

DESCRIPTION

Installation qualification is a documentation package ensuring receipt and proper installation of the appropriate parts and systems of the Process Equipment. Many years of direct experience has allowed United Science to assemble this comprehensive set of detailed documents that may be used as templates to assist those who desire to have GMP compliance on specified equipment. Included in this package are hundreds of pages of valuable documents and easy to use templates that will assist you in meeting cGMP and/or euGMP requirements associated with audits and inspection.

*Full SOP, IoT, MRP, ERP, Batch Record, LIMS, QMS documentation are available with purchase of igwLAB software. Annual igwLAB Software License (Part #80-9617).

Documentation includes Material Certifications for all:

- Wetted Surfaces
- Certified Gauges
- Calibration Certifications for all Extractor Quality Processes



DELIVERABLES

- Component Cut Sheets
- Required Utilities for Equipment Operation
- Installation Drawings
- Manufacturer Generated URS
- Control Panel Logic
- Top Level P&ID
- Top Level Assembly Drawings
- Alarms with Limits & Default Settings

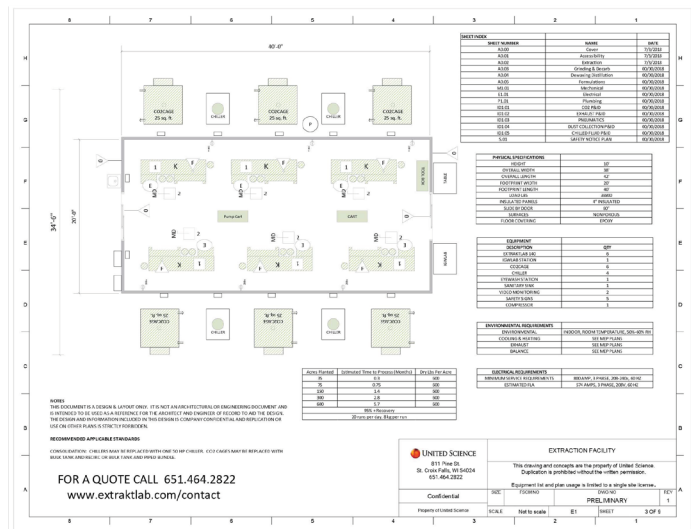


LISTS & MANUALS

- Packing List
- Operation & Maintenance Manuals
- Critical Spare Parts List: Quantity of Each & Lead time if ordered from supplier
- Equipment Instrument List

SCHEMATICS

- Equipment & Electrical Point to Point
- Electrical Panel
- Control & PLC Logic



PROCEDURES

- FAT Test Results & Procedures
- SAT Test

CERTIFICATES (3-4 weeks)

- Product Contact Surface Material Certificates
- Instrument Calibration Certificates

Please Note: Product is cGMP or euGMP Documentation for extraktLAB equipment.

*Must be ordered at the same time as equipment.

* Condition of Delivery: Sign non-circumvention agreement.

ADDITIONAL NOTES:

- Additional requested items will be charged to the customer at \$2K USD per item.
- Documentation is supplied in PDF format, property of United Science, and confidential for the specified equipment.
- When applicable, supplemental component manuals will be provided to the customer.
- c/euGMP certification package must be specified prior to equipment purchase.
- This GMP package has no implied or expressed warranty or guarantee of compliance with local, federal, or international regulations.

extraktLAB
SERVICES

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GMP Documentation Package
To Order: Ask for GMP Documentation during quote process
Sold Separately: Annual igwLAB Software License, Part #80-9617

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