

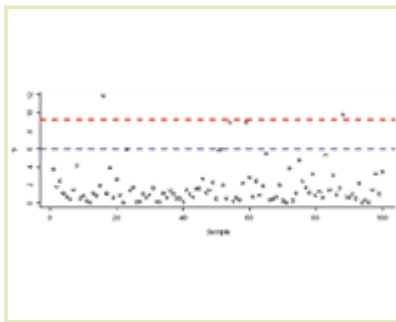
Multivariate Control Chart for Environmental Monitoring



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Calculated T2 values with $p = 0.8$,
and $\lambda = 2$ (in control data)

INTRODUCTION? Environmental monitoring in the manufacturing of pharmaceuticals provides quality assurance that the products are free of microbial contamination. It is required both by regulatory guidance and law. Samples at a manufacturing sites are routinely collected, assayed, and analyzed. Traditionally the Shewhart control chart is used to ensure the manufacturing environment is in a state of control. The Shewhart control chart consists of a baseline and two sets of limits, which are calculated as baseline $\pm 2x$ standard deviation (SD) and $3x$ SD. The former is called alert limits, and the...

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