EAPHARMICS®

Electronic Applications For Pharmaceutical Companies

electronic Stability Testing Analyses and Reporting

EAPHARMICS eSTAR stability software is a web based application integrated with oracle database to monitor all type of pharmaceutical (including **controlled drug substances** and **biological products**) stability programs. **EAPHARMICS eSTAR** is exceptionally suitable software for international regulatory guidelines like United States Food Drug Administration - **USFDA**, Therapeutic Products Programme - **TPP**, International Conference on Harmonisation - **ICH**, Therapeutic Goods Administration - **TGA**, National Institute of Health Sciences - **NIHS** and European Medicines Agency EMA of European Union **EU** guidelines. The software is designed for pre-clinical, R& D and Post market for Innovator / generic **pharmaceutical companies** throughout the world.

EAPHARMICS eSTAR stability software completely supports the stability studies of Investigational New Drug Applications (**IND**), New Drug Applications (**NDA**) for both New Molecular Entities (**NMEs**) and **Non-NMEs**., New Dosage Forms, Abbreviated New Drug Applications (**ANDAs**) and Post Marketed Annual Stability Products for the drug substances and drug products.

EAPHARMICS eSTAR stability software easily manages thousands of stability studies with extremely intuitive browser based user interface that allows the user to access multiple levels of details with the powerful security features of **ORACLE** database.

EAPHARMICS eSTAR stability software is a fully validated software system. It combines the ease of use of an object oriented browser style user interface and industry standard document that meets the regulatory requirements reporting systems. **Drug stability studies** are managed with more efficiency using **EAPHARMICS eSTAR stability software's** combination of multilevel features that helps to **reduce the CGMPs operational errors**, **deviations** and **maximizing the regulatory approvals**.

EAPHARMICS eSTAR stability software has the following multiple functional areas:

- 21 CFR Part 11 complaint features
- Specifications and test method data base
- Study design and Study conditions modules
- Stability data / analysis / reporting and Information data base
- Stability samples Inventory management (Regulated and Controlled drugs substances)
- Evaluation shelf life / trend / regression analysis for stability products.
- Bar code labeling system
- Electronic Audit Trails
- 21 CFR part 11 Electronic Records; Electronic Signatures
- Electronic stability testing analyses and reporting
- Electronic e-ticket for services.
- Secure system access to maintains data integrity
- Rich Internet Application User Interface with secure Oracle Database

electronic Stability Testing Analyses and Reporting

EAPHARMICS eSTAR stability software is specialized in pharmaceutical stability software with cost effectiveness and scalability that allows it to remain affordable. **EAPHARMICS eSTAR stability software** is a product developed and maintained by scientists, stability, rich internet application and oracle experts. **EAPHARMICS eSTAR stability software** includes on-site installation, complete software validations (IQ,OQ and OQ) user and administration level training, customer support through online 24/7 services (web based e-ticketing system).

Some of our latest features include

- **Upgraded the inventory control** by documenting when sample is pulled, who pulled the inventory and how much was taken. An alert has been added to inform designated users when sample is scheduled to be tested but the inventory has not been designated at being pulled. This alert takes the form of an on screen display for selected users and an email alert for designated system users and other persons as listed in the email alert list. **Bar Code capabilities** to allow seamless inventory reduction by scanning stability label on samples pulled from the chamber. Upgraded the label generation function to include bar code, due date, interval, and "x of y" numbering for each printed label per test interval. Label control for printing any additional labels.

- Added a "**Testing Started**" field to the laboratory pending list so tracking of the testing cycle can be recorded. Again there is an on screen display and email alerts when sample is pulled but the testing has not started within a user defined time frame.
  - ✓ This includes bar code capabilities to automatically designate test initiation in the sample pending list.

- Added a "**Testing Completed**" field to the laboratory pending list so tracking of the testing cycle can be recorded. Again there are on screen and email alerts when sample has been pulled, testing has been started but the testing cycle has not been completed within a user defined time frame.
  - ✓ This includes bar code capabilities to automatically designate test completion in the sample pending list.

- The bar code capabilities can be used to recall any study for any function such as editing, data entry, report generation, charting, and evaluations. Simply scan the bar code from a label or off another report to access the study. **Document attachment function** to allow recall of external documents that are related to a stability study, such as Investigations, methods, and chromatograms, etc. Updated application security to allow for both "group" defined access and individually customized application access.

- Customizable data approval functions that allow "**Level 1 Approval**" and "**Level 2 Final Approval**" with data locking at both approval levels to disallow change without proper authorization.

The application contains two modules for expiration dating using the FDA model for linear regression and 95% confidence evaluations. We have also added an export function so you will be able to export the **stability data into statistical packages** such as Sigma Plot or Stat Graphics, Excel, or Word. This will allow the user to perform any number of statistical analysis on the data.