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

Compounders International Analytical Laboratory
4760 Castleton Way, Suite A, Castle Rock, CO 801019
Toll Free: 800-788-9922 Phone: 303-471-8015 Fax: 303-569-6101
lab@compounderslab.com www.CompoundersLab.com

2024 Testing Services & Price List

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 for <797> batch release.	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.
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 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>, which requires one hand per competency evaluation.	10	1 plate	**$50**	per plate / hand. Multiple plates can be submitted, requiring unique identifier.
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.
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**	
Sterility	**STE**	<71>	Test for microbial contamination of sterile products. Must be compliant with <71> batch sizes. Required for <797> batch release.	14	1 container	**$130**	Must be from same batch.
Sterility	**STE**	<71>		14	2 - 5 containers	**$160**	
Sterility	**STE**	<71>		14	6 - 10 containers	**$175**	
Sterility	**STE**	<71>		14	11+ containers	**$205**	
Sterility - Rapid Scan (2024 Q2)	**STR**	<71>	Test for microbial contamination of sterile products using Rapid Scan technology, reducing the incubation time.	7	(See STE)	**Starting at $270**	* Coming 2024 Q2 *
Sterility Method Suitability	**SMS**	<71>	Verify the suitability of the sterility testing method. Required for <797> compliance.	14	3 x USP batch	**$500**	Must be from same batch.
Sterility Method Suitability - Rapid Scan (2024 Q2)	**SMR**	<71>	Verify the suitability of the sterility testing for Rapid Scan method.	7	3 x USP batch	**Starting at $1,300**	* Coming 2024 Q2 *

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

2024 Testing Services & Price List

Compounders International Analytical Laboratory
4760 Castleton Way, Suite A, Castle Rock, CO 801019
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*
Test for Specified Microorganisms in Nonsterile Products	**SM**	<62>	Checks for presence of E. coli, Salmonella, Staphylococcus, and/or Pseudomonas 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.
Media Fill (≤100 mL per container)	**MED**	<797>	Incubation and observation according to <797>.	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.
			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 $195**	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 $195**	Requires Cleaning Validation. Priced same as respective Potency.
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 labelled amount.	7	10 containers	**$250**	Reported based on testing of 10 containers.
Potency (UHPLC)	POT	<621>	Determines the concentration of active(s) in any dosage form.	7	5 g or mL or units	**$195**	Priced same as respective Potency. If raw material (API), request quote.
Potency (LC-MS)	POT	<621>	Determines the concentration of active(s) in any dosage form.	7	5 g or mL or units	**$240**	Commonly used for products with lower concentrations.
Potency (GC)	POT	<621>	Determines the concentration of active(s) in any dosage form.	10	5 g or mL or units	**$210**	Commonly used for Diethylene Glycol / Ethylene Glycol testing.
Potency (Protein / Peptide)	POT	<621>	Determines the concentration of active(s) in any dosage form.	7	5 g or mL or units	**$260**	Refer to CIAL API List.
Potency (Desiccated Thyroid)	POT	<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.	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	1 g	**Starting at $250**	Method development required if not listed in <467>.

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

2024 Testing Services & Price List

Compounders International Analytical Laboratory
4760 Castleton Way, Suite A, Castle Rock, CO 801019
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*
Stability Indicating Assay - Method Development / Validation (Phase 1)	SIA	<1225>	Develops and validates Stability Indicating Assay (SIA) methods to establish BUD's, per <795> <797>.	(SIA queue)	250 g or mL	**Starting at $9,500**	Requires Quote. Placement in SIA queue required prior to beginning method development.
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 can begin.
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**	CIAL	Documents the condition of formula upon receipt and/or 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 crystalline 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.
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>	Determined 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.
Specific Gravity	**SPG**	<841>	Determines the density of a fluid, allowing for formulation conversions between weight and volume.	7	10 mL	**$100**	

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

Compounders International Analytical Laboratory
4760 Castleton Way, Suite A, Castle Rock, CO 801019
Toll Free: 800-788-9922 Phone: 303-471-8015 Fax: 303-569-6101
lab@compounderslab.com www.CompoundersLab.com

2024 Testing Services & Price List

Test Name	Test Code	USP	Description	Turnaround (bus. days)	Amount of Sample	Price	Notes
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	**PRT**	<788>		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**	
Subvisible Particulates Method 2 - Ophthalmic	**PRT**	<789>		7	25 mL	**$300**	Must have Method 1 performed first.
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).
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.
Water Activity	**WA**	<922>	Tests for the susceptibility of microbial growth in products. Required for aqueous / non-aqueous determination in <795>.	7	5 mL	**$95**	<0.6 aW categorized as non-aqueous, ≥0.6 aW categorized as aqueous.
Water Determination (Karl Fischer)	**WAT**	<921>	This test specific for water and determines the water content in an API powder or lyophilized product.	7	1 g	**$200**	Performed using Method 1a.

CIAL has a policy of not charging for the majority of reference standards needed to perform testing on our Price List. Periodically, we are requested to test an active whose standard is very expensive and/or per specific monographs. In such cases, the customer will be informed prior to being charged for any additional costs.

Please refer to CIAL's API List for actives that are commonly tested via LC-MS or classified as a "Peptide / Protein".

For CIAL's Sample Submission documents, refer to the following: 503A and 503B Sample Submission forms, Rush Request form, and Change Request form.

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

Payment is due when test results are released and can be paid via credit card or purchase order / invoice. CIAL requires a current credit card to be on file before testing begins.

If payment is not received within **45 days** after report(s) are released, a late charge of **10%** will be added to the total invoiced amount.
If payment is not received within **180 days** after report(s) are released, an additional **25%** charge will be added to the total invoiced amount.

According to ISO 17025, Compounder's International Analytical Lab (CIAL) is required to have a Statement of Conformity and a Decision Rule which corresponds to the Conformity Statement. The Conformity Statement and Decision Rule CIAL has adopted has been combined. Therefore, CIAL conforms to the USP chapter which regulates the expression of values obtained when reporting on a particular test requested by the customer. The Decision Rule states that the USP limitations are the values which will be followed unless specifically requested otherwise by the customer.