



"The Gold Standard in Quality Testing"

**Compounder's International
Analytical Laboratory**

Better Quality Through Quality Testing

Compounder's International Analytical Laboratory

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Lab@CompoundersLab.com

2024 Sample Submission Form (503A)

Date: _____

Contact Name: _____

Organization: _____

Address: _____

City: _____ State: _____ Zip: _____

Phone: _____

Email: _____

Reference/Purchase Order #: _____

CIAL USE ONLY (RECEIVING)

R01

USPS

FedEx

UPS

Drop-Off

CIAL Tracking #: _____

E: _____

R: _____

* ONLY ONE (1) LOT PER SUBMISSION FORM *

Formulation Worksheet required prior to testing. "N/A" any section intentionally left blank.

Lot:

Batch Size:

Unit(s) Sent:

Fill Volume:

CAM #:

Formula ID:

Compounding Date:

Storage: Room Temp (23°C ± 3°)

Refrigerator (4°C)

Freezer (-20°C)

Controlled (25°C, 60% RH)*

Accelerated (40°C, 75% RH)*

(*Additional Charge)

☐☐☐☐☐

Active(s) in form to be reported as:

Concentration(s):

Test Code(s):

Acceptance Criteria (ie: Endotoxin Limits, etc):

Quote Number (if applicable):

Comments / Instructions:

Consult our website (www.CompoundersLab.com) for Price List and Rush Request Form

2024 Price List and Quotes

* Click on "Services" then "Pricing List" to download (PDF) *

For quotes, email lab@compounderslab.com

Rush Request Form

* Approval required. Sample(s) must be received by 11:00 am MST *

Same Day (24 hr) and 2 - 3 Day available

CIAL has a policy of not charging for the majority of reference standards needed to perform testing, per 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.

A valid credit card is required to be on file prior to samples being tested. Customers are required to fill out a Credit Card Authorization form when setting up account. Payment, via Invoice or Credit Card, is due when reports are released. If payment is not received within 45 days after release, a late charge of +10% will be added to the total amount.



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 *



2024 Testing Services & Price List

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>.



2024 Testing Services & Price List

Test Name	Test Code	USP	Description	Turnaround (bus. days)	Amount of Sample	Price	Notes
Stability Indicating Assay - Method Development / Validation (Phase 1)	SIA	<u><1225></u>	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	<u><795></u> <u><797></u>	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	<u><905></u>	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	<u><1207.2></u>	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	<u><695></u>	Characterizes compliance of crystalline API powders under polarized light.	5	10 mg	\$100	
Identity by Chemical Reaction	CID	<u><191></u>	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	<u><197></u>	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	<u><197></u>	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	<u><731></u>	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	<u><741></u>	Identifies or verifies purity of an API powder / liquid based on its melting temperature or range.	7	(Quote)	(Quote)	
Metals Analysis (ICP-OES)	MET	<u><730></u>	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	<u><730></u>	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	<u><781S></u>	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	<u><785></u>	Determines the osmotic strength (tonicity) of parenterals, nasal sprays / inhalants, or ophthalmic solutions.	5	1 mL	\$110	
pH	PH	<u><791></u>	Determines the pH of an API or finished product.	7	3 mL	\$70	If raw material (API), quote required.
Specific Gravity	SPG	<u><841></u>	Determines the density of a fluid, allowing for formulation conversions between weight and volume.	7	10 mL	\$100	



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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.