試し打ち

http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm124787.htm#7

In warning letters to firms, why has FDA objected to the practice of using actual samples to perform system suitability testing (sometimes also referred to as “trial,” “test,” or “prep” runs)?

FDA wants to discourage the practice of “testing into compliance.” In some situations, the use of actual samples to perform system suitability testing can be a means of testing into compliance. (See the guidance for industry Investigating Out-of-Specification Results. http://www.fda.gov/downloads/Drugs/Guidances/ucm070287.pdf)

According to USP, system suitability tests should include replicate injections of a standard preparation or other standard solutions to determine if requirements for precision are met (ref. USP General Chapter <621> Chromatography). System suitability tests, including the identity of the preparation to be injected and the rational for its selection, should be performed according to the firm’s established written procedures and the approved application or applicable compendial monograph (§ 211.160).

If an actual sample is to be used for system suitability, it should be a properly characterized secondary standard and written procedures should be established and followed (§ 211.160 and 211.165). All data should be included in the data set that is retained and subject to review unless there is documented scientific justification for its exclusion.

References:

ICH guidance for industry Q2(R1) Validation of Analytical Procedures: Text and Methodology