

Topic	21 CFR Part 211 Regulation
HPLC sequence aborted without investigation	211.192 requires investigation whenever an OOS result is obtained
SOP inadequate	211.160 requires control mechanisms, including procedures, that are scientifically sound
Potential impact to data integrity; risk of incomplete and/or inaccurate data	211.194 requires completeness of data for all tests needed to assure compliance with specifications and standards

For detailed guidance on handling of OOS results, including GMP investigations and retesting, refer to “Guidance for Industry: Investigation of Out-of-Specification (OOS) Test Results for Pharmaceutical Production. US FDA CDER, 2006. Accessed February 2008.
<https://www.fda.gov/downloads/Drugs/.../Guidances/ucm070287.pdf>