

(Effective 01 / 01 / 25)

# **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

Test Name	Test Code	USP	Description	Turnaround (bus. days)	Amount of Sample	Normal TAT	Rush* (2 - 3 Day)	Rush* (24 Hour)
			Microbiology Testing					
Antimicrobial Effectiveness	AET	<u>&lt;51&gt;</u>	Determine if the antimicrobial agent in the formulation is effective. Required for <795> <797> multi-dose formulations. Requires 35 day incubation.	40	55 mL	\$1,200		
Endotoxin	END	<u>&lt;85&gt;</u>	Determines levels of bacterial endotoxin in finished product.  Required per <797> 12.3 when Sterility is performed.	3	1 container	\$135		\$270
Endotoxin Validation	ENDV	<u>&lt;85&gt;</u>	Validation of the Endotoxin test method. Limit Specifications required.	3	1 container	\$480		\$960
Environmental Plate	ENP	<u>&lt;797&gt;</u>	Incubation and enumeration per <797>. Will require Microbial Identification if limits are exceeded. Multiple plates can be submitted, requiring unique identifier(s).	10	1 plate	\$50		
Environmental Swab	ENS	<797>	Processed day of receipt. Will require Microbial Identification if limits are exceeded. One (1) blank swab required.	10	1 swab	\$65		
Fungi (Mold / Yeast)	FUN	<u>&lt;71&gt;</u>	Generally performed in conjunction with Sterility, this test specifically checks for the presence of fungal contamination.	14	1 container	\$85		
Growth Promotion Test	GPT	N/A	Determines if growth media (TSA / TBA) is suitable for sterility testing against 5 microorganisms. Must be identical containers.	7	12 plates or 6 containers	\$500		
Media Fill (≤100 mL per container)	MED	<797>	Incubation and observation according to <797> 2.3.	14	1 - 20 containers	\$100		
Media Fill (>100 mL per container)	MED	<u>&lt;797&gt;</u>	Additional +\$5 (≤100 mL) and +\$10 (>100 mL) per container.	14	1 - 20 containers	\$200		
Microbial Enumeration of Nonsterile Products	ME	<u>&lt;61&gt;</u>	Determines total viable aerobic microbial count present in	10	10 mL	\$160		
Microbial Enumeration of Nonsterile Products Validation	MEV	<u>&lt;61&gt;</u>	finished products. Commonly known as Bioburden testing. If raw material (API), quote required.	10	10 mL	\$500		
Sterility Method Suitability	SMS	<u>&lt;71&gt;</u>	Verify the suitability of the sterility testing method. Required for <797> 12.2 compliance. Must be from the same batch.	14**	3 x USP batch	\$500		
Sterility		<u>&lt;71&gt;</u>		14**	1 container	\$130		
Sterility	STE	<u>&lt;71&gt;</u>	Test for microbial contamination of sterile products. Must be	14**	2 - 5 containers	\$160		
Sterility		<u>&lt;71&gt;</u>	compliant with <71> batch sizes. Required for <797> 12.2 compliance. Must be from the same batch.	14**	6 - 10 containers	\$175		
Sterility		<u>&lt;71&gt;</u>		14**	11+ containers	\$205		



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Sterility Method Suitability - Rapid	RAM	<u>&lt;71&gt;</u>	Verify the suitability of the Rapid Sterility testing method. Required for <797> 12.2 compliance. Not compatible with previous Sterility Method Suitability (SMS). Must be from the same batch.	7**	3 x USP batch	\$1,300		
Sterility - Rapid			Reduced incubation time for testing microbial contamination of sterile products. Must be compliant with <71> batch sizes. Must be from the same batch. Can roll into STE (14 day incubation) with advance notice (+\$130).	7**	1 - 9 containers	\$270		
Sterility - Rapid	RAP	<u>&lt;71&gt;</u>		7**	10+ containers	\$300		
Test for Specified Microorganisms in Nonsterile Products	SM	<u>&lt;62&gt;</u>	Checks for presence of Candida Albicans, E. coli,	7	(Quote)	\$130		
Test for Specified Microorganisms in Nonsterile Products Validation	SMV	<u>&lt;62&gt;</u>	Pseudomonas, Salmonella, and/or Staphylococcus in a finished product. Cost per microbe.	7	(Quote)	\$230		
Water Activity	WA	<u>&lt;922&gt;</u>	Tests for the susceptibility of microbial growth in products.  Determines non/aqueous classification per <795> 10.3.  Categorized as non-aqueous (<0.6 aW) or aqueous (≥0.6 aW).	7	5 mL	\$95	\$143	\$190
			Chemistry Testing					
Cleaning Validation	CLV	<u>&lt;800&gt;</u>	Tests for residue of API's remaining on compounding surfaces after cleaning procedure. Contact CIAL for cleaning procedure.  1 swab per surface and 4 blank swabs.	7	(Quote)	(Quote)		
Content Uniformity	ТМВ	<u>&lt;3&gt;</u>	Tests for consistency in topically applied products. Commonly referred to as "Top, Middle, Bottom" testing. Cost based on 3 x respective Potency.	7	1 container	Starting at \$585	Starting at \$878	
Dissolution Testing	DIS	<u>&lt;711&gt;</u>	Determines the time required for release of the active(s) from immediate / extended release tablets or capsules. Method development required if no available monograph. Requires Quote.	10	6 dosage units	Starting at \$990	Starting at \$1,485	
Hazardous Drug Residue	HDR	<u>&lt;800&gt;</u>	Requires Cleaning Validation. Priced same as respective Potency.	7	1 swab / surface	Starting at \$585	Starting at \$878	
Identification by Retention Time	IRT	<u>&lt;621&gt;</u>	Verifies the identity of an API by retention time and UV spectra or molecular weight. If Potency is not requested, respective Potency cost will be applied.	7	(See Potency)	\$60	\$90	\$120
Minimum Fill	MF	<u>&lt;755&gt;</u>	Ensures the volume of product in a container conforms to the labeled amount. Testing based on 10 containers.	7	10 containers	\$250	\$375	\$500
Potency (Titration)	TIT	<u>&lt;541&gt;</u>	Determines the concentration of active(s) when chromatographic methods are unavailable. If raw material (API), request quote.	7	5 g or mL or units	\$195	\$293	\$390



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Potency (UHPLC)	РОТ	<u>&lt;621&gt;</u>	Determines the concentration of active(s) in nearly any dosage form. If raw material (API), quote required. Refer to CIAL API List for available methods.	7	5 g or mL or units	\$195	\$293	\$390
Potency (LC-MS)		<u>&lt;621&gt;</u>		7	5 g or mL or units	\$240	\$360	\$480
Potency (GC)		<u>&lt;621&gt;</u>		10	5 g or mL or units	\$210	\$315	\$420
Potency (Protein / Peptide)		<u>&lt;621&gt;</u>		7	5 g or mL or units	\$260	\$390	\$520
Potency (Desiccated Thyroid)		<u>&lt;621&gt;</u>	Also known as "Porcine Thyroid", it determines the concentrations of Liothyronine (T3) and Levothyroxine (T4). Due to incubation time, this test cannot be rushed.	10	5 g or mL or units	\$285		
Potency Over Time	POS	<u>&lt;621&gt;</u>	Determines the stability of a finished product at various intervals on non-validated method(s). Quote required, with pricing based on respective Potency.	7	(Quote)	Starting at \$195		
Residual Solvents (GC)	RES	<u>&lt;467&gt;</u>	Determines the identity and amount of solvent present that may occur during the manufacturing process. Method development required if not listed in <467>.	10	(Quote)	Starting at \$250	Starting at \$375	
Stability Indicating Assay - Method Validation (Phase 1)	SIA	<1225>	Develops and validates Stability Indicating Assay (SIA) methods to extend BUD's, per <795> <797>. Requires Quote. Placement in the SIA queue required prior to beginning method development.	(SIA queue)	250 g or mL	Starting at \$9,500		
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)		
Uniformity of Dosage Units	UDU	<u>&lt;905&gt;</u>	Tests for consistency of each dosage unit. Reported based on testing of 10 dosage units, per <905>. Cost based on 10 x respective Potency.	7	10 dosage units	Starting at \$1,950	Starting at \$2,925	Starting at \$3,900
			Special Chemistry Testing					
Appearance	AOC	N/A	Documents the physical condition of formula over time. Protocol required.	7	1 container	\$70	\$105	\$140
Container Closure Integrity	CCI	<1207.2>	Tests the integrity of the container closure system by dye intrusion technique. Results based on 2 containers.  Additional +\$20 per container.	7	4 containers	\$175	\$263	\$350
Crystallinity	CRY	<u>&lt;695&gt;</u>	Characterizes compliance of API powders under polarized light.	5	10 mg	\$100	\$150	\$200
Identity by Chemical Reaction	CID	<u>&lt;191&gt;</u>	Verifies the presence of a chemical substance by means of a chemical reaction (ie: Chloride, Sodium, Citrate, etc) in API.  Determined based on individual monograph.	7	(Quote)	(Quote)		



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Identity by Infrared	IR	<u>&lt;197&gt;</u>	Determines the identity of an API powder / liquid by comparing an infrared spectral "fingerprint" to a known standard. If raw material (API), request quote.	7	(Quote)	(Quote)		
Identity by UV/Vis	UV	<197U>	Determines the identity of an API powder / liquid using Ultraviolet and Visible wavelengths of light. If raw material (API), request quote.	7	(Quote)	(Quote)		
Loss on Drying	LOD	<u>&lt;731&gt;</u>	Determines the % of volatile substances in an API powder such as residual solvents and water. If raw material (API), request quote.	7	1 g	\$120	\$180	
Melting Point / Range	MP	<u>&lt;741&gt;</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>&lt;730&gt;</u>	Determines the amount of a single Metal (known) in an API or finished product. If raw material (API), request quote.	7	5 mL	\$225	\$338	\$450
Metals Analysis (ICP-OES) - Heavy Metals (4)	MET	<u>&lt;730&gt;</u>	Determines the amount of the common 4 heavy metals (Arsenic, Cadmium, Lead, Mercury) in an API or finished product. If raw material (API), request quote.	7	10 mL	\$700	\$1,050	\$1,400
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	\$188	\$250
Optical / Specific Rotation	OR	<u>&lt;781&gt;</u>	Tests for the identity or purity of an optically active (chiral) API. (ie: Levo or Dextro). Tested per the individual monograph.	5	(Quote)	(Quote)		
Osmolality	оѕм	<u>&lt;785&gt;</u>	Determines the osmotic strength (tonicity) of parenterals, nasal sprays, inhalants, or ophthalmic solutions.	5	1 mL	\$110	\$165	\$220
рН	PH	<u>&lt;791&gt;</u>	Determines the pH of an API or finished product. If raw material (API), request quote.	7	3 mL	\$70	\$105	\$140
Residue on Ignition	ROI	<u>&lt;281&gt;</u>	Determines the total level of inorganic impurities in an API powder / liquid. Also known as Sulfated Ash. If raw material (API), request quote.	7	2 g	\$250	\$375	\$500
Specific Gravity	SPG	<u>&lt;841&gt;</u>	Determines the density of a fluid, allowing for formulation conversions between weight and volume.	7	10 mL	\$100	\$150	\$200
Subvisible Particulates Method 1 - Injection	PRT	<u>&lt;788&gt;</u>	Determines the number of subvisible particles in parenteral solutions at specified ranges (10 µm and 25 µm). Must have	7	25 mL	\$150	\$225	\$300
Subvisible Particulates Method 2 - Injection		<u>&lt;788&gt;</u>	Method 1 performed prior to Method 2.	7	25 mL	\$300	\$450	\$600



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Test Name	Test Code	USP	Description	Turnaround (bus. days)	Amount of Sample	Normal TAT	Rush* (2 - 3 Day)	Rush* (24 Hour)
Subvisible Particulates Method 1 - Ophthalmic	PRT	<u>&lt;789&gt;</u>	Determines the number of subvisible particles in ophthalmic solutions at specified ranges (10 µm, 25 µm, and 50 µm). Must have Method 1 performed prior to Method 2.	7	25 mL	\$150	\$225	\$300
Subvisible Particulates Method 2 - Ophthalmic		<u>&lt;789&gt;</u>		7	25 mL	\$300	\$450	\$600
Visible Particulates - Injection	VP	<u>&lt;790&gt;</u>	Checks for presence of visible particulates in solutions of 10 parenteral containers against white / black backgrounds.  Additional +\$10 per container.	5	10 containers	\$70	\$105	\$140
Viscosity - Rotational Methods	VIS	<u>&lt;912&gt;</u>	Determines the ability of a fluid to cling to a surface such as skin, throat, or eye. Amount based on expected viscosity (cP), contact CIAL to confirm the amount.	7	(Call CIAL)	\$175	\$263	\$350
Water Determination (Karl Fischer)	WAT	<u>&lt;921&gt;</u>	Performed using Method 1a, this test is specific for and determines the water content in API powder or lyophilized products.	7	1 g	\$200	\$300	\$400

For Quotes, please submit requests to <a href="mailto:lab@compounderslab.com">lab@compounderslab.com</a>.

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

<sup>\*</sup> Requires CIAL-approved Rush Request form with 24-hr notice.

<sup>\*\*</sup> Turnaround in *calendar* days, based on respective incubation time.