

# Quality by Design Template Statistical Quality Control Analysis

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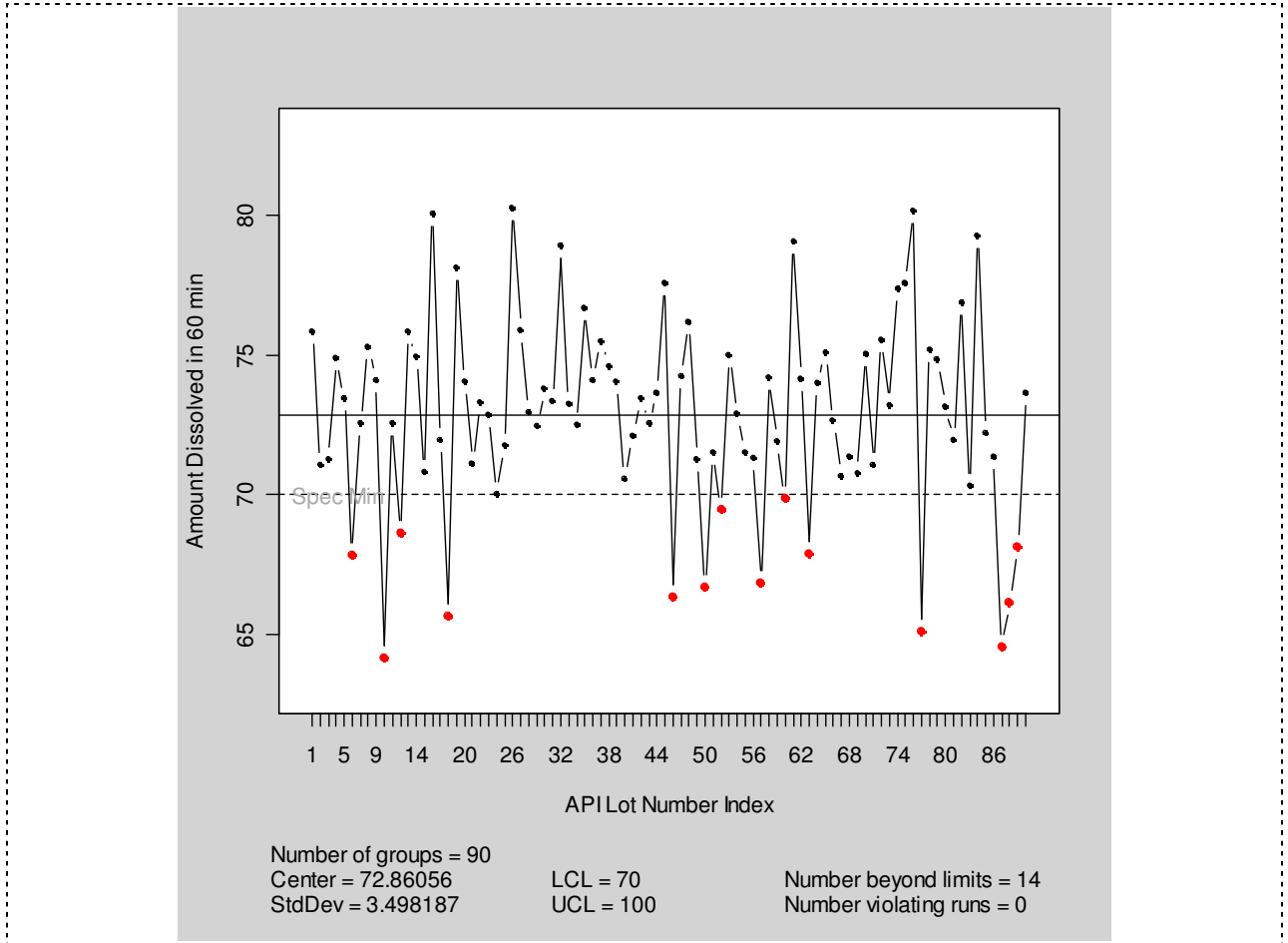
## Objective and Approach

**Objective:** Investigate the process for manufacturing tablets at a single dose. The key performance metric is 60-minute mean dissolution. The objective of the manufacturing team is to investigate the process and improve sigma capability.

**Approach:** The manufacturing facility have been producing single dose tablet for several years. Current measurement systems are based on storing finished material, while offline QA tests are performed to assure the finished product meets performance specifications. In this step of the investigation we will use some Quality by Design tools from the Statistic Quality Control arena to establish the current state of the process based on an analysis of the manufacturing data.

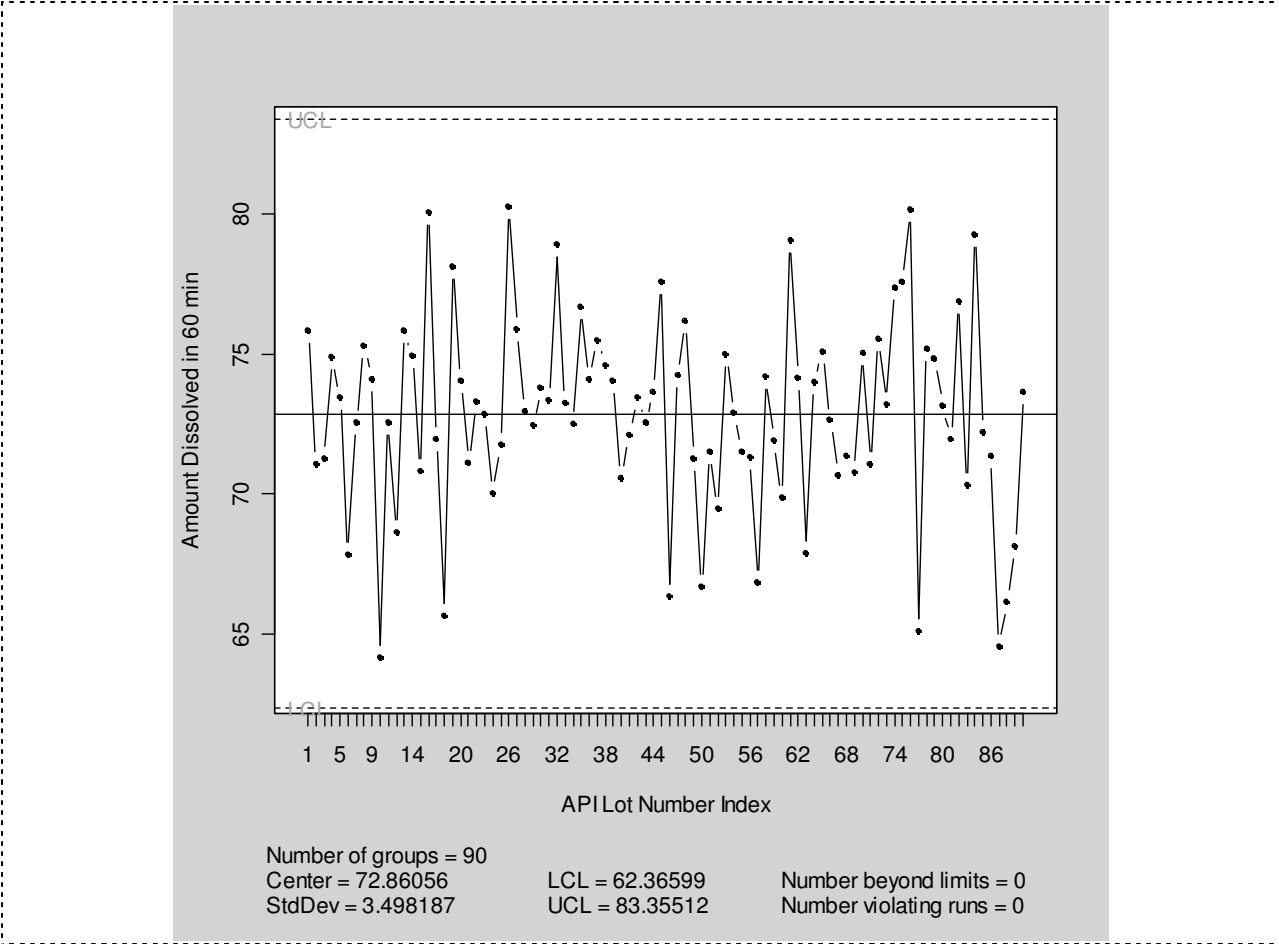
**Drug Product Manufacturing Status**

**What is the Problem with the Manufacturing Process?**



The analysis shows that 14 out of 90 batches failed to meet the 60-minute dissolution requirement.

Is Manufacturing Process Unders Statistical Control?

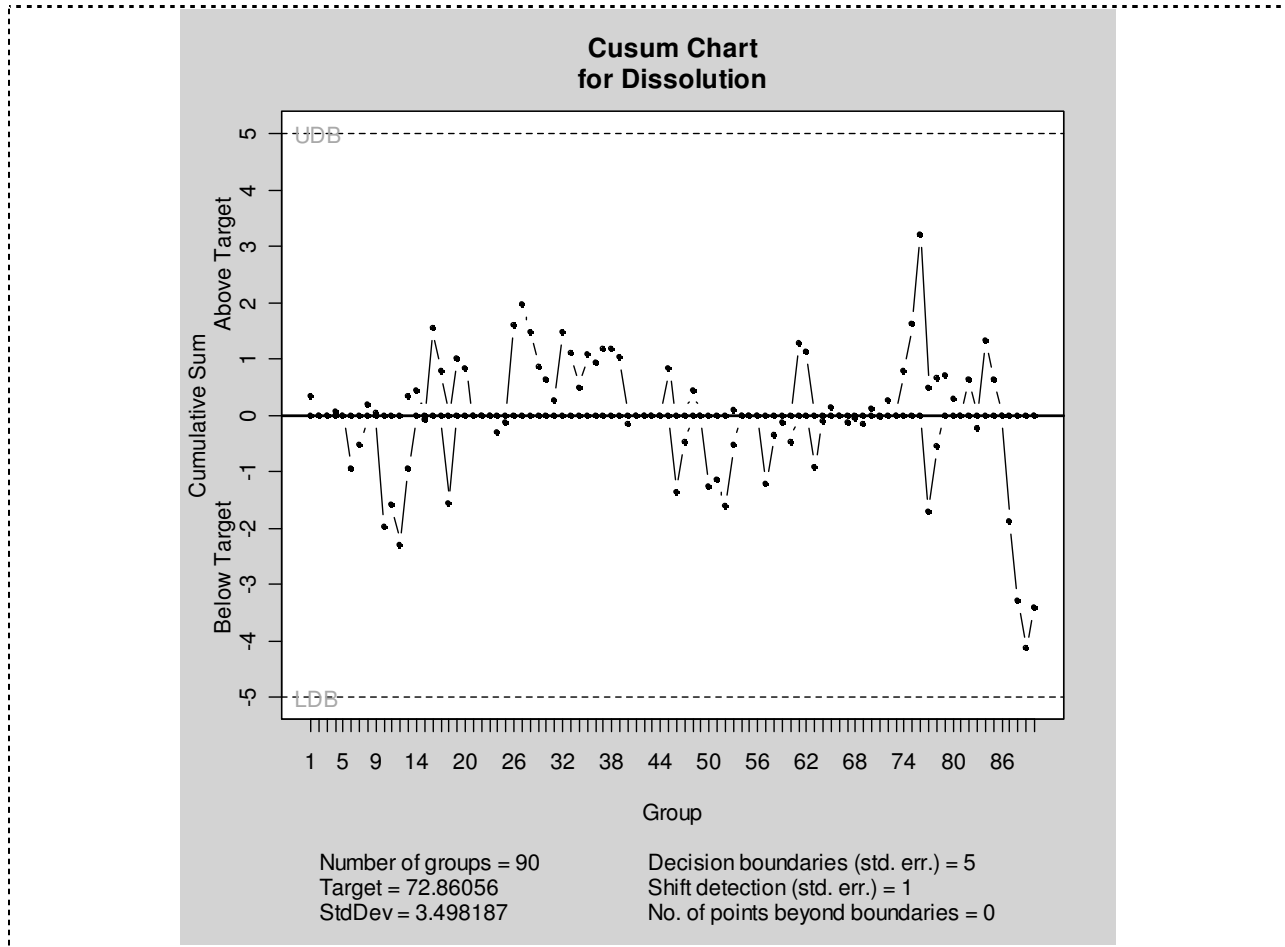


The analysis shows that the manufacturing process is under statistical control because the 60-minute percent dissolution for all historical batches falls within 3 sigmas of the long-term process center for all batches.

## Manufacturing Trend Analysis

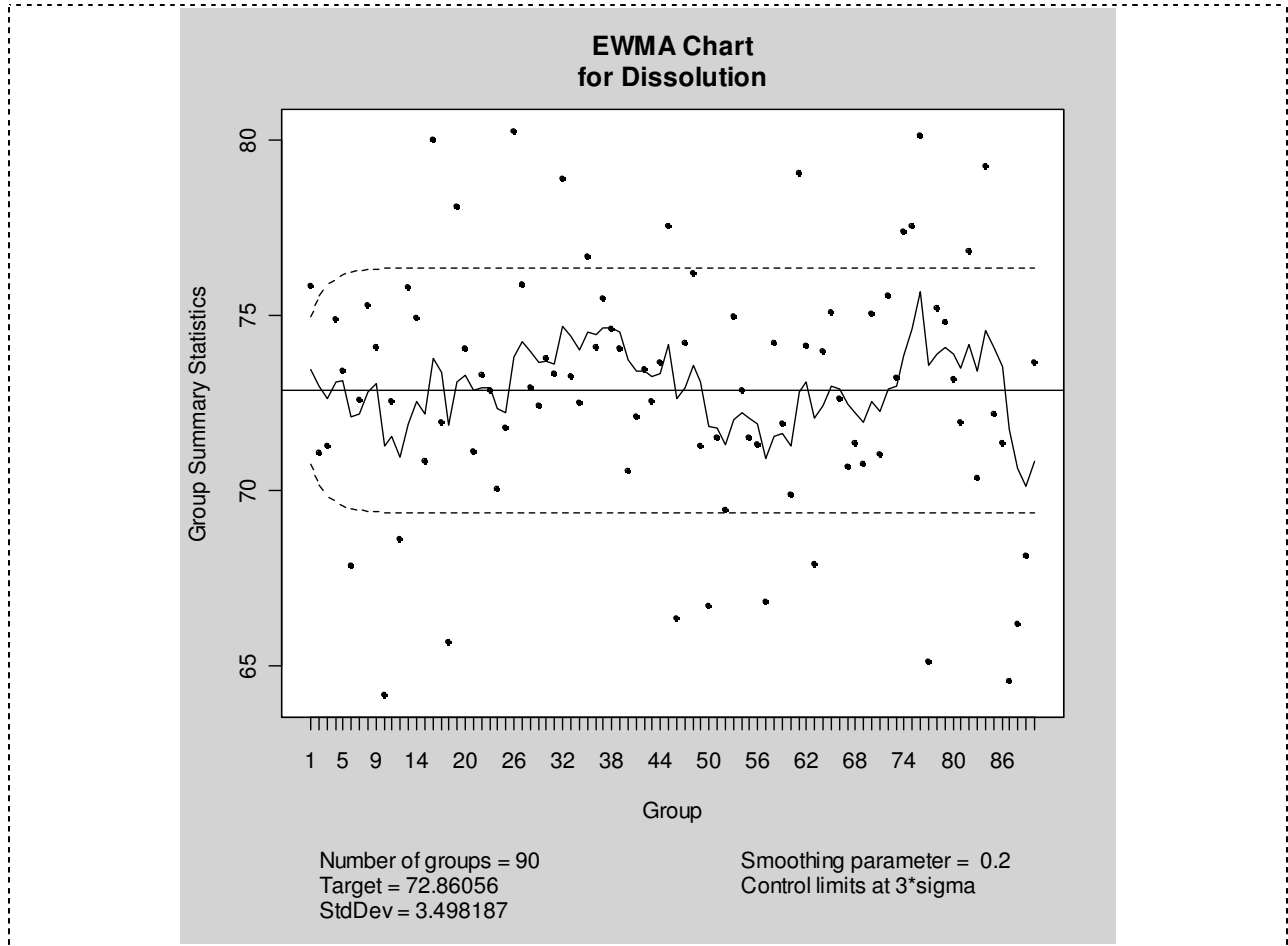
### Cusum Chart of the Manufacturing Process

Cusum charts display how the group summary statistics deviate above or below the process center or target value, relative to the standard error of the summary statistics. They are useful to detect small and permanent variation of the mean of the process.



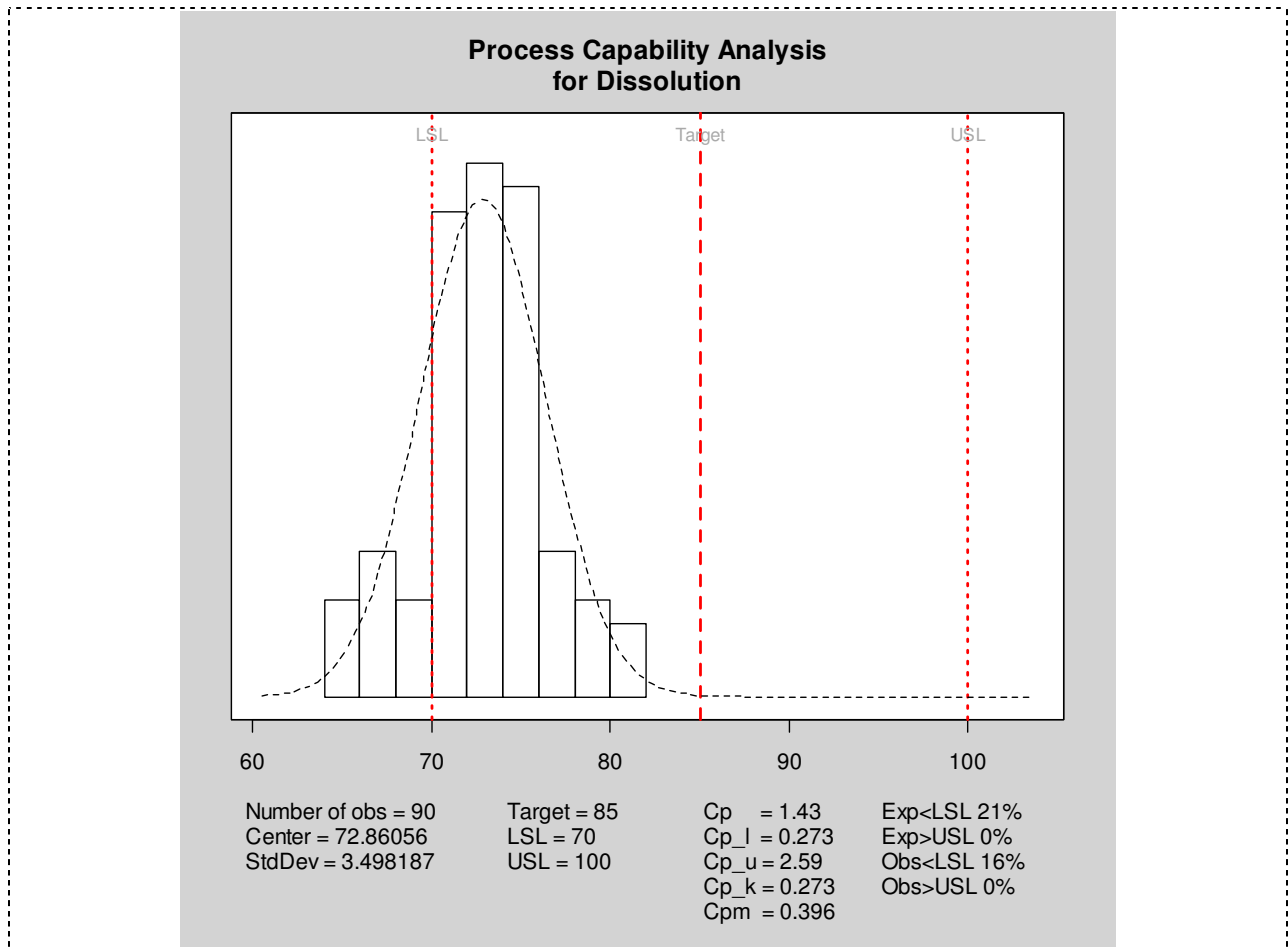
## EWMA Chart of the Manufacturing Process

Exponentially weighted moving average (EWMA) charts smooth a series of data based on a moving average with weights which decay exponentially. As for the cusum chart, this plot can also be used to detect small and permanent variation on the mean of the process.



## Process Capability Analysis

However, once a process is under control the question arises, "to what extent does the long-term performance of the process comply with engineering requirements or managerial goals?" For example, how many of the manufactured tablet batches fall within the design specification limits? In more general terms, the question is, "how capable is our process (or supplier) in terms of producing items within the specification limits?" Process capability analysis allows us to summarize the process capability in terms of meaningful percentages and indices and provides the basis for assigning product specifications.



It is important to note that the observed overall process capability is due to contributions of measurement system capability and manufacturing process capability, which in turn is due to contributions of supplier process capability and production process capability. Given this caveat, the results display fair process capability—that is, the distribution is off-center although the spread is narrow. The objective in development then becomes to move the distribution toward the center while maintaining the same spread.