ACHIEVING COMPETITIVE ADVANTAGE THROUGH PRACTICING TQM TOOLS IN PHARMACEUTICALS COMPANY

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Abstract: *In order to survive in a competitive market, improving quality and productivity of Product or process is a must for any company. And in case of pharmaceutical industry, effective quality assurance policy implementation is the most important goal. The main objective of this paper is to apply the Total Quality Management (TQM) tools in a pharmaceutical company and prove its advantage. Here Control Chart, Fishbone diagram, EWMA were used and the control limits were improved. This activity resulted in more perfect control limit recommendations which actually capable of reducing the material cost. The TQM perspective views quality as the pivotal purpose of the organization. Present review attempts to furnish a wide overview of the TQM tools leading to quality improvement of Pharmaceuticals Company.*

Keywords: *TQM, Control Chart, Fishbone Diagram, EWMA Control Chart, Competitive advantage.*

INTRODUCTION

Total Quality Management (TQM) is one of quality oriented approaches that many organizations adopt. It is generally acknowledged that manufacturing companies need to be quality oriented in conducting their business to survive the business world[1]. TQM is an integrated management philosophy and a set of practices that emphasizes top management commitment, customer focus, supplier relationship, benchmarking, quality-oriented training, employee focus, zero-defects, process improvement, and quality measurement[2,3]. As defined by ISO-"TQM is a management approach of an organization, centered on quality, based on the participation of all its members and aiming at long-term success through customer satisfaction, and benefits to all members of the organization and to society."

TQM, combined with effective leadership, results in an organization doing the right things right, first time[4]. The application of TQM and its tools & techniques within a pharmaceutical industry not only improves its processes and Quality of products, but also adds a new step towards the overall improvement of the whole organization.

Actually in this paper, the detailed analysis was done on a pharmaceutical company. Almost all pharmaceutical companies use a highly improved technology and manufacturing processes. Hence they serve products of almost zero defects. But with the goal of achieving zero defects, they may not be so conscious of the production cost which can be reduced by applying TQM tools. Cost is one of the important dimensions of quality which is to be balanced with it for increased productivity and profit.

LITERATURE REVIEW

As the application of TQM tools & techniques within a pharmaceutical industry improves its processes and Quality of products with the overall improvement of the whole organization, it is important to introduce the tools.

These are Pareto chart, Histogram, Fishbone diagram, Flow chart, Check point, Scatter diagram, Control chart, EWMA control chart, Poke Yoke, Loss function, PDCA cycle, KAIZEN, Tree diagram etc.[5]. Pareto chart is one of the total quality management tools and usually used during the define stage in six sigma. A simple rule, Pareto, 20 % issues causes 80 % results. This means, 80 % of problems come from 20 of reasons. 80 % of results come from 20% of work. 80% of costs come from 20% of spent area...and so on.

One of the Total Quality Management Tools is the Histogram. This graph is used to show frequency distributions. It looks very much like a bar chart. This chart graphs data distributions. If we have numerical, variable, continuous data we can use the chart. The chart organizes and sorts the data. It shows the data in a pictorial format.

Fish Bone Diagram also called Cause-and-Effect Diagram or Ishikawa Diagram. The Cause and Effect diagram identifies many possible causes for an effect or a problem. It can used to structure a brainstorming session because it immediately sorts ideas into key categories[6,7].

Control charts, also known as Shewhart charts or process-behavior charts, in statistical process control are tools used to determine whether a manufacturing or business process is in a state of statistical control. To determine whether a process should undergo a formal examination for quality-related problems is the actual purpose. Another chart, called EWMA

control chart is used to find out the inherent problems in the process when the process is actually in control.

CASE STUDY

Here all relevant data of this paper were collected from SQUARE PHARMACEUTICALS LIMITED, the leading manufacturer of pharmaceuticals in Bangladesh. SQUARE Cephalosporin's Limited (SCL) was built as a separate manufacturing plant at the kaliakoir site for Cephalosporine Antibiotics in 2006. They manufacture Cephalosporin's Anti-biotics in various pharmaceutical dosage forms comprising tablets, capsules, dry powder for suspensions, pediatric drops etc. Among the huge list of their products Cefotil 500 Tablet is chosen for the detailed study.

Cefotil (Cefuroxime) is a well-characterized and effective antibacterial agent, which has broad-spectrum bactericidal activity against a wide range of common pathogens. Cefotil 500 Tablet is a quick moving product but it need not to produce per day. Monthly almost eight batch is produced to meet the market demand. The batch size of Cefotil 500 Tablet is 65,000 tablets. The individual weight data of Cefotil 500 tablet is found from different inspection bench.

Table 1. Weight data table of Cefotil 500 Tablet

Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
924	932	954	956	954
956	944	942	951	944
954	947	963	933	963
948	952	955	946	945
973	959	941	954	939
955	961	954	976	952
973	983	940	962	955
949	970	953	947	943
959	963	958	959	949
959	937	947	948	958
950	960	956	962	949
945	953	959	964	957
959	963	971	962	955
936	954	955	961	950
970	959	947	952	960
955	964	940	956	964
975	952	968	955	958
951	952	957	956	951
957	944	960	954	946
950	952	966	959	953

They have some known defects as milling defects, compression defects, coating, thickness variation, blister packing etc. Among them almost all are in negligible amount in their view but this paper focus on the limits why certain defects are always negligible to them. All the defects are actually in

negligible amounts and control limits used by them for the quality concern is also perfect. But in case of weight variation and thickness variation, they do not pay much heed in setting good control limits or other statistical quality control tools. This in turn increases its material cost (though tablet performance is perfect in work).

Here sample no is, N=20
Mean weight of every 100 Tablets= Weight (mg) of 100 tablets /100
Mean weight of every 100 Tablets = 95443/100 mg
$$= 954.43 \text{ mg}$$

Here the range for the weight of tablets are, Upper Limit = 966 mg, Lower Limit = 874 mg

The mean weight is assumed as the average weight of the 100 tablets. I.e. 954.43 mg.

The acceptable range is, Mean $\pm$ 5% And not more than two shall deviate from this limit as well as the critical limit for acceptance is , Mean $\pm$ 10% and none shall deviate from this limit.

Now standard deviation is calculated using

$$\text{Variance}, \sigma^2 = \frac{\sum_{i=1}^{5} (X_i - \mu)^2}{N-1} \qquad (i)$$

$$= 9458.51/(100-1)$$
$$= 95.54 \text{mg}$$

where, σ = Standard deviation
    i = 1 to 5
    X_i= weight of sample i
    N = Data No / Observation No
    μ = Mean weight

So, Standard Deviation, $\sigma = \sqrt{(\text{variance})}$ (ii)
$$= \sqrt{95.54} = 9.77 \text{ mg}$$

Hence for the used range, upper limit is +1.18 σ & lower limit is 8.23 σ. 1st acceptance limit is $\pm$4.86 σ and 2nd acceptance limit is almost $\pm$9.76 σ.
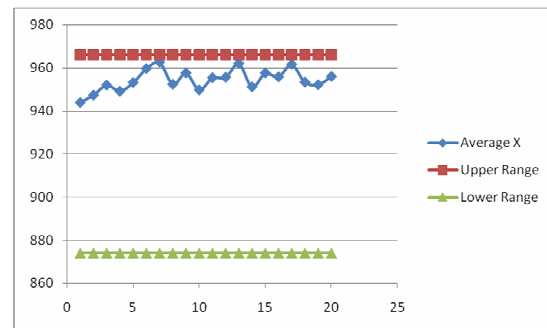

Figure 1. Graph showing Range limits of SCL
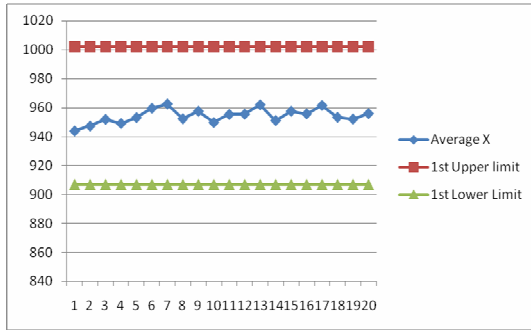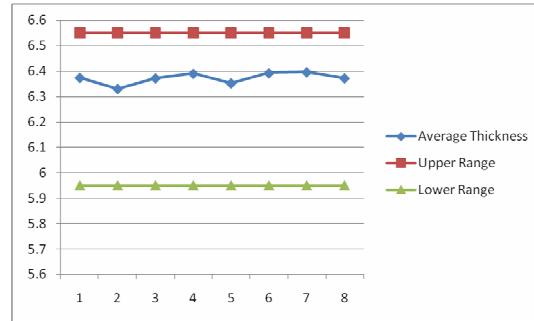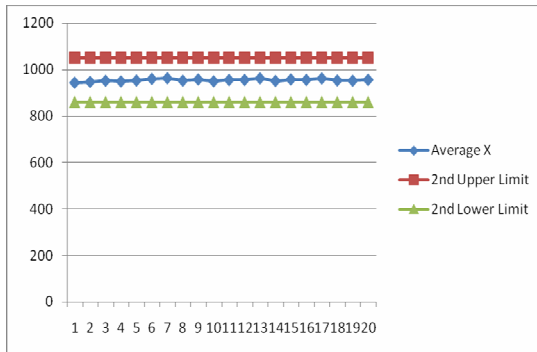
Figure 2. Graph showing 1st acceptance limits of SCL

Figure 3. Graph showing 2nd acceptance limits of SCL

Table 2. Thickness data table of Cefotil 500 Tablet

Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
6.28	6.42	6.41	6.39	6.37
6.21	6.38	6.37	6.41	6.28
6.38	6.40	6.39	6.30	6.39
6.40	6.37	6.39	6.40	6.39
6.32	6.41	6.37	6.27	6.39
6.44	6.37	6.39	6.39	6.37
6.41	6.40	6.39	6.39	6.39
6.34	6.38	6.39	6.39	6.36

Here sample no is, N=8
Mean thickness of every 40 Tablets= thickness (mm) of 40 tablets /40 =254.89/40
$$= 6.37225 \text{ mm}$$

Here the range for the thickness of tablets are, Lower range= 5.95 mm, Upper range = 6.55 mm

The mean thickness is assumed as the average thickness of the 40 tablets, i.e. 6.37225 mm

The standard deviation of the thickness data is obtained using equation (i) and (ii) as,
$$\sigma = 0.04610398$$
Hence for the used range, upper limit is +3.85 σ & lower limit is -9.15 σ. This is shown in below figure.

Figure 4. Graph showing range limits for thickness data

The control limits the Square Cephalosporin's Limited follows are shown in above calculations . The data reveals some important facts about their quality control tasks.

1. The weight and thickness of tablets are not same and the mean is based upon the obtained data average. Hence there is no standardized mean as well as mean may vary and can assume any value that is very much undesirable according to the sense of QUALITY.

2. The standard deviation obtained from these data is 9.77 for weight & 0.046 for thickness. Operating with these deviations respectively causes selection of wider control limit. Which may in turn show the in control situation when the process is actually out of control.

3.The next fact that which is almost clear to all is they do not maintain any σ limit which should obviously be narrowed for maintaining QUALITY and decreasing their material cost.

POSSIBLE IMPROVEMENTS
In case of weight data
    The first recommendation is to set a unique Mean. Let, μ = 945 mg
The standard deviation obtained also is very large which can be narrowed to further quality improvement. The standard deviation may be , σ = 5

Hence the first acceptance range is
Upper Limit = 945 + 945×5% = 992.25 mg
& Lower Limit = 945 - 945×5% =897.75 mg

The critical limit for acceptance is Mean $\pm$ 10%i.e.
Upper Limit = 945 + 945×10% =1039.5 mg
& Lower Limit = 945 + 945×10%=850.5 mg

Here the limits are also wide but upper limits are less than before and constant as mean is constant. This can be improved by changing their concept of acceptable range in terms of % of mean to standard deviation concept.

Control chart using standard deviation concept
The control limits for the control chart are,

Upper control limit (UCL) = μ + L ϭ
$$= 945 + 3 \times 5$$
$$= 960 \text{ mg}$$
Control Limit (CL) = μ = 945 mg
Lower control limit (LCL) = μ - L ϭ
$$= 945 - 3 \times 5$$
$$= 930 \text{ mg}$$

where, μ = Mean i.e. 945
ϭ = Standard Deviation i.e. 5 mg (as recommended)
L = Distance of the control limits from center line.
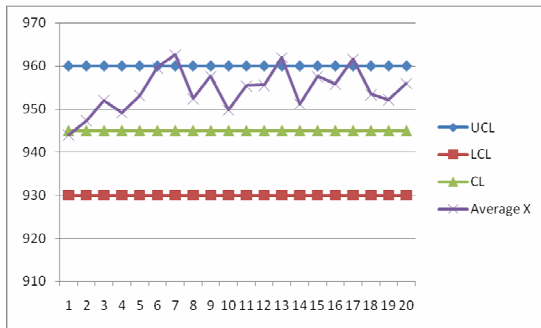In most cases for quality improvement L is considered as 3. Hence the limits become 3ϭ Control Limit.

Figure 5. Control Chart using standard deviation

Another control chart (X-bar and R chart)
Another control chart can be developed for variables. The chart is $\bar{x}$ - R chart is given in Table 3.

Table 3. Chart for calculating X-bar and R-bar

observation no	X1	X2	X3	X4	X5	average X	R= Xmax-Xmin
1	924	932	954	956	954	944	32
2	956	944	942	951	944	947.4	14
3	954	947	963	933	963	952	30
4	948	952	955	946	945	949.2	10
5	973	959	941	954	939	953.2	34
6	955	961	954	976	952	959.6	24
7	973	983	940	962	955	962.6	43
8	949	970	953	947	943	952.4	27
9	959	963	958	959	949	957.6	14
10	959	937	947	948	958	949.8	22
11	950	960	956	962	949	955.4	13
12	945	953	959	964	957	955.6	19
13	959	963	971	962	955	962	16
14	936	954	955	961	950	951.2	25
15	970	959	947	952	960	957.6	23
16	955	964	940	956	964	955.8	24
17	975	952	968	955	958	961.6	23
18	951	952	957	956	951	953.4	6
19	957	944	960	954	946	952.2	16
20	950	952	966	959	953	956	16
						954.43	21.55

Hence the limit becomes for X-bar chart
$UCL_x = \bar{\bar{X}} + A_2 * \bar{R} = 954.43 + 0.577 \times 21.55$
$$= 966.86$$
CL $= 954.43$
$LCL_x = \bar{\bar{X}} - A_2 * \bar{R} = 954.43 - 0.577 \times 21.55$
$$= 941.99$$

For R chart
$UCL_R = D_4 * \bar{R} = 2.004 \times 21.55 = 43.186$
CL = 21.55
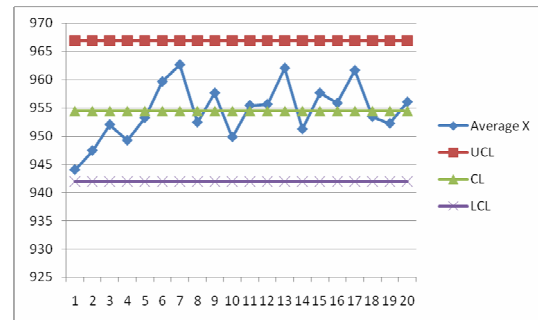$LCL_R = D_3 * \bar{R} = 0 \times 21.55 = 0$
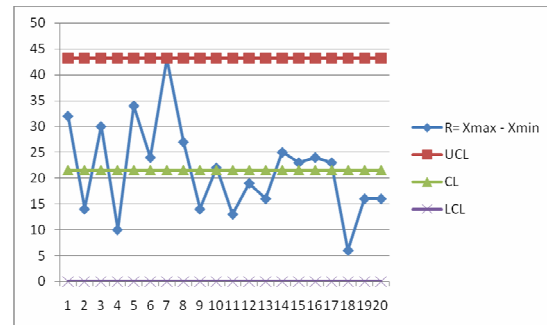
Figure 6. X- bar Control Chart

Figure 7. R Control Chart

The EWMA Control Chart
The EWMA is a special type of control chart which is capable of finding amy hidden errors of process.
The chart is built by a huge amount of calculations. For SQUARE datas the EWMA requires below calculations.
For i = 1
Control Limit= $\bar{\bar{X}}$ = 954.43

$$UCL = \bar{\bar{X}} + L \times \frac{S}{\sqrt{n}} \times \sqrt{\left(\frac{\lambda}{(2-\lambda)}\right)} \sqrt{[1-(1-\lambda)^{2i}]}$$
$$= 954.43 + 3 \times 9.77 \sqrt{[(0.25/(2-0.25)) \times \{1-(1-0.25)^{(2\times1)}\}]}$$

$\lambda = 0.25$ assumed where ($0 < \lambda < 1$)
(S /√n) = ϭ = 9.77
Now, For observation 1
$Z_{i-1} = \bar{\bar{X}}$ = 954.43
$Z_i = \lambda \bar{x_i} + (1-\lambda) z_i$
$$= 0.25 \times 944 + (1-0.25)$$
$$= 951.82$$

Table 4. Z & limit Calculation Table

| observation no	Mean	SECOND PART	Z value	UCL	LCL
1	954.4	1.638151082	951.82	956.1	952.8
2	954.4	2.047688852	950.72	956.5	952.4
3	954.4	2.245466129	951.04	956.7	952.2
4	954.4	2.349410654	950.58	956.8	952.1
5	954.4	2.405906758	951.23	956.8	952
6	954.4	2.437110346	953.32	956.9	952
7	954.4	2.454488045	955.64	956.9	952
8	954.4	2.464209147	954.83	956.9	952
9	954.4	2.469660452	955.52	956.9	952
10	954.4	2.47272153	954.09	956.9	952
11	954.4	2.474441722	954.42	956.9	952
12	954.4	2.475408804	954.71	956.9	952
13	954.4	2.475952622	956.54	956.9	952
14	954.4	2.476258468	955.2	956.9	952
15	954.4	2.476430489	955.8	956.9	952
16	954.4	2.476527246	955.8	956.9	952
17	954.4	2.47658167	957.25	956.9	952
18	954.4	2.476612283	956.29	956.9	952
19	954.4	2.476629502	955.27	956.9	952
20	954.4	2.476639188	955.45	956.9	952
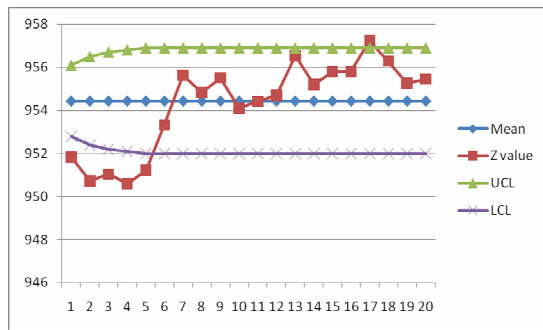
Figure 8. EWMA Control Chart

In case of thickness data

As the weight data, here the first recommendation is to set a unique Mean and standard deviation also. Let, $\mu = 6.35$ mm And $\sigma = .04$
Here control charts using standard deviation concept, X-bar & R chart, EWMA control charts may be used for setting good control limits.

Control chart using standard deviation concept

The control limits for the control chart are-
Upper Control limit=$\mu + L\sigma = 6.35 + 3*0.04$
$= 6.47$mm
Lower control limit=$\mu - L\sigma = 6.35 - 3*0.04$
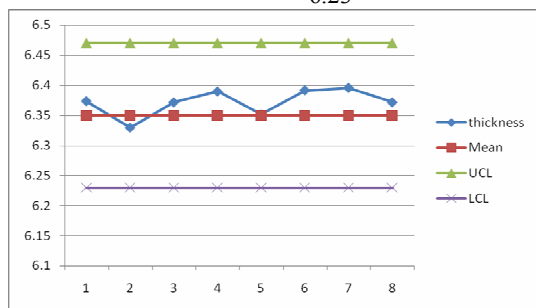$= 6.23$

Figure 9. Control Chart using standard deviation for thickness data

X-bar and R chart

X-bar and R chart can also be constructed.

Table 5. Chart for calculating X-bar and R-bar

Obs No	X1	X2	X3	X4	X5	Average	Xmax-Xmin
1	6.28	6.42	6.41	6.39	6.37	6.374	0.14
2	6.21	6.38	6.37	6.41	6.28	6.33	0.2
3	6.38	6.4	6.39	6.3	6.39	6.372	0.1
4	6.4	6.37	6.39	6.4	6.39	6.39	0.03
5	6.32	6.41	6.37	6.27	6.39	6.352	0.14
6	6.44	6.37	6.39	6.39	6.37	6.392	0.07
7	6.41	6.4	6.39	6.39	6.39	6.396	0.02
8	6.34	6.38	6.39	6.39	6.36	6.372	0.05
						6.37225	0.09375

For X-bar char-
$UCL_x = \overline{\overline{X}} + A_2 * \overline{R}$ =6.37225+.577*.09375= 6.4263
CL=6.37225
$LCL_x = \overline{\overline{X}} - A_2 * \overline{R}$ =6.37225- .577*.09375=6.3182
And for R chart-
$UCL_R = D_4 * \overline{R}$ =2.004*.09375=.187875
CL=.09375
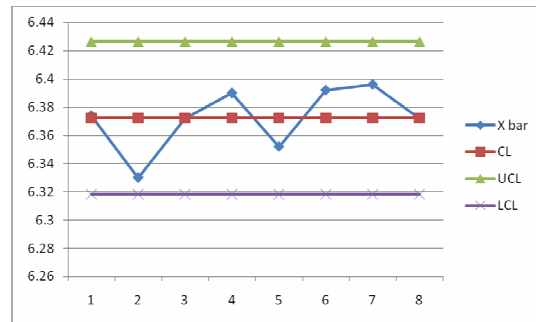$LCL_R = D_3 * \overline{R}$ =0*.09375=0

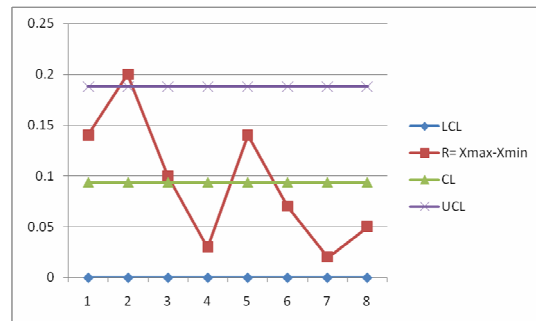Figure 10. X bar chart for thickness data

Figure 11. R chart for thickness data

The EWMA Control Chart

As like as calculations of EWMA control chart for weight data, the control limit calculations are for observation no 1-

Control Limit= $\overline{\overline{X}}$ = 6.37225

$$UCL = \overline{\overline{X}} + L\frac{S}{\sqrt{n}}\sqrt{\frac{\lambda}{2-\lambda}[1-(1-\lambda)^{2i}]}$$

$UCL_1 = 6.37225 + 3 \times 0.046\sqrt{[(0.25/(2-0.25)) \times \{1-(1-0.25)^{(2\times1)}\}]}$

$\lambda = 0.25$ assumed where ($0 < \lambda < 1$)

$(S/\sqrt{n}) = \sigma = 9.77$

Now, For observation 1

$Z_{i-1} = \overline{\overline{X}} = 6.37225$

$Z_i = \lambda \overline{x}_i + (1-\lambda) z_i$
$= 0.25 \times 6.374 + (1-0.25)*6.37225$
$= 6.37688$

Table 6. Chart for calculating UCL, LCL and Z value

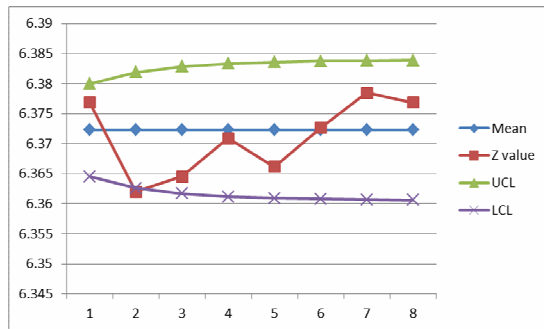| Xbar	Mean	Z value	UCL	LCL
6.374	6.37225	6.37688	6.37996	6.36454
6.33	6.37225	6.36202	6.38189	6.36261
6.372	6.37225	6.36451	6.38282	6.36168
6.39	6.37225	6.37088	6.38331	6.36119
6.352	6.37225	6.36616	6.38358	6.36092
6.392	6.37225	6.37262	6.38372	6.36078
6.396	6.37225	6.37847	6.38381	6.36069
6.372	6.37225	6.37685	6.38385	6.36065

Figure 12. EWMA Control Chart for thickness

ANALYSIS OF OBTAINED CHARTS
The Control Charts and other charts including EWMA Control Charts shows that the datas belong to a large range. In different charts different circumstances are obvious-
1. The range charts shows the datas are within the limit. But if we concentrate on the graph , it is clear that most of the datas are near to the upper range. Whereas they are far apart from lower range. It is desired for any process that data are to be clustered near the midlevel between two ranges. So that fault should be overcome by the process.And a more suitable range must be set.
2. The next graph of their (SCL's) calculated acceptance limit shows the very wider control limit.
3. The third graph shows the process acceptance limit is more than before.

4. The Control Chart for standard deviation shows a large amount of data falls beyond the control limit in case of weight data. Hence for those points process needs to be improved.
5. Another Control Chart (X-bar and R chart) shows process within control limit but some points approaching towards the UCL & LCL. So the process needs to be improved to cluster the points towards CL.
6. The EWMA Control chart shows more improved control limit based on existing data. The limit is narrower, hence some points go beyond the acceptance limit in both case. So it is sure that if the process is more improved such that, all the data exists between the EWMA control limits then it is a highly reliable and improved process.

IMPROVEMENT BY FISHBONE DIAGRAM
There are some problems in Pharmaceutical companies , but these are very infrequent as occurs once in every six month or once in a year . So it can be said pharmaceutical companies are very much improved and quality focused. But here in this paper it is shown that they do not pay much heed on usage of excess material as a result the weights of antibiotics vary. The main or root causes behind the problem can be found by the Fishbone Diagram or Ishikawa Diagram.
Here the causes behind the weight and thickness variation may include lacking of man, machine, material, method and measurement etc.
1. Sometimes man may have faster operating tendency that causes weight variation.
2. The materials sometimes are less compressed.
3. Compression time for tablets may be not highly accurate.
4. There are no proper control limits for tablet weights.
5. The coating of tablets is not uniform in many times.

RECOMMENDATION
Some recommendations may be offered to SQUARE CEPHALOSORINS LIMITED.

1. At first they can pay their attention on what weighted & how much thick tablets they actually want.
2. Then they should concentrate on their control limit.
3. The control limit must be not in the way they currently follow. They should use Control Chart concept for the control limit selection.
4. The control limit can be narrowed and they can practice it for both antibiotic and hormonal tablets.
5. At first they can pay their attention on what weighted & how much thick tablets they actually want.
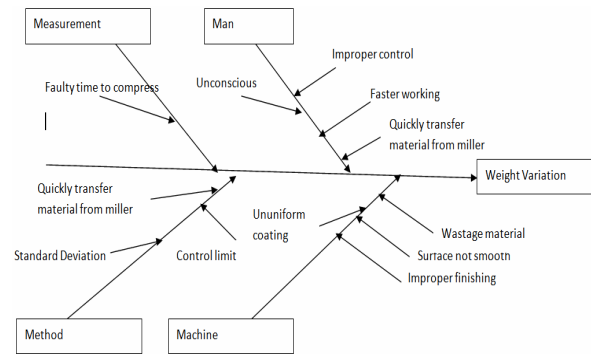
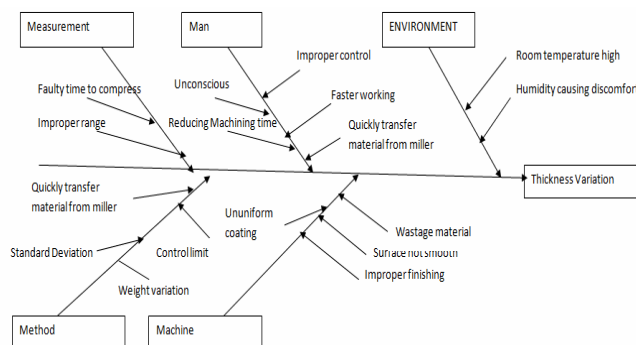Figure 13. Fishbone diagram for weight variation

Figure 14. Fishbone diagram for thickness variation

6. At first they can pay their attention on what weighted & how much thick tablets they actually want.
7. Then they should concentrate on their control limit.
8. The control limit must be not in the way they currently follow. They should use Control Chart concept for the control limit selection.
9. The control limit can be narrowed and they can practice it for both antibiotic and hormonal tablets.
10. The thickness of coating on tablets should be reviewed.
11. The time to compress the tablets should be known by the all operators.
12. The operators must be motivated to perform jobs in time but not faster than required time.
13. The operating environment should be reviewed.

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