

Laboratory Management Software (LMS)

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A brief introduction:

Software Objectives:

The principal objective is to provide the Laboratory Manager with an effective tool to maintain laboratory data in a computerized environment, aid in Laboratory administration and enable him to provide statistically analyzed QC data to Management.

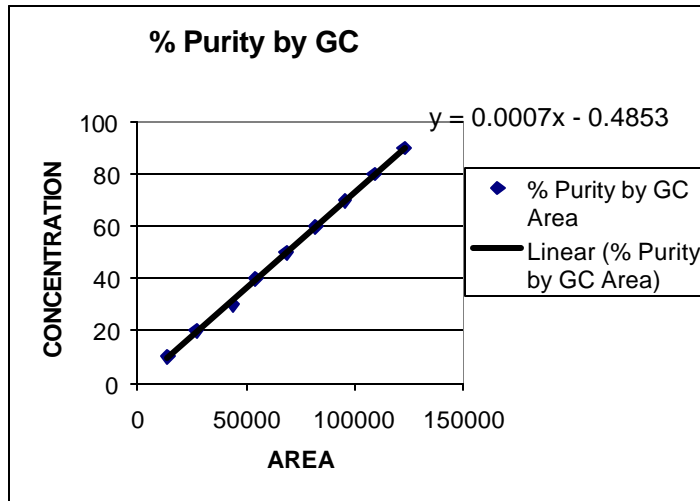
Software Features:

- 1) Provision of Specification Master to incorporate Tests, their SOPs and the valid limits of test result. Different limits can be set for different specifications like IP, USP etc.,
- 2) Automatic Validation of Test values against specification limits to determine compliance with parameters,
- 3) Multi-user access with provision to allow sample issuing department to log in sample details,
- 4) Security and confidentiality of data:
Through a User Definition module, the program ensures that a user has access to only those forms and data to which the administrator authorizes him. Also, to ensure total backward tracing on each entry in the system, each form carries the "Entered by" and "Approved by," details. These details are automatically carried into reports such as "Certificate of Analysis".
- 5) Creator and Approver trace ability for every record,
- 6) Generation of Blank Worksheets with/without SOPs for chemists to record test data,
- 7) User-friendly interface for recording of Sample data and analysis,
- 8) Automated calculation of Test Results on input of test variables with the help of pre-mastered formulae,
- 9) Facility to store images from Instruments like GC etc. along with sample analysis.
- 10) Automatically updating Sample Status to "Completed" on Approval entry by appropriate authority,
- 11) Auto E-mailing option for Certificate of Analysis,

- 12) Maintaining data on Instrument Calibration and Reagent Standardization, with ready scheduling report:

Facility has been provided to enter data on calibration of instruments and the calibration expiry dates. If any test is conducted without recalibrating the instrument on this date, the program alerts the user and qualifies the report generated. It can also be programmed to deny data entry of the test variables where calibration has expired. Schedule of calibration of instruments is available in the form of a report.

- 13) Graphical report with linear equation of calibration check results:

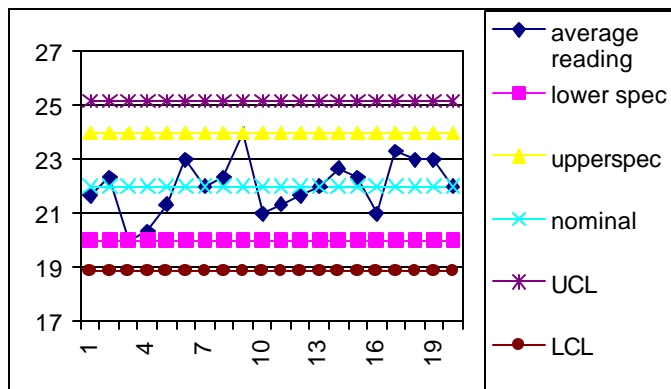


On entry of calibration checking data, a report is available on test results along with a graphical representation of the curve formed by the data plot of test results and its linear equation. A sample of this is shown alongside.

- 14) Details on Product Stability Tests for Pharmaceutical Laboratories with scheduling etc.,

- 15) Statistical analysis of Test Results with graphical presentation of data:

Test Data for various batches of any product can be statistically analyzed. The



program automatically calculates the mean and standard deviation to provide graphical comparison of test results with UCL and LCL on a Control Chart. This feature can be used to compare test results of products, raw materials etc. including material sourced from a specific

vendor and identify trends, consistency etc.

The analysis also provides details on number of records analyzed (sample size), maximum value, minimum value and range.

- 16) Observation of GLPs like Method Validation incorporating Accuracy analysis and Precision (Repeatability) analysis with automatic calculation of RSD and graphical presentation of test data in Control Chart format:

In Accuracy Analysis, the program automatically calculates LCL and UCL of test observations and tells the user whether the variation in results of tests performed on material under testing fall within acceptable limits vis-à-vis test results generated on certified “True Value” sample so as to certify the procedure as capable of giving accurate results.

Under Precision Analysis, the program calculates the RSD% (Relative Standard Deviation) to enable the user to determine a measure of repeatability of results on any instrument or method.

- 17) Laboratory Stores management and inventory accounting:

This module takes care of the inventory management aspect in the Laboratory Store. User can create Item Master, record receipt of materials, issue materials against specific tests or on day basis, inquire about stock in hand and make requisitions. Provision has been made to auto generate requisition for items where inventory level has fallen below re-order level.

- 18) Automated Chemist Performance Appraisal,

- 19) Preparing the laboratory for ISO-9000 & other accreditations.

Facility has been provided to allot a Form Number and Revision Number, if any, on each form, which is a part of the software along with the approval date and approving authority. This feature coupled with elaborate data validations, modules for GLPs, formula based derivation of test results, automatic comparison with specification limits for determining compliance, trace ability of each test result and tracking of Instrument calibration and reagent standardization prepare the laboratory to go for ISO and other accreditations as also certification by Test Agencies.

- 20) Invoicing Module for Public Analytical Laboratories:

This covers Rate Master for tariff card on tests, Customer Master with discount rate, Invoice generation and recording receipts from Customers.

- 21) Amenable to quick customization.

Reports:

Following reports are provided in the software:

- 1) Master Specification.
- 2) Blank Worksheet (Protocol of Analysis) with/without SOP.
- 3) Certificate of Analysis.
- 4) Instruments Calibration checking results.
- 5) Instruments Calibration Schedule.

- 6) Instrument History Sheet showing additions/modifications carried out and the related cost and details of Service Calls made during a specified period with break-down time and service cost.
- 7) Lab Stores – Requisition Form
- 8) Lab Stores – Material Inward and Material Issued reports.
- 9) Lab Stores – Monthly Material Transaction Report
- 10) Method Validation – Accuracy Analysis Test Report
- 11) Method Validation – Precision Analysis Test Report
- 12) Chemist Performance Report
- 13) Summary of Test Result with Statistical Analysis for single and multiple tests.
- 14) Laboratory Activity Log with Test Status.
- 15) Product Stability Tests Schedule
- 16) Test Failure Report – Sample No. wise list of samples not meeting test specification criteria.
- 17) Invoice Module – Listing of Invoice raised during a particular period.
- 18) Customer Ledger – Customer wise statement of bills raised during a particular period, payments received and outstanding bills.