

## **OTC and Prescription Drugs**

Recalls have shown that stringent testing is needed for the health of the pharmaceutical industry. UL offers a broad spectrum of quality assurance programs to OTC and prescription drug manufacturers.

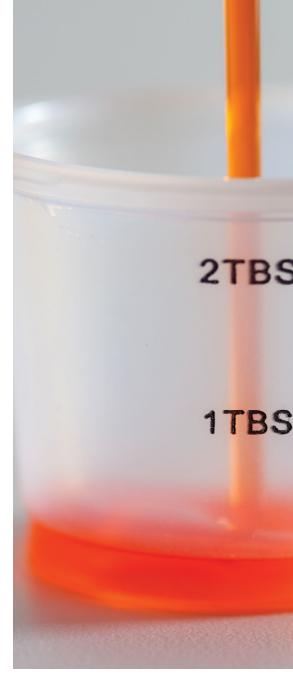
The pharmaceutical industry is one of the most heavily regulated industries in our global marketplace—and it should be—people's lives, health, and comfort depend on it!

Purity, potency, and safety are deliverables that every over-the-counter (OTC) and prescription drug consumer demand. But increased recalls, along with heightened media and regulatory attention, can make it increasingly difficult for companies to maintain credibility and consistency.

From testing the purity and potency of raw material ingredients and finished products, to verifying compliance with strict regulatory requirements, to measuring consumer acceptability, UL's full spectrum of OTC and prescription drug services help your products meet stringent industry, regulatory, and consumer demands for safety, effectiveness, and quality. In our state-of-the-art facilities, our expert staff of regulatory affairs consultants, microbiologists, and chemists help our clients maintain product quality and safety.

UL uses recognized methods to test your products for compliance to international, federal, and regional regulations.

- Pharmacopeia testing to USP, EP, and JP standards
- Compliance testing to DSHEA, USP and FDA cGMPs





For more information email QAInfo@ul.com.



## **RAW MATERIAL AND FINISHED PRODUCT TESTING\***

MICROBIOLOGICAL	<ul> <li>Aspergillus brasiliensis</li> <li>Bacterial Endotoxins</li> <li>Bile-tolerant Gram-negative Bacteria</li> <li>Bioburden</li> <li>Candida albicans</li> <li>Clostridia</li> </ul>	<ul> <li>E.coli</li> <li>Pseudomonas aeruginosa</li> <li>Salmonella</li> <li>Staphylococcus aureus</li> <li>Sterility</li> <li>Total Plate Count</li> <li>Yeast and Mold</li> </ul>
ANALYTICAL	<ul> <li>Acid Value</li> <li>Alkalinity</li> <li>Anisidine Value</li> <li>Ash</li> <li>Carbonate</li> <li>Chloride</li> <li>Clarity</li> <li>FTIR Identification</li> <li>Iodine Value</li> <li>LOD</li> </ul>	<ul> <li>Melting Range</li> <li>Peroxide Value</li> <li>Readily Carbonizable Substances</li> <li>Specific Rotation</li> <li>Sulfate</li> <li>Unsaponifiable Matter</li> </ul>
PHYSICAL	<ul> <li>Bulk Density</li> <li>Dimensions</li> <li>Disintegration</li> <li>Flowability</li> <li>Net Contents</li> <li>Particle Size</li> <li>pH</li> </ul>	<ul> <li>Product &amp; Packaging Workmanship</li> <li>Specific Gravity</li> <li>Viscosity</li> <li>Weight Measurements</li> <li>Weight Variation</li> </ul>
ACTIVE INGREDIENTS	<ul> <li>Caffeine</li> <li>Dissolution</li> <li>Naproxen Sodium</li> <li>Diphenhydramine HCL</li> </ul>	<ul><li>Lidocaine</li><li>Ibuprofen</li><li>Acetaminophen</li></ul>
CONTAMINATION	<ul><li>Heavy Metals</li><li>Pesticide Residue</li></ul>	Residual Solvents

\*Representative sample of UL testing capabilities. Additional tests can be performed.

## UL provides additional consumer product services including:

- Antimicrobial preservatives
   effectiveness studies
- Accelerated and ambient stability testing
- Antibiotic assays
- Container, closure and packaging testing
- Sensory evaluations and consumer studies
- Claims substantiation
- Label reviews
- Regulatory consultation
- SOP development and implementation
- Method development and validation
- Manufacturing audits

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