"The Gold Standard in Quality Testing"
Compounder's International Analytical Laboratory
Better Quality Through Quality Testing

2024 Price List

(Effective 09 / 01 / 24)

Compounders International Analytical Laboratory
4760 Castleton Way, Suite A, Castle Rock, CO 80109
Toll Free: 800-788-9922 Phone: 303-471-8015 Fax: 303-569-6101
lab@compounderslab.com www.CompoundersLab.com

Test Name	*Test Code*	*USP*	*Description*	*Turnaround (bus. days)*	*Amount of Sample*	*Price*	*Notes*
			Microbiology Testing				
Antimicrobial Effectiveness	**AET**	<51>	Determine if the antimicrobial agent in the formulation is effective. Required for <795> <797> multi-dose formulations.	40	55 mL	**$1,200**	Requires 35 day incubation.
Endotoxin	**END**	<85>	Determines levels of bacterial endotoxin in finished product. Required per <797> 12.3 when Sterility is performed.	3	1 container	**$135**	If raw material (API), quote required.
Endotoxin Validation	**ENDV**	<85>	Validation of the Endotoxin test method.	3	1 container	**$480**	
Environmental Plate	**ENP**	<797>	Incubation and enumeration per <797>. Will require Microbial Identification if limits are exceeded.	10	1 plate	**$50**	per plate. Multiple plates can be submitted, requiring unique identifier(s).
Environmental Swab	**ENS**	<797>	Processed day of receipt. Will require Microbial Identification if limits are exceeded.	10	1 swab	**$65**	per swab. One (1) blank swab required.
Fungi (Mold / Yeast)	**FUN**	<71>	Check specifically for the presence of fungal contamination.	14	1 container	**$85**	Should be performed in conjunction with Sterility test.
Gloved Fingertip Testing	**GLF**	<797>	Incubation and enumeration per <797> 2.2, which requires one hand per competency evaluation.	10	1 plate	**$50**	per plate / hand. Multiple plates can be submitted, requiring unique identifier(s).
Growth Promotion Test	**GPT**	N/A	Determines if growth media (TSA / TBA) is suitable for sterility testing against 5 microorganisms.	7	12 plates or 6 containers	**$500**	NLT 60 mL, must be identical containers.
Media Fill (≤100 mL per container)	**MED**	<797>	Incubation and observation according to <797> 2.3.	14	1 - 20 containers	**$100**	Additional +$5 per container.
Media Fill (>100 mL per container)	**MED**	<797>		14	1 - 20 containers	**$200**	Additional +$10 per container.
Microbial Enumeration of Nonsterile Product - Burkholderia	**BCC**	<60>	Determine the possible presence of Burkholderia Cepacia Complex in product.	7	10 mL	**$200**	
Microbial Enumeration of Nonsterile Products - Burkholderia Validation	**BCCV**	<60>		7	10 mL	**$400**	
Microbial Enumeration of Nonsterile Products	**ME**	<61>	Determines total viable aerobic microbial count present in finished products. Commonly known as Bioburden testing.	10	10 mL	**$160**	If raw material (API), quote required.
Microbial Enumeration of Nonsterile Products Validation	**MEV**	<61>		10	10 mL	**$500**	
Subvisible Particulates Method 1 - Injection	**PRT**	<788>	Determines the number of subvisible particles in parenteral solutions at specified ranges (10 µm and 25 µm).	7	25 mL	**$150**	
Subvisible Particulates Method 2 - Injection				7	25 mL	**$300**	Must have Method 1 performed first.
Subvisible Particulates Method 1 - Ophthalmic	**PRT**	<789>	Determines the number of subvisible particles in ophthalmic solutions at specified ranges (10 µm, 25 µm, and 50 µm).	7	25 mL	**$150**	

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Subvisible Particulates Method 2 - Ophthalmic	**PRT**	<789>	Determines the number of subvisible particles in ophthalmic solutions at specified ranges (10 µm, 25 µm, and 50 µm).	7	25 mL	**$300**	Must have Method 1 performed first.
Sterility	**STE**	<71>	Test for microbial contamination of sterile products. Must be compliant with <71> batch sizes. Required for <797> 12.2 compliance.	*14**	1 container	**$130**	Must be from same batch. * Requires 14 calendar days for incubation.
Sterility		<71>		14*	2 - 5 containers	**$160**	
Sterility		<71>		14*	6 - 10 containers	**$175**	
Sterility		<71>		14*	11+ containers	**$205**	
Sterility Method Suitability	**SMS**	<71>	Verify the suitability of the sterility testing method. Required for <797> 12.2 compliance.	14*	3 x USP batch	**$500**	Must be from same batch. * Requires 14 calendar days for incubation.
Sterility - Rapid	**RAP**	<71>	Reduced incubation time for testing microbial contamination of sterile products. Must be compliant with <71> batch sizes.	7*	1 - 9 containers	**$270**	Compliant with <71>. Must be from same batch. * Requires 6 calendar days for incubation. Can roll into STE (14 day incubation) with advance notice (+$130).
Sterility - Rapid		<71>		7*	10+ containers	**$300**	
Sterility Method Suitability - Rapid	**RAM**	<71>	Verify the suitability of the Rapid Sterility testing method. Required for <797> 12.2 compliance.	7*	3 x USP batch	**$1,300**	Must be from same batch. Not compatible with previous Sterility Method Suitability (SMS).
Test for Specified Microorganisms in Nonsterile Products	**SM**	<62>	Checks for presence of Candida Albicans, E. coli, Pseudomonas, Salmonella, and/or Staphylococcus in a finished product.	7	10 mL	**$130**	per microbe. If raw material (API), quote required.
Test for Specified Microorganisms in Nonsterile Products Validation	**SMV**	<62>		7	10 mL	**$230**	per microbe. If raw material (API), quote required.
Water Activity	**WA**	<922>	Tests for the susceptibility of microbial growth in products. Determines non/aqueous classification per <795> 10.3.	7	5 mL	**$95**	<0.6 aW categorized as non-aqueous, ≥0.6 aW categorized as aqueous.
			Chemistry Testing				
Cleaning Validation	**CLV**	<800>	Tests for residue of API's remaining on compounding surfaces after cleaning procedure.	7	(Quote)	**(Quote)**	Contact CIAL for cleaning procedure. 1 swab per surface and 4 blank swabs.
Content Uniformity	**TMB**	<3>	Tests for consistency in topically applied products. Commonly referred to as "Top, Middle, Bottom" testing.	7	1 container	**Starting at $585**	3 x respective Potency.
Dissolution Testing	**DIS**	<711>	Determines the time required for release of the active(s) from immediate / extended release tablets or capsules.	10	6 dosage units	**Starting at $990**	Requires Quote. Method development required if no available monograph.
Hazardous Drug Residue	**HDR**	<800>	Tests for residue of API's remaining on compounding surfaces after cleaning procedure.	7	1 swab / surface	**Starting at $585**	Requires Cleaning Validation. Priced same as respective Potency.

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Test Name	***Test Code***	*USP*	*Description*	*Turnaround (bus. days)*	*Amount of Sample*	***Price***	*Notes*
Identification by Retention Time	**IRT**	<621>	Verifies the identity of an API by retention time and UV spectra or molecular weight.	7	(See Potency)	**$60**	If Potency is not requested, respective Potency cost will be applied.
Minimum Fill	**MF**	<755>	Ensures the volume of product in a container conforms to the labeled amount.	7	10 containers	**$250**	Reported based on testing of 10 containers.
Potency (UHPLC)	**POT**	<621>	Determines the concentration of active(s) in nearly any dosage form.	7	5 g or mL or units	**$195**	If raw material (API), quote required.
Potency (LC-MS)		<621>		7	5 g or mL or units	**$240**	Commonly used for products with lower concentrations.
Potency (GC)		<621>		10	5 g or mL or units	**$210**	Common for testing of Diethylene Glycol (DEG) and Ethylene Glycol (EG).
Potency (Protein / Peptide)		<621>		7	5 g or mL or units	**$260**	Utilized specialized (UHPLC) instrumentation. Refer to CIAL API List.
Potency (Desiccated Thyroid)		<621>	Determines the concentration of Liothyronine (T3) and Levothyroxine (T4).	7	5 g or mL or units	**$285**	Porcine Thyroid. Due to incubation time, this test cannot be rushed.
Potency (Titration)	**TIT**	<541>	Determines the concentration of active(s) when chromatographic methods are unavailable.	7	5 g or mL or units	**$195**	If raw material (API), request quote.
Potency Over Time	**POS**	<621>	Determines the stability of a finished product at various intervals on non Stability Indicating Assay (SIA) method(s).	**7**	(Quote)	**Starting at $195**	Quote required. Priced same as respective Potency.
Residual Solvents (GC)	**RES**	<467>	Determines the identity and amount of solvent present that may occur during the manufacturing process, per <467>.	10	(Quote)	**Starting at $250**	Method development required if not listed in <467>.
Stability Indicating Assay - Method Development / Validation (Phase 1)	**SIA**	<1225>	Develops and validates Stability Indicating Assay (SIA) methods to extend BUD's, per <795> <797>.	(SIA queue)	250 g or mL	**Starting at $9,500**	Requires Quote. Placement in SIA queue required prior to test initiation.
Stability Indicating Assay - Beyond Use Dating (Phase 2)	**BUD**	<795> <797>	Using the SIA method developed in Phase 1 (SIA), study will establish the Beyond Use Date (BUD), per <795> <797>.	(SIA queue)	(Quote)	**(Quote)**	Requires Phase 1 (SIA) completion before Phase 2 (BUD) testing. Requires signed Customer Approved Method (CAM).
Uniformity of Dosage Units	**UDU**	<905>	Tests for consistency of each dosage unit. Reported based on testing of 10 dosage units, per <905>.	7	10 dosage units	**Starting at $1,950**	10 x respective Potency.
			Special Chemistry Testing				
Appearance	**AOC**	N/A	Documents the physical condition of formula over time.	7	1 container	**$70**	Protocol required.
Container Closure Integrity	**CCI**	<1207.2>	Tests the integrity of the container closure system by dye intrusion technique. Results based on 2 containers.	7	4 containers	**$175**	Verified by <381>. Additional +$20 per container.
Crystallinity	**CRY**	<695>	Characterizes compliance of API powders under polarized light.	5	10 mg	**$100**	
Identity by Chemical Reaction	**CID**	<191>	Verifies the presence of a chemical substance by means of a chemical reaction (ie: Chloride, Sodium, Citrate, etc) in API.	7	(Quote)	**(Quote)**	Determined based on individual monograph.

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Test Name	*Test Code*	*USP*	*Description*	*Turnaround (bus. days)*	*Amount of Sample*	*Price*	*Notes*
Identity by Infrared	**IR**	<197>	Determines the identity of an API powder / liquid by comparing an infrared spectral "fingerprint" to a known standard.	7	(Quote)	**(Quote)**	If raw material (API), quote required.
Identity by UV/Vis	**UV**	<197>	Determines the identity of an API powder / liquid using Ultraviolet and Visible wavelengths of light.	7	(Quote)	**(Quote)**	If raw material (API), quote required.
Loss on Drying	**LOD**	<731>	Determines the % of volatile substances in an API powder such as residual solvents and water.	7	1 g	**$120**	If raw material (API), quote required.
Melting Point / Range	**MP**	<741>	Identifies or verifies purity of an API powder / liquid based on its melting temperature or range.	7	(Quote)	**(Quote)**	
Metals Analysis (ICP-OES)	**MET**	<730>	Determines the amount of a Single Metal (known) in an API or finished product.	7	5 mL	**$225**	If raw material (API), quote required.
Metals Analysis (ICP-OES) - Heavy Metals (4)	**MET**	<730>	Determines the amount of the common 4 heavy metals (Arsenic, Cadmium, Lead, Mercury) in an API or finished product.	7	10 mL	**$700**	If raw material (API), quote required.
Microscopic Examination of Unknown Substance	**MEX**	N/A	Determine possible identity and/or source of unknown microscopic particles under a magnification of up to 12,500X.	3	1 container	**$125**	
Optical / Specific Rotation	**OR**	<781S>	Tests for the identity or purity of an optically active (chiral) API. (ie: Levo or Dextro)	5	(Quote)	**(Quote)**	Determined based on individual monograph.
Osmolality	**OSM**	<785>	Determines the osmotic strength (tonicity) of parenterals, nasal sprays, inhalants, or ophthalmic solutions.	5	1 mL	**$110**	
pH	**PH**	<791>	Determines the pH of an API or finished product.	7	3 mL	**$70**	If raw material (API), quote required.
Residue on Ignition	**ROI**	<281>	Determines the total level of inorganic impurities in an API powder / liquid. Also known as Sulfated Ash.	7	2 g	**$250**	If raw material (API), quote required.
Specific Gravity	**SPG**	<841>	Determines the density of a fluid, allowing for formulation conversions between weight and volume.	7	10 mL	**$100**	
Visible Particulates - Injection	**VP**	<790>	Checks for presence of visible particulates in solutions of 10 parenteral containers against white / black backgrounds.	5	10 containers	**$70**	Additional +$10 per container.
Viscosity	**VIS**	<912>	Determines the ability of a fluid to cling to a surface such as skin, throat, or eye.	7	(Call CIAL)	**$175**	Amount based on expected viscosity (cP), contact to confirm amount(s).
Water Determination (Karl Fischer)	**WAT**	<921>	This test is specific for water and determines the water content in an API powder or lyophilized product.	7	1 g	**$200**	Performed using Method 1a.

For Quotes, please submit requests to lab@compounderslab.com.

By submitting sample(s), Customer agrees to CIAL's Terms and Conditions.