ELIMINATE VARIABILITY WITH QUALITY BY DESIGN

FOR PHARMACEUTICAL DEVELOPMENT

The Measure of Confidence

Agilent Technologies

ENSURE QUALITY WITH RISK ASSESSMENT

Agilent Solutions Help You Evaluate CQAs

Critical quality attributes for drug substances typically include those properties or characteristics that affect identity, purity, biological activity, and stability. For example, the dissolution capability of solid oral dose forms is recognized as a CQA and is vital in demonstrating how critical process parameters such as blending time, granulation, excipients, or tablet hardness influence the dissolution rate.

Agilent's dissolution testing portfolio provides everything you need.

Hardware, software, accessories, consumables

Informatics: Compliance; data acquisition, processing, storage and retrieval; procedure management; decision-making tools

Solutions: Training, troubleshooting, regulatory assistance, etc.

Due to their potential impact on drug safety, impurities are an important class of potential CQAs. These comprise organic impurities (including potential genotoxic impurities), inorganic impurities, and residual solvents. In particular, there has been recent emphasis on elemental impurities requiring much more specific instrumental methods.

Agilent 7900 ICP-MS system provides reliable analysis of all 16 regulated elements in USP<233>.

Use 2D-LC to resolve impurities that are difficult to separate with routine LC analysis.

MOVING BEYOND TRADITIONAL QUALITY-CONTROL METHODS

Quality by design (QbD) helps ensure consistent drug quality by moving beyond traditional quality-control methods to a risk-based control strategy for well-understood products and processes. QbD places extra emphasis on quality controls upstream through detailed scientific investigation into eliminating variability in processes. Pharmaceutical laboratories have started applying QbD concepts, viewing analytical methods as processes.

Agilent strives to provide the tools and technologies you need to support QbD implementation in drug development. Agilent offers tools that support science- and risk-management-based approaches to ensure consistency in product quality through detailed investigation of variability. With the help of our tools, you can set the design space for robust analytical methods, eliminate variability in method transfer, and evaluate critical quality attributes, or CQAs.

Easily Evaluate the Best Chemistries for Your Separation

Agilent Method Development Kits include a range of column chemistries and selectivities, giving you the tools you need to save time and perfect your separation. What's more, Agilent columns are manufactured to the industry's tightest quality control specifications for reliable, reproducible performance. Learn more at www.agilent.com/chem/methoddevkits.

Ensure Analytical Instrument Compliance

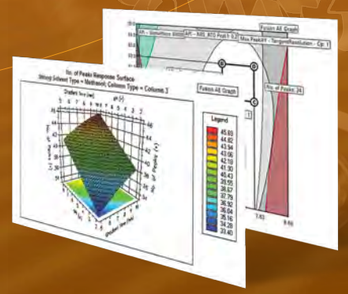
Agilent Automated Compliance Engine (ACE) software is designed to satisfy the most stringent regulatory requirements while providing controlled flexibility to satisfy future requirements.

ELIMINATE VARIABILITY IN ANALYTICAL METHOD DEVELOPMENT

Agilent Delivers Process Automation and Multivariate Analysis

Agilent supports the QbD approach to analytical method development by providing instrumentation and software tools that automate the process and facilitate the multivariate experiments required to implement QbD principles. The Agilent 1200 Infinity Series Method Development Solution can be combined with sophisticated QbD method development software such as ChromSword, ACD labs/AutoChrom, and S-Matrix/Fusion AE.

Agilent 1200 Infinity Series Method Development Solution



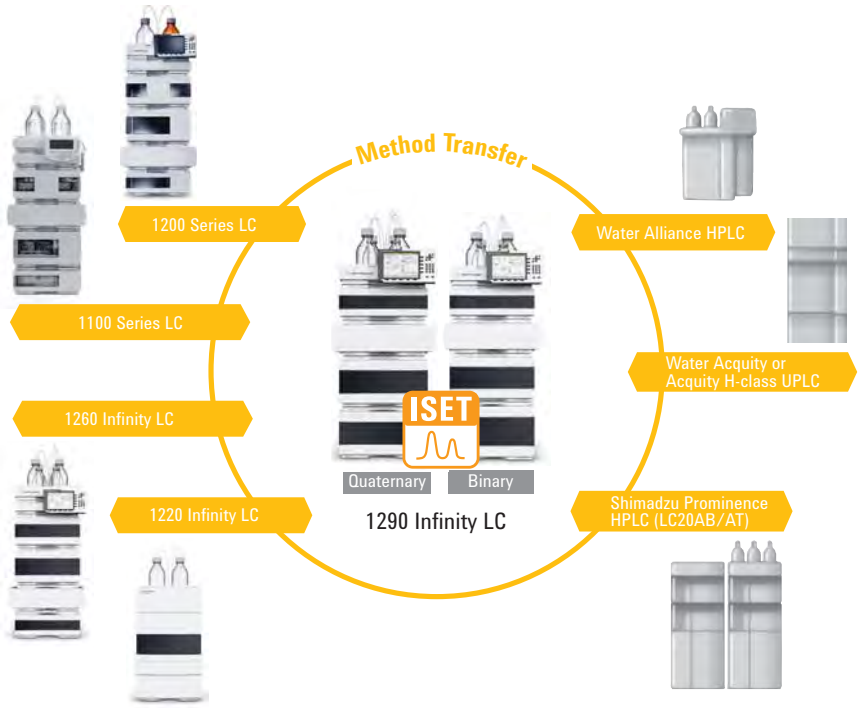
Characterization of a method design space using sophisticated QbD software solutions

Agilent provides a comprehensive portfolio of qualification services for your analytical lab.

ELIMINATE VARIABILITY IN METHOD TRANSFER

Agilent Intelligent System Emulation Technology Ensures Consistency

Transferring analytical methods between research-and-development departments, contract research organizations, and manufacturing is essential in the lifecycle of a new pharmaceutical product. Factors that affect your ability to transfer a method from one system to another include differences in design between LC instrumentation (such as power range, delay volume, mixing behavior, temperature control, extra column volume, and detector cell design) as well as differences in the level of analyst experience in redeveloping methods. Agilent's Intelligent System Emulation Technology can execute any legacy HPLC or newer UHPLC method and deliver the same chromatographic results, without the need to change the original method or modify the instrument hardware.



Automated Online Solvent Mixing

By replacing manual solvent mixing with automated/dynamic online mixing using the Agilent 1290 Infinity quaternary pump, you can minimize not only the instrument-specific contribution to the variance, but also the operator contribution.

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