DHEA</td> <td style="text-align: right;">\$165</td> <td style="text-align: right;">\$180</td> </tr> <tr> <td>Second Active: Estriol</td> <td style="text-align: right;">\$ 95</td> <td style="text-align: right;">\$180</td> </tr> <tr> <td>Third Active: Estradiol</td> <td style="text-align: right;">\$ 95</td> <td style="text-align: right;">\$180</td> </tr> <tr> <td>Fourth Active: Estrone</td> <td style="text-align: right;">\$ 95</td> <td style="text-align: right;">\$180</td> </tr> <tr> <td>Fifth Active: Progesterone</td> <td style="text-align: right;">\$ 95</td> <td style="text-align: right;">\$180</td> </tr> <tr> <td>Sixth Active: Testosterone</td> <td style="text-align: right;">\$ 95</td> <td style="text-align: right;">\$180</td> </tr> <tr> <td>Total Charge:</td> <td style="text-align: right;">\$640</td> <td style="text-align: right;">\$1,080</td> </tr> </tbody> </table> <p>That's a \$440 savings!</p> <p>Second Example (Tri-est): 3 Active Ingredients that can be assayed together</p> <table style="width: 100%; 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<p style="text-align: center;">RUSH CHARGES</p>	<p style="text-align: center;">Potency Rush Charge Per Sample 2-3 days: \$50 Same Day (24 hr.): \$100 Advanced notice required. Must arrive before 11AM</p>																																																																																	
<p style="text-align: center;">PAYMENT FOR TESTING SERVICES</p>	<p>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.</p> <p>If payment is not received within 45 days after reports are released, a late charge of 10% will be added to the total amount.</p> <p>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 rarely seen. In such cases we will contact the customer and request help to share in the cost.</p>																																																																																	