



## Raw Materials *Express* Testing Offers Rapid 5-Day Turnaround Time

At no additional cost to clients, Lancaster Laboratories offers rapid turnaround time for Raw Materials testing expressly for certain routine USP and EP tests. Have results in 5 days if compendia methodology and noncustomized documentation formats suit your project needs. And with LabAccess.com<sup>SM</sup>, our 24/7 web portal, view all your data such as analysts' notebooks, chromatograms and individual test results as your projects progress.

Contact us to discover the benefits of partnering with global scientific innovators and how we can meet your comprehensive bio/pharmaceutical outsourcing needs.

### USP/NF and EP Materials Eligible for Express Testing

*If both USP and EP are requested, please double the sample amount.*

- Acetic Acid, Glacial (350 mL)
- Acetone (300 mL)
- Alcohol, Ethanol (2300 mL)
- Ammonia Solution, Strong (300 mL)
- Ammonium Sulfate (300 g chem/35 g micro)\*
- Corn Starch (Maize starch) (300 g chem/35 g micro)
- Dextrose (Glucose anhydrous) (300 g)
- Dextrose Excipient (Glucose monohydrate) (300 g)
- Edetate Disodium (50 g)
- Eucalyptol (Cineole) (250 g)\*\*
- Glutamine (25 g)\*
- Hydrochloric Acid (100 mL)
- Hydrochloric Acid, Diluted (175 mL)
- Lactose, Anhydrous (200 g chem/35 g micro)
- Lactose, Monohydrate (250 g chem/35 g micro)
- Microcrystalline Cellulose (500 g chem/35 g micro)



- Methionine (50 g)
- Phosphoric Acid (75 mL)
- Potassium Chloride (75 g)
- Potassium Hydroxide (20 g)
- Potassium Phosphate Monobasic (Potassium Dihydrogen Phosphate) (100 g)
- Potassium Phosphate Dibasic (DiPotassium Phosphate) (100 g)
- Saccharin, Sodium (100 g)
- Sodium Chloride (200 g chem/1g micro)
- Sodium Citrate (30 g)
- Sodium Hydroxide (25 g)
- Sodium Phosphate Dibasic (Disodium Phosphate Dihydrate) (100 g)
- Sodium Phosphate Monobasic (Sodium DiHydrogen Phosphate Dihydrate) (120 g)
- Sucrose (125 g)
- Sulfuric Acid (100 g)

\* This material is USP only

\*\* Not including Relative Substances Analysis

Any sample with micro testing will be a 7-calendar-day TAT due to incubations. Sterility testing is not included in the Express program as the incubation period is 14 days.

For materials not on the Express list, standard 8-day TAT would apply (with rush service available upon pre-approval). Material/minimum sample amount needed for full testing.

Discover our solutions at: [LancasterLabsPharm.com](http://LancasterLabsPharm.com)

#### Global Services:

Biochemistry  
Cell Bank Manufacturing  
Facility & Process Validation  
Method Development & Validation  
Microbiology  
Molecular & Cell Biology

Mycoplasma Services  
Raw Materials Testing  
Release Testing  
Residuals & Impurities Testing  
Stability Testing & Storage  
Viral Clearance & Viral Safety

#### Facilities:

USA  
Lancaster, PA | 717-656-2300  
Portage, MI | 269-323-3366

Ireland  
Dungarvan Co. Waterford | 00 353 (0) 58 48300



## Sample Qualifications

- The testing can be USP/NF and/or EP compendia only, including specifications.
- The testing will use Lancaster Labs' reporting format and documentation practices.
- The data will only be available on LabAccess.com<sup>SM</sup>.
- Separate containers must be provided for chemistry and microbiology testing.
- Express Testing must be written on the outside of the

box when shipped, or one of the Raw Materials Express labels needs to be used.

- The Express Testing request form must be used, or Express must be handwritten on the submission form.
- The paperwork for these samples must be provided at least one day prior to samples so that the samples can be pre-entered and quickly sent to the lab for testing.
- Residual solvent testing is not included in this program.
- Microbiology validations must be performed prior to this service.

**Acetone** — EP Water by KF requires an initial method deviation, which may exceed the 5-day turnaround for the first test. All testing thereafter will be eligible for Express Testing.

**Alcohol, Ethanol** — We prefer clients to send all organic solvent material in unopened vendor packaging, although we realize that this is not always possible. If a subsample must be performed, the following subsample process should be followed: The container selected for the subsample should be a clean glass bottle. It should have a screw-top cap with a Teflon liner well-sealed in the lid. Prior to subsampling, the subsample container should be thoroughly rinsed (at least three times) with the solvent material. The rinses should be discarded. While pouring the sample into the subsample container, it is important that the solvent does not dribble down the neck or label of the bottle and then drip into the subsample container. Please be sure that the sample submission container is appropriately sized. There should be as little headspace as possible. All of these guidelines will help prevent an out-of-spec result for solvents undergoing impurities testing.

**Corn Starch** — Indicate whether the material is intended for use in preparing Absorbable Dusting Powder as the *Staphylococcus aureus* and *Pseudomonas aeruginosa* tests are only required for this situation. For the Identification A test, we will use a microscope with a polarized filter to address that "the starch granules show a distinct black cross intersecting at the hilum" since we do not have a crossed nicol prism.

**Lactose Anhydrous** — Indicate if labeling includes the relative quantities of alpha and beta lactose and provide the labeled quantities.

**Lactose Monohydrate** — Indicate whether this material is the modified form of lactose monohydrate and also indicate the required method for particle size distribution (sieving or light diffraction).

**Microcrystalline Cellulose** — Do not submit the samples in plastic bags or plastic containers. Samples should be submitted in a glass container with screw-top cap. The Particle Size Distribution Test is required only if there are functionality-related concerns regarding the Particle Size Distribution of the article, and the Particle Size Distribution is part of the labeling. We are currently not able to offer the Particle Size Distribution estimation testing since we are not set up to perform laser light scattering Particle Size Testing. We can perform Particle Size analysis by sieving. If this is requested, please contact your client service representative.

**Phosphoric Acid** — Specify if the sample is concentrated or diluted.

**Potassium Chloride** — Indicate whether the material is intended for use in hemodialysis. The Aluminum <206> test is only required for materials that are labeled for this usage. The USP method for aluminum by GFAA has been problematic, and we are not able to offer this testing at this time. According to USP PF Vol. 30 (@) [Mar.-Apr. 2004] pp. 685-690, a proposal is in place to change the testing from a Graphite Furnace Atomic Absorption test to a Fluorometric test.

**Sodium Chloride** — Indicate whether sodium chloride is intended for use in the manufacture of injectable dosage forms, peritoneal dialysis solutions, hemodialysis solutions or hemifiltration solutions. Only materials labeled for use in peritoneal dialysis solutions, hemodialysis solutions or hemifiltration solutions require the Aluminum and Limit of Potassium tests. The Limit of Potassium is also required for injectable dosage forms. Bacterial Endotoxin Testing is required where sodium chloride must be subjected to further processing during the preparation of injectable dosage forms.

**Sodium Phosphate, Dibasic** — Indicate whether this material is anhydrous, monohydrate, dihydrate, heptahydrate or dodecahydrate.

**Sodium Phosphate, Monobasic** — Indicate whether this material is anhydrous, monohydrate or dihydrate.

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