REVIEW ARTICLE

Control chart: A statistical process control tool in pharmacy

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Control chart is the most successful statistical process control (SPC) tool, originally developed by Walter Shewhart in the early 1920s. A control chart can easily collect, organize and store information, calculate answers and present results in easy to understand graphs. It helps to record data and allows to see when an unusual event, e.g., a very high or low observation compared with "typical" process performance, occurs. Computers accept information typed in manually, read from scanners or manufacturing machines, or imported from other computer databases. The resulting control charts can be examined in greater detail, incorporated into reports, or sent across the internet. A stable process is a basic requirement for process improvement efforts. A computer collecting information in real time can even detect very slight changes in a process, and even warn you in time to prevent process errors before they occur. First, control charts demonstrate how consistently process is performing, and whether you should, or should not, attempt to adjust it. Next, the statistical process control chart compares the process performance to standard pharmaceutical requirements, providing a process capability index as an ongoing, accurate direction for quality improvement. Finally, control charts and its resulting process capability index quickly evaluate the results of quality initiatives designed to improve process consistency. This review focuses on elements of control chart and types of various control charts along with example. Advantages of various control charts are also included.

Key words: *Attribute chart, Shewhart chart, trend chart, variable chart*

INTRODUCTION

Control charts, also known as Shewhart charts or process-behavior charts, in statistical process control are tools used to determine whether a manufacturing of dosage form in pharmaceutical industry is in a state of statistical control or not. A control chart is a "Trend Chart" with the addition of statistically calculated upper and lower control limits drawn above and below the process average line.[1] The charts are used to provide a visual graphic representation of instances when a process is beginning to go out of control.

The purpose of the chart is to indicate this trend in order that the system may be brought back into control. They contain a centerline representing the process average or expected performance, as well as upper and lower control limits that set bounds for an acceptable area of deviation from the centerline. Control limits are not the same as specification limits. Control limits indicate the process capability. They are not an indication of how a process should perform.

The conventional approach of drug formulation development suffers from several pitfalls. The stated approach is: time consuming, money expending, energy utilizing unfavorable to plug errors and unpredictable.[2] Control charting is the most technically sophisticated tool of "Statistical Quality Control." When the charts are used correctly, they can serve to improve the economic effectiveness of a process.

Statistical quality control is a method by which companies gather and analyze data on the variations which occur during production in order to determine if adjustments are needed. All processes have some form of variations. Variation in process can exist either because of common cause or special cause. Variation because of inbuilt fault in the design of the system leading to numerous, ever present differences in the process is called common cause variation. Variation because of causes which are not normally present in the process but caused by employees or by unusual circumstances or events is called special cause variation.

A stable process is a process that exhibits only

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common variation, or variation resulting from inherent system limitations. A stable process is a basic requirement for process improvement efforts. One of the most common methods used in order to achieve this goal is the quality control chart.

Popularity of control charts are due to following reasons.
a) It is a proven technique for improving productivity.
b) It is effective in defect prevention.
c) It prevents unnecessary process adjustment.
d) It provides diagnostic information.
e) It provides information about process capability.

ELEMENTS OF CONTROL CHARTS

A control chart is made up of six elements [Figure 1].[3]

1. Title: The title briefly describes the information which is displayed.
2. Legend: This is information on how and when the data were collected.
3. Measuring Parameter
    a) Parameter to be plotted on the X-axis (horizontal axis); e.g. Sample ID, order, sequence, run time, site, etc.
    b) Parameter to be plotted on the Y-axis (vertical axis); e.g. Volume of solution/liquid filled in bottle, tablet hardness, weight of tablet
4. Centre line: Central solid line is target value or historical process average and/or range. It is drawn at the process characteristic mean, which is calculated from the data. It represent the values of parameter which decide centrality of process i.e. arithmetic mean or any other measurement of central tendency.
5. Control line: Two dotted parallel lines indicate the limits within which practically all the observed results should fall as long as the process is under normal variation (statistically control).
    a) Upper control line (UCL): It is the line drawn parallel to central line from the Y-axis at such a point which is considered to be a upper threshold value. This is plotted generally three times standard deviation above the central line.
    b) Lower control line (LCL): It is the line drawn parallel to the central line from the Y-axis at such a point which is considered to be a lower threshold value. This is plotted generally three times standard deviation below the central line.
    - In a control chart, control line (limits) are calculated by the following formula:
      (Average Process Value) ± {3 × (Standard Deviation)}
      where the standard deviation is due to unassigned process variation only.
6. Data collection section: The counts or measurements are recorded in the data collection section of the control chart prior to being graphed.
    - Points inside the UCL and LCL are in-control-points [Figure 2], while points above the UCL or below the LCL lines are out-of-control points [Figure 3].
        - It may have other optional features, including:
            - Upper and lower warning limits, drawn as separate lines, typically two standard deviations above and below the center line.
            - Division into zones, with the addition of rules governing frequencies of observations in each zone.

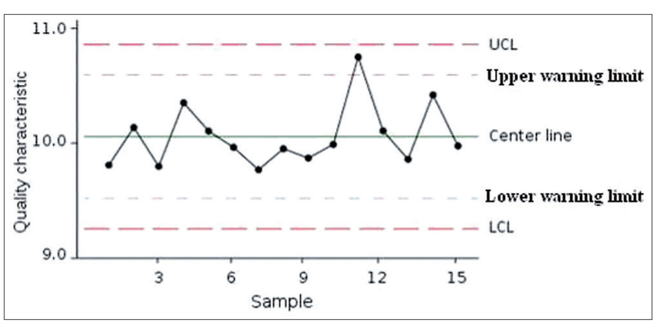

Figure 1: Elements of control chart

FUNCTION OF CONTROL CHARTS

The main purpose of using a control chart is to monitor, control, and improve process performance over time by studying variation and its source. There are several functions of a control chart:

1. It provides statistical ease for detecting and monitoring process variation over time.
2. It provides a tool for ongoing control of a process.
3. It differentiates special from common causes of variation in order to be a guide for local or management action.
4. It helps to improve a process to perform consistently and predictably to achieve higher quality, lower cost, and higher effective capacity.
5. It serves as a common language for discussing process performance.[4]

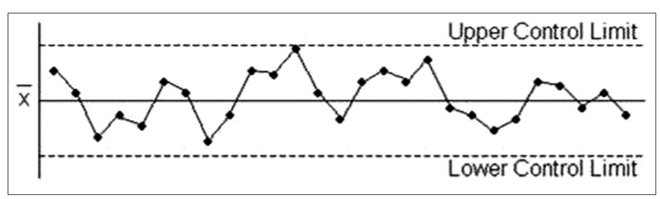

Figure 2: "In control" process

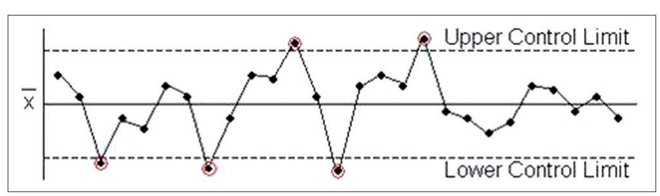

Figure 3: "Out of control" process

TYPES OF CONTROL CHARTS

A control chart is most effective when used for repetitive processes that are important to an organization and for which data can be obtained. There are two categories of control charts: variable control charts and attribute control charts

Variables control charts

It is used when measurements are quantitative (for example, height, weight, or thickness). Two types of variables control chart are as follow: X bar-R chart and X bar-S chart.

X bar-R chart

It is a specific member of a family of control charts. X-bar and range charts are a set of control charts for variables data (data that are both quantitative and continuous in measurement, such as a measured dimension or time).

The X-bar chart monitors the process location over time, based on the average of a series of observations, called a subgroup. The range chart monitors the variation between observations in the subgroup over time. X-bar and range charts are used when collected measurements are in groups (subgroups) of between two and ten observations.

X-bar and R charts consist of two charts, both with the same horizontal axis denoting the sample number. The vertical axis on the top chart depicts the sample means (X-bar) for a series of lots or subgroup samples. It has a centerline represented by X-bar bar, which is simply the overall process average, as well as two horizontal lines, one above and one below the centerline, known as the upper control limit or UCL and lower control limit or LCL, respectively. These lines are drawn at a distance of plus and minus three standard deviations (that is, standard deviations of the sampling distribution of sample means) from the process average.[5]

STASTICAL DATA REQUIRED FOR CONSTRUCTING CONTROL CHART

Determine the value for n (the number of subgroups)

In order to determine the upper (UCL) and lower (LCL) limits for the X-bar charts, subgroups (n) should be decided in given data. After determining value of n, one can obtain the correct constants (A_2, A_3, etc.) to complete control chart [Table 1]. The value of n is the number of subgroups within each data point. For example, during temperature measurements every min and there are three temperature readings per minute, then the value of n would be 3. And if this same experiment was taking four temperature readings per minute, then the value of n would be 4. Here are some examples with different tables of data to help further in determining n:
$n = 3$ since there are three readings of temperature.

Calculating grand average, average range, and average standard deviation

To calculate the grand average, first find the average of the *n* readings at each time point. The grand average is the average of these averages (X-bar bar). To calculate the grand range, first determine the range of the *n* readings at each time point. The grand range is the average of these ranges. To calculate the average standard deviation, first determine the standard deviation of the n readings at each time point. The average standard deviation is the average of these standard deviations.

For X-bar charts, the UCL and LCL may be determined as follows:
Upper control limit (UCL) = $X_{GA} + A_2R_A$
Lower control limit (LCL) = $X_{GA} - A_2R_A$
Where, X_{GA} = Grand average of X bar = X-bar bar,
R_A = Grand average of range R = R bar

For R-charts, the UCL and LCL may be determined as follows:
UCL = D_4R_A
LCL=D_3R_A Where, R_A= R bar

Table 1: Constant (factors for estimating three standards deviation limits)

Subgroup	Factors for X-bar chart		Factors for S-chart		Factors for R-chart	
n	A_2	A_3	B_3	B_4	D_3	D_4
2	1.886	2.659	0	3.267	0	3.268
3	1.023	1.954	0	2.568	0	2.574
4	0.729	1.628	0	2.266	0	2.282
5	0.577	1.427	0	2.089	0	2.114
6	0.483	1.287	0.03	1.97	0	2.004
7	0.419	1.182	0.118	1.882	0.076	1.924
8	0.373	1.099	0.185	1.815	0.136	1.864
9	0.337	1.032	0.239	1.761	0.184	1.816
10	0.308	0.975	0.284	1.716	0.223	1.777
11	0.285	0.927	0.322	1.678	0.256	1.744
12	0.266	0.886	0.354	1.646	0.283	1.717
13	0.249	0.85	0.382	1.619	0.307	1.693
14	0.235	0.817	0.407	1.593	0.328	1.672
15	0.223	0.789	0.428	1.572	0.347	1.653

Example

The performance of a filling machine for filling by weight a relatively viscous parenteral suspension in multiple dose containers can be followed with control chart. Two samples were removed from production floor and weighed approximately at every 20 min and average and range measurements were used to construct the control charts [Table 2a, b].

$UCL_x = X_{GA} + A_2R_A$
$= 12.200 + (0.37)\,0.017$
$= 12.21$

$LCL_x = X_{GA} - A_2R_A$
$= 12.200 - (0.37)\,0.17$
$= 12.19$

$UCL_R = D_4R_A$
$= (1.86)\,0.017$
$= 0.032$

$LCL_R = D_3R_A$
$= (0.14)\,0.017$
$= 0.0024$

Results

Average and range chart for Machine A indicates that the process is in control as six standard deviation spread between the upper and lower control limits cover 99.7% values in normal distribution with its mean at the centre line. It is said to show evidence of "control", since all points fall within the designated control limits. Control chart for averages (X bar chart) is a measurement of the central tendency [Figure 4]. Approximately half of the values are located above and half of the values are located below it. This would be expected if random variation is present and the process is under control. The control chart for ranges (R chart) indicates the variation present in a set of samples [Figure 5]. Both charts are necessary to plot, as in Machine A, average chart shows that process is in control but range chart indicates that process shows excessive variation.

Table 2a: Example for determination of number of subgroup

Time (min)	T_1	T_2	T_3
0	400.12	243.25	253.11
1	400.15	212.22	215.25
2	420.14	212.33	215.55
3	412.2	215.45	245.25
4	412.52	213.21	231.11
5	415.52	213.45	269.22

Table 2b: Example of Machine A

Sample no. (filled bottle)	Weight of sample		X-bar	R
	Sample A	Sample B		
1	12.200	12.180	12.190	0.020
2	12.215	12.190	12.203	0.025
3	12.210	12.180	12.195	0.030
4	12.210	12.205	12.208	0.005
5	12.210	12.190	12.200	0.020
6	12.205	12.200	12.203	0.005
7	12.220	12.200	12.210	0.020
8	12.200	12.190	12.195	0.010
Average			12.200	0.017

X bar-S chart

The X-bar chart monitors the process location over time, based on the average of a series of observations, called a subgroup. The sigma (S) chart monitors the variation between observations in the subgroup over time. X bar-S charts are generally employed for plotting variability of sub-groups with sizes greater than 10. X bar-S charts plot the process mean (the X bar chart) and process standard deviation (the S chart) over time for variables within sub-groups. Both the X bar-R and -S charts must be seen together to interpret the stability of the process. The X bar-S chart must be examined first as the control limits of the X bar chart are determined considering both the process spread and center.[5,6]

The sample variance (S)

If σ^2 is the unknown variance of a probability distribution, and then an unbiased estimator of σ^2 is the sample variance.

$$s^2 = \frac{\sum_{i-1}^{n}(x_i - \bar{x})^2}{n-1}$$

For S-charts, the UCL and LCL may be determined as follows:

$UCL = B_4S_A$

$LCL = B_3S_A$

The centerline is S_A.

Where, S_A = Average standard deviation = S bar

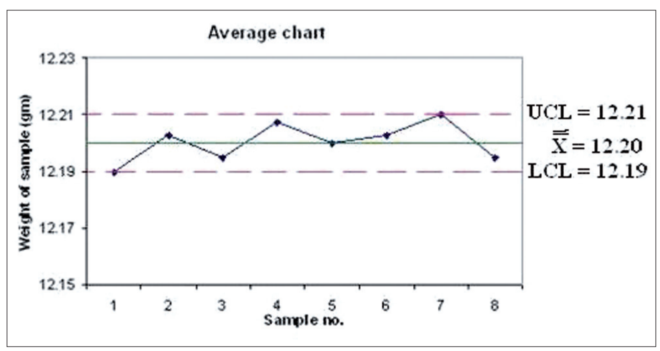

Figure 4: X-bar chart

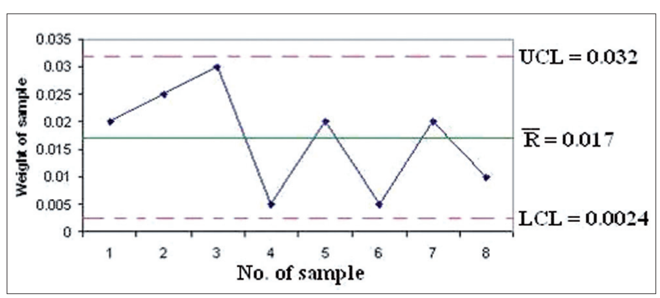

Figure 5: Range (R) chart

Example

Assume that in the manufacture of 1 kg Mischmetal ingots, the product weight varies with the batch. Below are a number of subsets taken at normal operating conditions, with the weight values given in kg. Construct the X-bar and S-charts for the following experimental data [Table 3]. Measurements are taken sequentially in increasing subset number.

Solution

First, the average, range, and standard deviation are calculated for each subset [Table 4].

Next, the grand average X_{GA}, average range R_A, and average standard deviation S_A are computed for the subsets taken under normal operating conditions, and thus the centerlines are known. Here n = 4.

$X_{GA} = 1.0004$
$R_A = 0.05428$
$S_A = 0.023948$

X-bar limits are computed (using R_A).

$UCL = X_{GA} + A_2R_A = 1.0004 + 0.729\ (0.05428) = 1.04$
$LCL = X_{GA} - A_2R_A = 1.0004 - 0.729\ (0.05428) = 0.96$

S-chart limits are computed.

$UCL = B_4S_A = 2.266\ (0.023948) = 0.054266$
$LCL = B_3S_A = 0\ (0.023948) = 0$

Table 3: Experimental data for construction of X-bar and S-charts

Subset	Values (kg)
1 (control)	1.02, 1.03, 0.98, 0.99
2 (control)	0.96, 1.01, 1.02, 1.01
3 (control)	0.99, 1.02, 1.03, 0.98
4 (control)	0.96, 0.97, 1.02, 0.98
5 (control)	1.03, 1.04, 0.95, 1.00
6 (control)	0.99, 0.99, 1.00, 0.97
7 (control)	1.02, 0.98, 1.01, 1.02
8 (experimental)	1.02, 0.99, 1.01, 0.99
9 (experimental)	1.01, 0.99, 0.97, 1.03
10 (experimental)	1.02, 0.98, 0.99, 1.00
11 (experimental)	0.98, 0.97, 1.02, 1.03

Result

Average [Figure 6] and S chart [Figure 7] indicate that the process is in control as six standard deviation spread between the upper and lower control limits. It is said to show evidence of "control", since all points fall within the designated control limits. Control chart for averages (X bar chart) is a measurement of the central tendency. Control chart for standard deviation (S chart) indicates the some degree of variation present in a set of samples. Both charts show that the process is in control.

ADVANTAGES OF VARIABLE CONTROL CHARTS

Variable control charts are more sensitive than attribute control charts. Therefore, variable control charts may alert

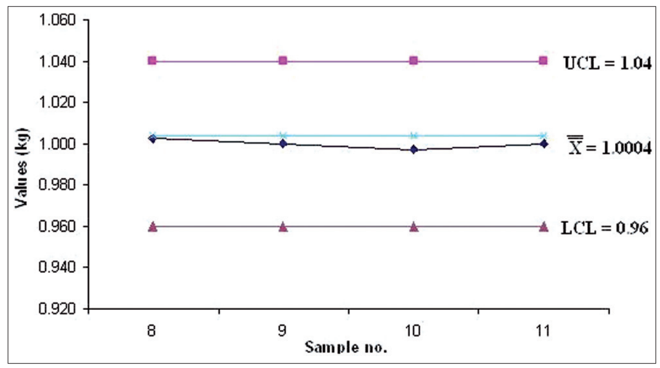

Figure 6: Average chart

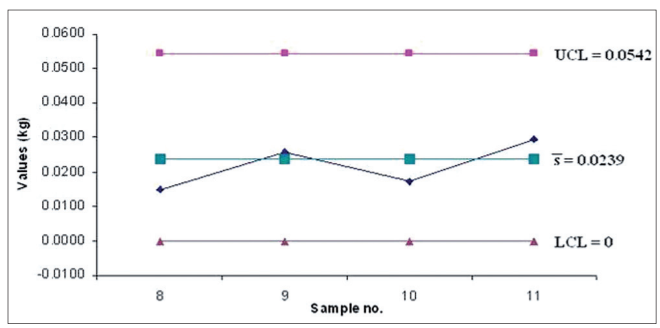

Figure 7: s-charts

Table 4: The average, range, and standard deviation for each subset

Subset	Values (kg)	Average (X)	Range (R)	Standard deviation (S)
1 (control)	1.02, 1.03, 0.98, 0.99	1.0050	0.05	0.023805
2 (control)	0.96, 1.01, 1.02, 1.01	1.0000	0.06	0.027080
3 (control)	0.99, 1.02, 1.03, 0.98	1.0050	0.05	0.023805
4 (control)	0.96, 0.97, 1.02, 0.98	0.9825	0.06	0.026300
5 (control)	1.03, 1.04, 0.95, 1.00	1.0150	0.09	0.043589
6 (control)	0.99, 0.99, 1.00, 0.97	0.9875	0.03	0.012583
7 (control)	1.02, 0.98, 1.01, 1.02	1.0075	0.04	0.018930
8 (experimental)	1.02, 0.99, 1.01, 0.99	1.0025	0.03	0.015000
9 (experimental)	1.01, 0.99, 0.97, 1.03	1.0000	0.06	0.025820
10 (experimental)	1.02, 0.98, 0.99, 1.00	0.9975	0.04	0.017078
11 (experimental)	0.98, 0.97, 1.02, 1.03	1.0000	0.06	0.029439
Average		1.0004	0.05428	0.023948

us to quality problems before any actual "un-acceptable" condition (as detected by the attribute chart) will occur. Variable control charts are leading indicators of trouble that will sound an alarm before the number of rejects increases in the production process. Generally, it is used for the statistical optimization study of drug formulation in pharmaceutical industry.[7]

Attributes control charts

a) It is used when measurements are qualitative, for example, accept/reject. Types of attributes control charts are:np-chart: It is a control chart for measurements which are counted, such as number of parts defective.
b) p-chart: It is a control chart for fraction nonconforming, i.e.for percentage measurements, such as percentage of parts defective.
c) c-chart: It is a control chart for number of defects or nonconformities, i.e. for measuring defects in units of constant size, for example, number of imperfections in panes of glass.
d) u-chart: It is a control chart for number of nonconformities per unit, i.e. for measuring defects in units of varying size, for example, number of imperfections in pieces of fabric.[8,9]

a) np-chart

The numbers of defectives (per batch, per day, per machine) are plotted against sample no. However, the control limits in this chart are not based on the distribution of rare events, but rather on the binomial distribution. Therefore, this chart should be used if the occurrence of defectives is not rare (e.g., they occur in more than 5% of the units inspected). For example, we may use this chart to control the number of units produced with minor flaws.

Center line

$$n\bar{p} = \frac{\sum_{j-1}^{m}(count)_j}{m}$$

where *m* is the number of groups included in the analysis.

UCL, LCL (Upper and Lower Control Limit)

$$UCL_{np} = n\bar{p} + 3\sqrt{n\bar{p}(1-\bar{p})}$$

$$LCL_{np} = MAX\left[0, n\bar{p} - 3\sqrt{n\bar{p}(1-\bar{p})}\right]$$

where *n* is the sample size, np-bar is the average count, and p-bar is calculated as follows:

$$\bar{p} = \frac{\sum_{j-1}^{m}(count)_j}{m \bullet n}$$

b) p-chart

For attribute data, such as arise from PASS/FAIL testing, the charts used most often plot either rates or proportions. The p-chart monitors the percent of samples having the condition, relative to either a fixed or varying sample size, when each sample can either have this condition, or not have this condition [Figure 8]. The proportion or fraction nonconforming (defective) in a population is defined as the ratio of the number of nonconforming items in the population to the total number of items in that population. The item under consideration may have one or more quality characteristics that are inspected simultaneously. If at least one of the characteristics does not conform to standard, the item is classified as nonconforming. The fraction or proportion can be expressed as a decimal, or, when multiplied by 100, as a percent.

For a constant sample size

If the sample size is constant, the formula for the value plotted on the p-chart is:

$$\hat{p}_i = \frac{D_i}{n}$$

The central line and control limits are computed as shown below:

Central line $\bar{p} = \frac{\sum_{i=1}^{m} p_i}{n}$

Limits $UCL = \bar{p} + 3\sqrt{\frac{\bar{p}(1-\bar{p})}{n}}$

$$LCL = \bar{p} - 3\sqrt{\frac{\bar{p}(1-\bar{p})}{n}}$$

For a variable sample size

Formulas are changed to take in count the variable sample size.

Value plotted $\hat{p}_i = \frac{D_i}{n_i}$

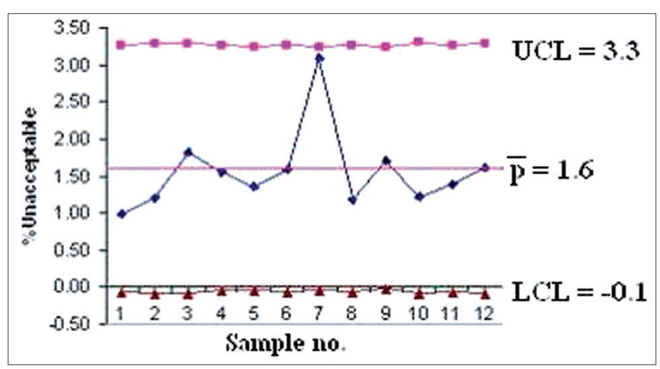

Figure 8: p-chart

Central line $\bar{p} = \frac{\sum_{i=1}^{m} \hat{D}_i}{\sum_{i=1}^{m} n_i}$

Limits $UCL = \bar{p} + 3\sqrt{\frac{\bar{p}(1-\bar{p})}{n}}$

$LCL = \bar{p} - 3\sqrt{\frac{\bar{p}(1-\bar{p})}{n}}$

c) c- chart

The focus of the chart is the number of nonconformities in a population. This number is called "c" and is directly plotted on a c-chart [Figure 9]. In this case again, m samples of n units are controlled and the sample size can be constant or not.

For a constant sample size

The central line and control limits are computed as shown below:

Central line $\bar{c} = \frac{\sum_{i=1}^{m} c}{m}$

Limits $UCL = \bar{c} + 3\sqrt{c}$

$LCL = \bar{c} - 3\sqrt{c}$

d) u- chart

In manufacturing, a u-chart is typically used to analyze the number of defects per inspection unit in samples that contain arbitrary numbers of units. In general, the events counted need not be "defects." A u-chart is applicable when the counts are scaled by a measure of opportunity for the event to occur [Figure 10] and when the counts can be modeled by the Poisson distribution.

Mathematical notions here are formulas for control chart characteristics:

Central line $\bar{u} = \frac{\sum_{i=1}^{m} x_i}{\sum_{i-1}^{i=m} n_i}$

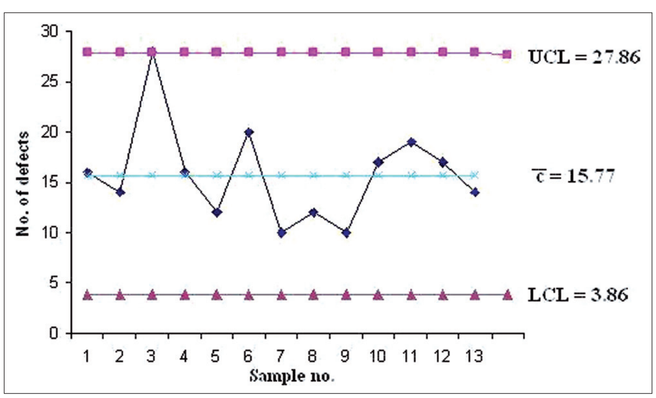

Figure 9: c-chart

Limits $UCL = \bar{u} + 3\sqrt{\frac{\bar{u}}{n_i}}$

$LCL = \bar{u} - 3\sqrt{\frac{\bar{u}}{n_i}}$

Advantages of attribute control charts

Attribute control charts have the advantage of allowing for quick summaries of various aspects of the quality of a product. It is easy to classify products as acceptable or unacceptable, based on various quality criteria. Thus, attribute charts sometimes bypass the need for expensive, precise devices and time-consuming measurement procedures. Also, this type of chart tends to be more easily understood by managers unfamiliar with quality control procedures; therefore, it may provide more persuasive (to management) evidence of quality problems. It is used for graphical representation of optimization result in drug formulation [Figure 11].

Rules for detecting "Out of Control" situations

The process is said to be in a state of statistical control if the values are within the control limits and the pattern is random. The process is called "out of control" when 2 or 3 points fall outside the warning limits (shift), when 8 points in a row fall above or below the centre line (shift), when 6 points in a row are steadily increasing or decreasing (trend), when 14 points in a row alternate up and down (two feed sources), when to implement these rules, it is helpful to also show on the chart the lines for ± 2 SE (warning limits) in addition to the control limits [Figure 12].[11]

CONCLUSION

Several drawbacks in the conventional approach of drug formulation development can be solved by using control charts as tools in statistical process control to determine whether a manufacturing of dosage form in pharmaceutical industry is in a state of statistical control or not. The control charts serve to illustrate the current operational condition of a process by providing a visual display that clearly indicates whether a process is within limits, out of control, or headed for an out of control condition, offering management time to take corrective action and avoid waste. By using these

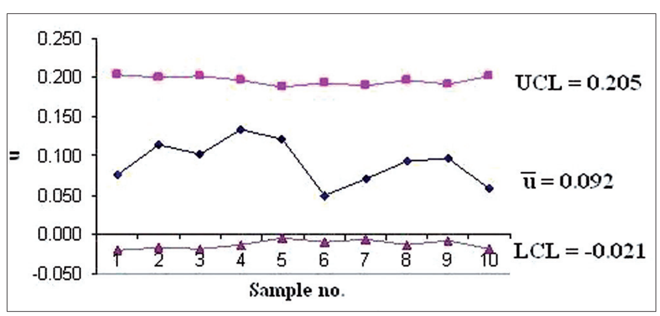

Figure 10: u-chart

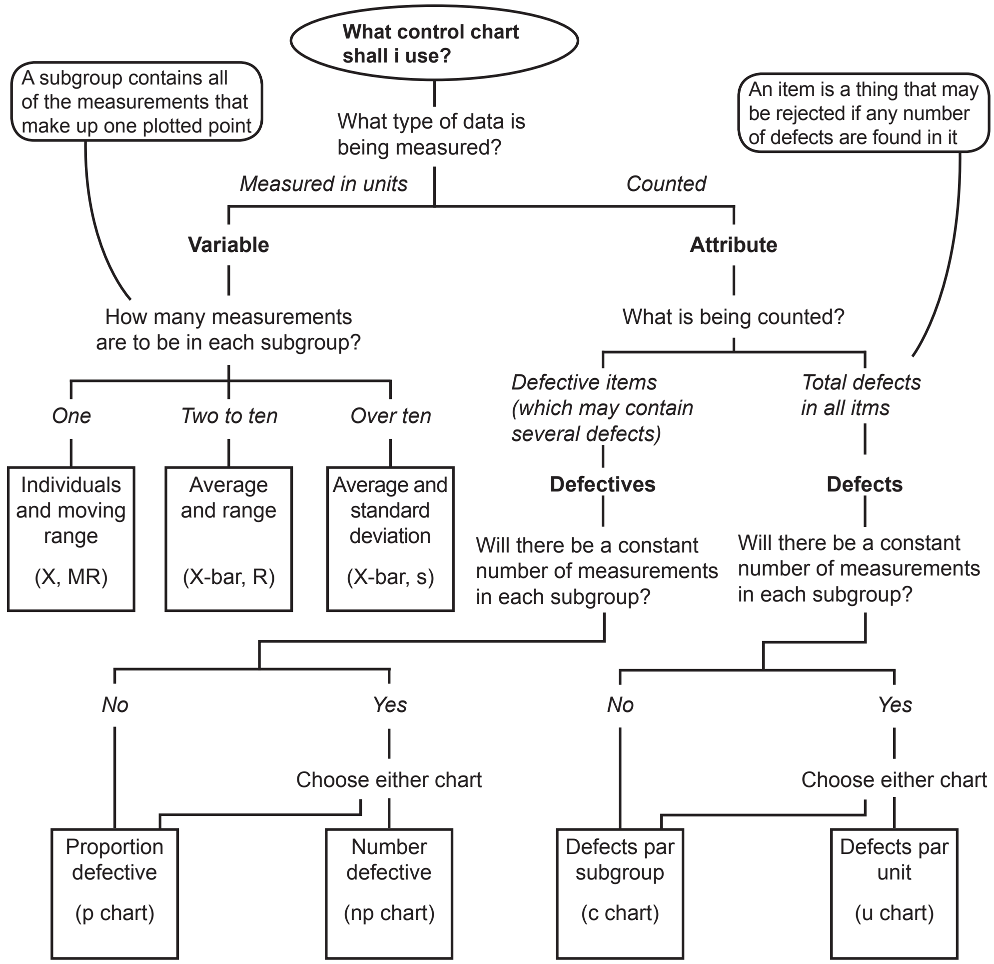

Figure 11: Choosing the right type of control chart

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    Any Point Above +3 Sigma
-------------------------------------------   +3 σLIMIT
    2 Out of the Last 3 Points Above +2 Sigma
-------------------------------------------   +2 σLIMIT
    4 Out of the Last 5 Points Above +1 Sigma
-------------------------------------------   +1 σLIMIT
    8 Consecutive Points on This Side of Control Line
================================   CENTER LINE
    8 Consecutive Points on This Side of Control Line
-------------------------------------------   -1 σLIMIT
    4 Out of the Last 5 Points Below - 1 Sigma
-------------------------------------------   -2 σLIMIT
    2 Out of the Last 3 Points Below -2 Sigma
-------------------------------------------   -3 σLIMIT
    Any Point Below -3 Sigma
```

Figure 12: General rules for detecting out of control or non-random situations

charts the system may be brought back into control. Control charts provide information regarding process capability and effectiveness in defect prevention. Nowadays, the control chart is proven a technique for improving productivity. In order for the control charts to be effective, however, the process must be continuously monitored so as to recognize the possible variations as close to their occurrence as possible.

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