

F U L L S U P P O R T O F

21 CFR Part 11

New release of
the time-tested
PharmSpec software
provides 21 CFR
Part 11 compliance
features and expanded
capabilities

PharmSpec 2.0

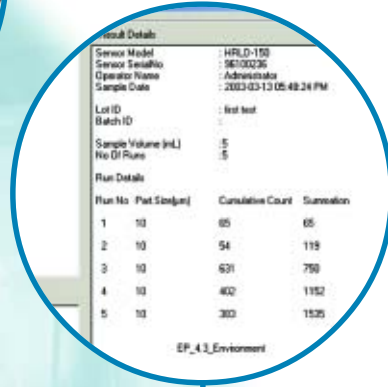
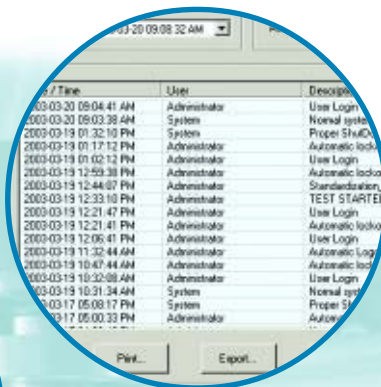
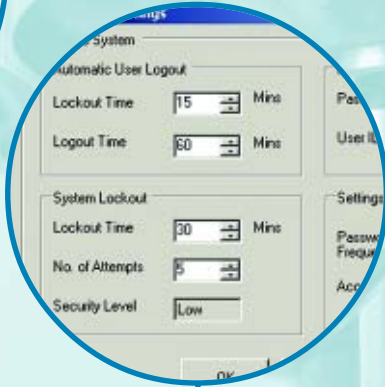
Network Backup and Archiving
Features to Support Part 11 Compliance
Designed for Windows® 2000, NT, XP
Supports New Korean Compendial Test
Create and Control User-Defined Tests
Familiar Environment for Quick Learning



PharmSpec 2.0

21 CFR Part 11 Support:

Key elements of this PharmSpec update provide full support for the Electronic Records [ER] and Electronic Signatures [ES] required in 21 CFR Part 11.



Unique user ID, full audit trails and secure database provide strong support for compliance.



Unique User ID

Within the Part 11 section on Electronic Signatures [ES] is the requirement for either a biometric or a minimum 2-element (User ID + Password) identification system. This system provides accurate, unique identification of the current user. In PharmSpec 2.0, a 3-element identification method is employed in which the third element is the user's public name that appears in reports and other general documents or screens. This public or Full Name element helps to protect the security of the actual User ID and Password elements.

User accounts can be set to expire, and users are directed to enter a new password, through the System Administration controls. Duplication of User Names is prevented. The Administrator can set minimum lengths for User IDs and Passwords.

Auto Logout for Inactivity

PharmSpec 2.0 has a programmable timer for inactivity to provide an automatic logout. After the specified period of time, the user must re-enter one or both identification elements to resume use of the program. Or, a new user can login and start activity if the previous user has been automatically logged out. These automatic actions are recorded in the Audit Trail.

Audit Trails

User actions and automatic system actions are recorded in a secure audit trail database. The database can be later reviewed and searched by the type of action, by specified dates or by user name. Information can be printed out but cannot be altered or removed.

Database Security

The SQL database is protected from operator access or alteration. It can be backed up or permanently archived on the local hard drive or on another network drive.

Reproducible Records

All data can be reproduced in human-readable form and can be re-accessed at any time.



EP, JP, KP and USP Compendial Tests

The recently released Korean compendial test [KP VIII <52>] for injectables is available in addition to the compendial tests for Europe, Japan and the USA. PharmSpec 2.0 only lists those tests that your application requires. These are quickly and simply accessed from a drop-down menu.



Network Support

Archiving and Backup functions can use mapped network drives as well as the local machine drive. Printing can be performed using a local or a network printer.



Compendial Version Administrative Control

As compendial tests are updated, supervisors can specify the active tests to prevent outdated tests from being used. PharmSpec 2.0 supports the current tests from the USA (USP), from Europe (EP), from Japan (JP) and from Korea (KP). As changes to the specific compendial tests occur, updates will be made available in a controlled process to help ensure that the system is current. The ability to select which tests are active on a system is controlled through restricted access by a Supervisor or Administrator for the system. The System is purchased with only the required compendial tests, avoiding unnecessary validation of unused tests.



Simulator Mode

For training and validation purposes, a Simulator mode is included. Training can be conducted in any convenient area, without requiring connection to the sampler system. System validation is supported through the accurate testing of thresholds and limits.



OS Support

PharmSpec 2.0 supports the current Windows platforms in all languages. You can use the local language installation in support of this product for these OS platforms: Windows 2000, NT and XP. PharmSpec 2.0 also supports international formats for Date, Time and Decimal Separator.



Full Range of Printers

All common printers supported by Windows OS can be used with PharmSpec 2.0. Laser and inkjet, black-and-white or color—all of these function with PharmSpec 2.0. For the most effective results, a color printer is recommended. To help save hardware costs, PharmSpec 2.0 supports printing across a network so that an existing printer can be used.

System Requirements

- HIAC Model 9703 System with firmware version 12 or higher
- Microsoft® Windows 2000, NT or XP system with Microsoft Internet Explorer 5.5 or higher
- Computer with these hardware characteristics:

Minimum	Recommended
Intel® Pentium®, 133 MHz	Intel Pentium III or higher processor, 450 MHz
96 MB RAM	128 MB RAM
Video, 1024 x 768	Video, 1024 x 768
320 MB Free Hard Disk space	500 MB Free Hard Disk space
(1) Serial Communications Port	(1) Serial Communications Port
Option: Microsoft Excel software (to access previous reports from PharmSpec Version 1.4 database)	

Ordering Information

For a permanent license for PharmSpec, please call or fax to quickly receive a license activation code. The following part numbers are used to specify PharmSpec 2.0 software:

700060	License, PharmSpec 2.0
700059	License, JP Compendial Test <11>, <24>
700058	License, EP Compendial Test <2.9.19>
700057	License, USP Compendial Test <788>
700056	License, KP Compendial Test <52>
700055	License, Procedure Builder for Custom Tests
2086804-01	User Manual and CD, PharmSpec Software
2086805-01	Validation (IQ/OQ) Documents and CD, PharmSpec software

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