

AURAS

PREP MODULE

AUTOMATE YOUR QUALITY CONTROL

Designed for the automated quality control of radiopharmaceuticals under FDA/ Pharmacopoeia regulations

- SIMPLE, INTUITIVE OPERATION
- FULLY COMPLIANT
- FLEXIBLE
- LOW RUNNING COSTS



The AURAS concept is an **A**utomated **R**adioactive **S**ample-handling module allowing you to upgrade your current quality control of radiopharmaceuticals.

It is a new concept for the automated quality control of radiopharmaceuticals. AURAS has been designed to provide users with the flexibility they need for the analysis of many radiotracers while allowing the adaptation of almost all analytical methods.

It is an all-in-one solution with in-built shielding, along with an optional external shielded cover for unparalleled radiation protection and measurement performance.

The Auras concept will allow you to automate your current quality control process with flexibility and independence, allowing the incorporation of your methods and standards.

The system is integrated into the GINA X software. The software facilitates easy and intuitive use. With Gina X you will be able to connect and communicate with most of the existing analytical instruments in your laboratory and to set up a chromatography data system (CDS), enabling centralized access and storage with the AURAS and all other relevant instrument data.

All data are stored on the GINA X SQL database and can be integrated into the (optional) SARA software solution for the generation of analysis certificates.

The software is designed for use in GMP environments and compliance with the requirements of the 21 CFR Part 11, including a user account control (UAC) module, a comprehensive audit trail and data security.

Features

- o Digitization and automation of your quality control.
- o Increase radiation protection.
- o Decrease the need for human intervention (and error rate).
- o Decrease qualification prerequisites for QC operators.
- o Reduce total duration of QC.
- o Work according to European pharmacopeia and FDA rules and methods
- o Keep your established analytical methods.
- o Run QC of multiple radiotracers.
- o 100% based on proven technology.

Technical specifications

AURAS will help you to automatize the determination of the:

- o Sample colour
- o Sample turbidity
- o Total activity
- o Radionucleic purity
- o Gamma spectrum
- o Half-life time
- o Radiochemical purity with a radio-HPLC and a radio-TLC
- o Chemical purity (Kryptofix)
- o Residual solvents
- o pH
- o Endotoxin level

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