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Application of Statistical Quality Control Techniques in Condom Manufacturing Industry

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Abstract: ***In the manufacturing environment, quality improves reliability, increases productivity and customer satisfaction. Quality in manufacturing requires the practice of quality control. This research work investigates the level of quality control in a condom manufacturing industry. The study involves inspection of some randomly selected finished products on daily bases. The main objective of this work is the application of statistical quality control technique in production department by the help of P-chart, X- chart and R-chart etc. and suggesting the area to be furnished.***

1. Introduction

A quality management system (QMS) is a collection of business processes focused on consistently meeting customer requirements and enhancing their satisfaction. It is aligned with an organization's purpose and strategic direction (ISO9001:2015). It is expressed as the organizational goals and aspirations, policies, processes, documented information and resources needed to implement and maintain it. Early quality management systems emphasized predictable outcomes of an industrial product production line, using simple statistics and random sampling. By the 20th century, labour inputs were typically the most costly inputs in most industrialized societies, so focus shifted to team cooperation and dynamics, especially the early signaling of problems via a continual improvement cycle. Benefits of using QMS are it brings a defined approach to achieve the objectives of an organization. Therefore, it provides the management team a clearly defined path that will lead to success. It sets a standardized requirement for all functions and departments. Therefore, assessing the process performance or providing them the expectations from the management becomes a simple task. Implementation of QMS increases the confidence level of the customers on your product/service. Thus the revenue and market share of an organization goes up. QMS ensures that the objectives of the organization are linked towards the customer needs and thus creates a perfect value chain. Implementation of QMS increases the effective use of resources. It sets clear objectives for each job role and each team, and thus miscommunication and ambiguity in the way of processing is avoided. It enables an organization to understand its pain areas, customer complaints and concerns, and work towards it.

2. Quality Control Tools

1) Flowchart

Most of us are familiar with flowcharts. You have seen flowcharts of reporting relationships in organizational structures. Flowcharts are also used to document work process flows. This tool is used when trying to determine where the bottlenecks or breakdowns are in work processes. Flow-charting the steps of a process provides a picture of what the process looks like and can shed light on issues within the process. Flowcharts are also used to show changes in a process when improvements are made or to show a new work flow process.

2) Check Sheet

A check sheet is a basic quality tool that is used to collect data. A check sheet might be used to track the number of times a certain incident happens.

3) Cause and Effect (fish bone) Diagram

A cause and effect diagram, also known as a fish-bone diagram, shows the many possible causes of a problem. To use this tool, you need to first identify the problem you are trying to solve and simply write it in the box (head of the fish) to the right. Next, you will list the major causes of the problem on the spine of the fish. Causes are typically separated into categories of people, process, materials and equipment. Causes are then identified through brainstorming with a group familiar with the problem. Once all of the possible causes are identified, they can be used to develop an improvement plan to help resolve the identified problem.

4) Pareto Chart

A Pareto chart is a bar graph of data showing the largest number of frequencies to the smallest. In this example, we are looking at the number of product defects in each of the listed categories. When you look at the number of defects from the largest to the smallest occurrences, it is easy to see how to prioritize improvements efforts. The most significant problems stand out and can be targeted first.

5) Control Charts

Control charts or run charts are used to plot data points over time and give a picture of the movement of that data. These charts demonstrate when data is consistent or when there are high or low outliers in the occurrences of data. It focuses on monitoring performance over time by looking at the variation in data points. And, distinguishes between common cause and special cause variations. The Dow Jones Industrial Average is a good example of a control chart.

6) Histograms

Histograms are bar chart pictures of data that shows patterns that fall within typical process conditions. Changes in a process should trigger new collection of data. A minimum of 50-75 data points should be gathered to ensure an adequate number of data points have been collected. The patterns that are detected demonstrate an analysis that helps understand variation.

7) Scatter Diagrams

Scatter diagrams are graphs that show the relationship between variables. Variables often represent possible causes and effect.

3. Literature survey

Douglas C. Montgomery, (2009), "*Introduction to Statistical Quality Control".* This book is about the use of modern statistical methods for quality control and improvement. It provides comprehensive coverage of the subject from basic principles to state-of-the-art concepts and applications. The objective is to give the reader a sound understanding of the principles and the basis for applying them in a variety of situations. Although statistical techniques are emphasized throughout, the book has a strong engineering and management orientation. Extensive knowledge of statistics is not a prerequisite for using this book. Readers whose background includes a basic course in statistical methods will find much of the material in this book easily accessible.
Dr. MuwafaqAlkubaisi, (2013), *"Statistical Quality Control (SQC) and Six Sigma Methodology: An Application of X-Bar Chart on Kuwait Petroleum Company".*In this paper an attempt is made to construct a Six Sigma based on data collected from a petroleum company in Kuwait to produce an x-bar chart. Unfortunately, it seems there are some serious deficiencies in the production process since the value of Cp and Cpk are less than 1 which means the process is not capable of meeting its specifications.

C.N. Nnamani1, (2013) "*Statistical Quality Control of Manufactured Products (Case Study of Packaging at Lifespan Pharmaceutical Limited)".* This work shows that there are many points that fall out of the control limits. This means that the production process is out of control and needs a thorough and complete process inspection and verification. Even though the proportion of 0.02634 (which is about 3 defectives out of 100 every sachets) is not too high, the fact that the production process is not within control limits calls for a decisive action by the company.

Pranay S. Parmar (2014), "*Implementation of Statistical Process Control Techniques in Industry: A Review".* This paper shows applicability of the statistical process control techniques in different manufacturing industries. In this research paper various research articles and the case studies on the implementation of the Statistical Process Control Techniques in the manufacturing industries are selected for the review.

R. T. SMALLWOOD, (1998) "*Application Of Statistical Quality Control Techniques To Pint And Half-Gallon Ice Cream Packaging Operations".* Describes about the implementation and application of statistical quality control techniques in a ice cream factory. This work is one of the earliest work done on the basis of statistical quality control. Quality control techniques employing control charts have been used simultaneously with other tools to help management achieve a more efficient operation with greater profits.

PavolGejdoš, (2015) *"Continuous Quality Improvement by Statistical Process Control".* This Article deals with the application of selected tools of statistical process control, through which we can achieve continuous quality improvement. The advantage of these tools is that they can identify the effects of the processes that cause unnatural variability in processes that result of errors and poor quality. Tools like capability index, histogram, model DMAIC, control chart, etc. can reliably determine the anomalous variability in the process and thereby contribute to quality improvement. In the paper through histograms and Shewhart control charts action exposing the systemic implications of the processes and therefore unnatural variability in processes, which result in non-compliance. The results clearly show that through the DMAIC model can systematically improve quality.

Maurício Guy de Andrade, (2017), *"Statistical quality control for the evaluation of the uniformity of microsprinkler irrigation with photovoltaic solar energy".* The objective of this work was to evaluate a microsprinkler irrigation system with water pumping by photovoltaic system, through uniformity coefficients and the total energy produced (W h) by the system using the statistical quality control, comparing the Shewhart control charts, Exponentially Weighted Moving Average (EWMA) and Cumulative Sum (CUSUM) and classifying the processes using the process capability index.

ĽubicaSimanová, (2015), *"The Use of Statistical Quality Control Tools to Quality Improving in the Furniture Business".* The main aim of the article is to illustrate the use of tools of operative quality management to prevent a decrease in quality during production, supportive and operational processes by the furniture manufacturing. There are more tools for achieving operative quality management targets and the most frequent method is probably measurement and evaluation of the capability of processes through capability indexes. In addition to other histogram and Ishikawa diagram are the next frequently used tools for quality improvement processes.

Michael W. Milo, (2015), *"A new statistical approach to automated quality control in manufacturing processes".* Automated quality control is a key aspect of industrial maintenance. In manufacturing processes, this is often done by monitoring relevant system parameters to detect deviations from normal behavior. Previous approaches define "normalcy" as statistical distributions for a given system parameter, and detect deviations from normal by hypothesis testing. This paper develops an approach to manufacturing quality control using a newly introduced method: Bayesian Posteriors Updated Sequentially and Hierarchically (BPUSH). This approach outperforms previous methods, achieving reliable detection of faulty parts with low computational cost and low false alarm rates

(~0.1%). Finally, this paper shows that sample size requirements for BPUSH fall well below typical sizes for comparable quality control methods, achieving True Positive Rates (TPR) >99% using as few as n = 25 samples.

M T Sembiring, (2018) "*Defect Analysis of Quality Palm Kernel Meal Using Statistical Quality Control In Kernels Factory*". In this paper it is detecting the error occurance in the industry using statistical quality control techniques. By using SQC the percentage oil content can be increased.

Michael Stuart, (1996), *"Statistical quality control and improvement"*. This paper argues that only through the broader perspective of a total quality approach can the fullest rewards of SPC and other statistical techniques be realised. With increasing emphasis on international quality standards it will be necessary to seek ways of bridging the differences in approach between total quality and certification, which need not and should not be in conflict.

Arshad Rashid, (2016), *"Applications of Statistical Quality Control Tools in Construction Industry a Quality Approach"*. Discussed about the implementation of SQC in construction firm and the following conclusions where made, the best of specifications cannot fully accomplish their objectives unless they are uniformly interpreted and enforced. However, uniformity in interpretation and enforcement can only be achieved through proper knowledge of what is involved in statistically adopted specifications. Adoption of statistically derived acceptance plans for materials or job compliance will undoubtedly present multitude of factors, some large as to involve administrativedecisions and other small enough to be tackled by field personnel.

4. Project Design and Methodology

4.1 Problem Statement

The industry reworked 4051.5 kg of condoms in the month of December and 500kg of products scrapped. This affects the overall quality of the process.

4.2 Process Flow

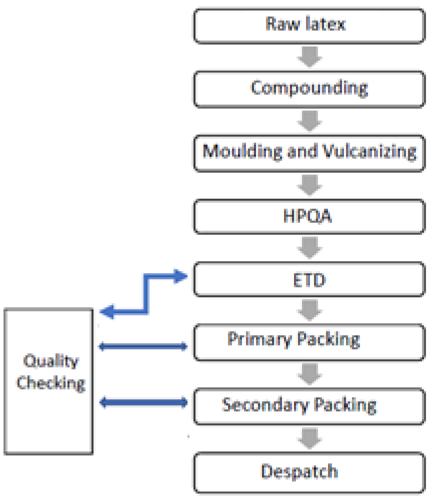

Figure 3.1: General Process Flow

4.3 Project Description

The rejection and rework data for the month of December is collected from the Production department. Table 3.2 shows the machine wise data for rework. Initial rejection is the quantity of condoms rejected by HPQA department for re-inspection of the lot and segregate good and bad condoms. Passed is the quantity of product accepted or it is the quantity that is re-inspected and free of defects. Scrap quantity is the rejected quantity after being salvaged. Table 3.1 shows the quantity of produced in weight.

Table 3.1: Total production

Month	Quantity (Kg)
April, 2018	23070
May, 2018	81184
June, 2018	126836
July, 2018	148333
Aug., 2018	109258
Sep, 2018	92681
Oct, 2018	110654
Nov., 2018	62495
Dec., 2018	57870
Jan., 2019	74220
Yearly Cum	886601

Table 3.2: Rework and scrap

SALVAGE			
Machine	Initial Rejection (QTY)	Passed (QTY)	Scrap (QTY)
MA	186.72	182.60	4.13
MB	279.45	258.16	21.29
MC	105.55	100.39	5.16
MD	337.26	156	10.68
MF	1371.89	1330.06	41.83
ME	1184.36	1157.18	27.18
MG	1495.25	1453.16	42.09
Total	4960.48	4637.55	152.36

From this table it is clearly depicted that 4960.48kg of condoms are rejected by HP department for rework and 4637.55kg of product passed the test and 152.36kg scrapped in the month of January. i.e. 6.7% of product is reworked which is pretty high.

Table 3.3: Visual Defects

MONTH	Jan-19								
DEFECT	MA	MB	MC	MD	ME	MF	MG	MH	Total Lots
TER	1	1			6	3			11
DTER		2							2
BERC			2			3	5		10
PNP		5	8						13
INK PREAD									0
SCRATCH									0
OIL			4	13	12	43	24		96
IS	21	4	3	3	69	52	82		234
WRI	3	34	2			2			41
DUST				1			1		2
BRK			3		4	4	6		17
LC	5	15							20
NPC									0
DSG	2					1	2		5
NUER									0
DISC									0
LD									0
BHL	2				1				3
NPC							2		2
FOAM			5	28	28	6	3		70
	34	61	27	45	120	114	125	0	526
SALVAGE LOTS	33	55	19	45	114	111	125	0	502

Table 3.4: Dimensional Defect

MONTH	Jan-18								
DEFECT	MA	MB	MC	MD	ME	MF	MG	MH	TOTAL
BVO			1	1	1	2	1		6
JIS				2		2	2		6
SCRC									0
VISIBLEHOLE									0
ERT					1				1
LB							1		1
BTOVER									0
length over	4				7		5		16
WS									0
DOTLEAK						1	1		2
	4	0	1	3	9	5	10	0	32

Table 3.3 shows the data for machine wise visual defects. From the dashboard we can say that Oil and IS (Internal Sticking) is more for machines ME, MF, MG (i.e. from plant- D). The data shows almost 65% of the defects came from plant D. Table 3.4 shows the dimensional defect data. From the dashboard we can say that JIS out (pin-hole), Dot leak, and length constitutes 75% of the whole defects. From both the dashboards we can depict that some manufacturing issues exist in Plant - D. So the quality study is mainly focusing on machines ME, MF, MG.

Table 3.5- Pinhole Machine ME

Date	Body	Nipple	Shoulder	Nipple Bur	Within 2.5	Dot Leak	Shower Leak	Ribbed Leak	Total Leak
26-01-2019	2								2
27-01-2019		1			2				3
28-01-2019	1			2	1		1		5
29-01-2019	2				2				4
30-01-2019	3	1	1		2	1			8
31-01-2019	1		1		1				3
01-02-2019					5				5
02-02-2019	1								1
03-02-2019	1								1
04-02-2019					1				1
05-02-2019	1				2				3
06-02-2019					3				3
07-02-2019					2				2
08-02-2019									NP
									41

Table 3.6: Pinhole Machine MF

Date	Body	Nipple	Shoulder	Nipple Bur	Within 2.5	Dot Leak	Ribbed Leak	Total Leak
26-01-2019	2	1	2		2			7
27-01-2019	1				4			5
28-01-2019					3			3
29-01-2019	3		2					5
30-01-2019	2	1						3
31-01-2019	4		2	1	4			11
01-02-2019	2							2
02-02-2019	4				2			6
03-02-2019	6				3			9
04-02-2019	2				1			3
05-02-2019	1				5			6
06-02-2019	5			1	8			14
07-02-2019		1			3			4
08-02-2019	5		1		1			7
								85

Table 3.7: Pinhole Machine MG

Date	Body	Nipple	Shoulder	Nipple Bur	Within 2.5	Dot Leak	Shower Leak	Ribbed Leak	Total Leak
26-01-2019			1		5				6
27-01-2019	2				6		1		9
28-01-2019	1				4				5
29-01-2019	1	1					1		3
30-01-2019	6		1		3	2			12
31-01-2019	7				1				8
01-02-2019					1				1
02-02-2019	1								1
04-02-2019					3				3
05-02-2019					6				6
06-02-2019	3	1			4				8
07-02-2019	2	1	1		2				6
08-02-2019					1				1
									69

Above tables shows that the pinhole for the machine ME, MF, MG in the month of January. From the table we can see that total pinhole for the MF, MG is high when compared to ME. In the table body leak and within 2.5 is critical it constitutes more than 75% of the leak. So the study is extended to the dimension length of the condom. Table and figure shows the dashboard for the length of condom for 15 days. The data in the table is collected from the SAP software in the industry and dashboard representation is done through Tableau software for better representation.

Table 5.8: Length from SAP

Day	Avg.Length
26.12.2018	184.8125
27.12.2018	184.9591837
28.12.2018	185.1190476
29.12.2018	185.2096774
30.12.2018	185.3157895
31.12.2018	185.3095238
01.01.2019	185.5652174
02.01.2019	185.6595745
03.01.2019	185.5531915
04.01.2019	185.6447368
05.01.2019	185.2948718
06.01.2019	185.1777778
07.01.2019	185.4081633
08.01.2019	185.0638298
09.01.2019	185.3229167

Table 3.9 shows the Average weight and single wall thickness dashboard from SAP. For quality analysis of the condom the study is broadened towards average weight and thickness. The objective is to find whether any correlation exist between the average weight and single wall thickness.

Table 3.9: Avg.wt and Thickness –ME

Date	Avg. Wt	Single Wall Thickness
26-12-2018	1.8353	0.0653
27-12-2018	1.835	0.065648
28-12-2018	1.832	0.066875
29-12-2018	1.8433	0.065929
30-12-2018	1.8425	0.066052
31-12-2018	1.8164	0.064861
01-01-2019	1.8187	0.066714
02-01-2019	1.8271	0.065938
03-01-2019	1.8327	0.067667
04-01-2019	**1.807**	**0.066214**
05-01-2019	1.8191	0.06425
06-01-2019	1.8298	0.0638
07-01-2019	1.8065	0.064969
08-01-2019	1.8192	0.064563
09-01-2019	1.8027	0.067125
10-01-2019	1.8537	0.0645

Table 3.10: Avg.wt and Thickness – MF

Date	Avg. Wt	Single Wall Thickness
26-12-2018	1.817625	0.0628
27-12-2018	1.800344	0.0636
28-12-2018	1.818781	0.0654
29-12-2018	1.826	0.0655
30-12-2018	1.828435	0.0655
31-12-2018	1.819063	0.0643
01-01-2019	1.835656	0.063
02-01-2019	1.829906	0.0641
03-01-2019	1.826	0.0661
04-01-2019	1.830063	**0.0641**
05-01-2019	1.828219	0.0611
06-01-2019	1.832219	0.063
07-01-2019	1.82688	0.0642
08-01-2019	1.824188	0.0644
09-01-2019	1.824125	0.0655
10-01-2019	1.812344	0.0655

Table 3.11: Avg.wt and Thickness – MG

Date	Avg. Wt	Single Wall
26-12-2018	1.7825	0.066636
27-12-2018	1.819862	0.067188
28-12-2018	1.817857	0.065708
29-12-2018	1.806188	0.067538
30-12-2018	1.832063	0.065378
31-12-2018	1.807281	0.065115
01-01-2019	1.827516	0.066563
02-01-2019	1.851094	0.068678
03-01-2019	1.834219	0.067471
04-01-2019	1.8054	0.067729
05-01-2019	1.795179	0.066963
06-01-2019	1.837906	0.068083
07-01-2019	1.80925	0.067522
08-01-2019	1.838323	0.069133
09-01-2019	1.810906	0.068188
10-01-2019	1.826188	0.0664

As a part of quality analysis study, the average weight is calculated online from the production before washing of the product and examine whether the process is in control or not.

Table 3.12: Online Average Weight

Date	Average Weight ME Machine	Average Weight MF Machine	Average Weight MG Machine
16-01-2019	1.821	1.8225	1.8192
17-01-2019	1.8163	1.8115	1.8263
18-01-2019	1.814	1.8129	1.8167
19-01-2019	1.8171	1.8167	1.8131
20-01-2019	1.8102	1.819	1.8108
21-01-2019	1.8263	1.8222	1.8265
22-01-2019	1.811	1.8163	1.8121
23-01-2019	1.8069	1.8155	1.8238
24-01-2019	1.8235	1.8234	1.8202
25-01-2019	1.8133	1.8210	1.8204
26-01-2019	1.8123	1.8177	1.8245
27-01-2019	1.8029	1.8067	1.7831
28-01-2019	1.8158	1.8215	1.8192
29-01-2019	1.8208	1.8046	1.8066
30-01-2019	1.8152	1.8128	1.8204
31-01-2019	1.8146	1.8215	1.8159

5. Data Analysis

5.1 Analysis of Pinhole

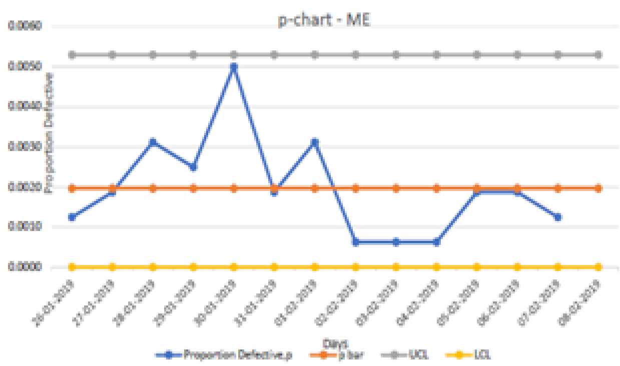

Figure 4.1: P-chart ME

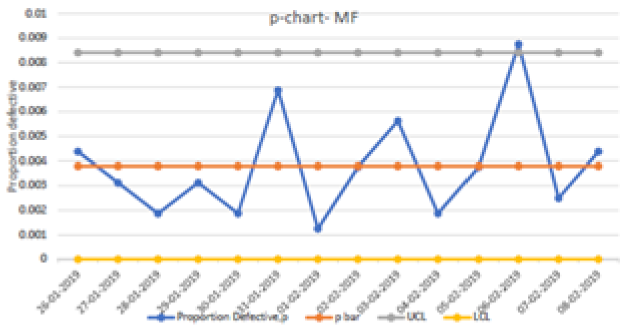

Figure 4.2: P-chart MF

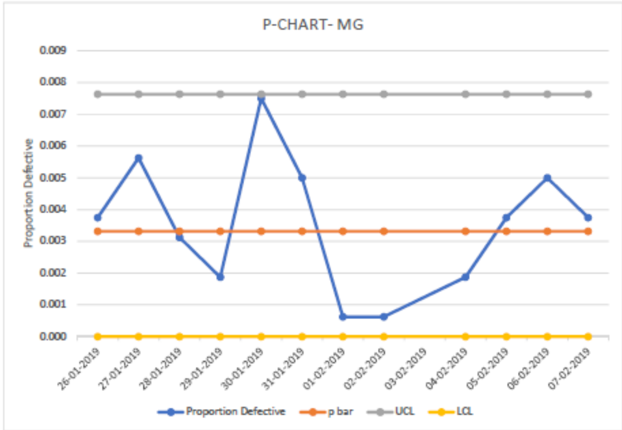

Figure 4.3: P-chart MG

Quality analysis tool, control chart is chosen for pinhole. Above figure shows the p-chart for pinhole, from the data it is analyzed that process is in control for machine ME. But for machine MF one point is out of control and as well as for machine MG one point is about to be out from the limits. Pinhole can happen because of various reasons such as Foam, Dust, scratch, water drops etc… The below fishbone diagram will explain the root cause for the pinhole.

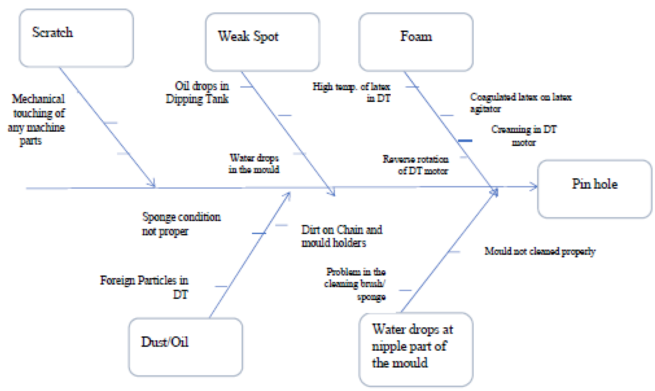

Figure 4.4: Cause and Effect Diagram

5.2 Analysis of Length

Table 4.2 Length Dashboard and Cpk calculation

Day	Avg.Length	Range	CL	UCL	LCL
26.12.2018	184.813	0.847074	185.294400	185.783162	184.805638
27.12.2018	184.959	0.847074	185.294400	185.783162	184.805638
28.12.2018	185.119	0.847074	185.294400	185.783162	184.805638
29.12.2018	185.210	0.847074	185.294400	185.783162	184.805638
30.12.2018	185.316	0.847074	185.294400	185.783162	184.805638
31.12.2018	185.310	0.847074	185.294400	185.783162	184.805638
01.01.2019	185.565	0.847074	185.294400	185.783162	184.805638
02.01.2019	185.660	0.847074	185.294400	185.783162	184.805638
03.01.2019	185.553	0.847074	185.294400	185.783162	184.805638
04.01.2019	185.645	0.847074	185.294400	185.783162	184.805638
05.01.2019	185.295	0.847074	185.294400	185.783162	184.805638
06.01.2019	185.178	0.847074	185.294400	185.783162	184.805638
07.01.2019	185.408	0.847074	185.294400	185.783162	184.805638
08.01.2019	185.064	0.847074	185.294400	185.783162	184.805638
09.01.2019	185.323	0.847074	185.294400	185.783162	184.805638

Standard deviation	0.247866967
Variance	0.061438033
Cpl	4.430333656
Cpu	2.293703382
Cpk	**2.29**

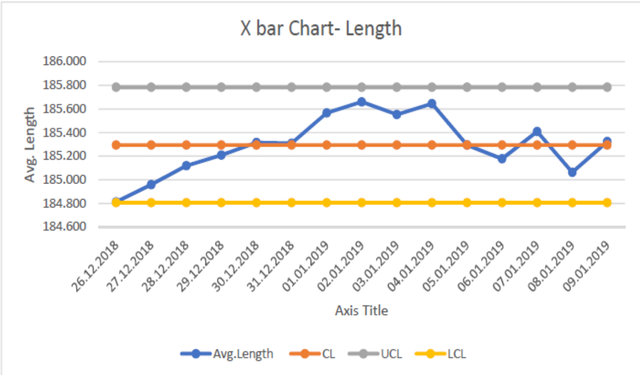

Figure 4.5: Control Chart-Length

From analysis it is clearly evident that process is within control limit for the specification length. The process capability index Cpk is calculated and the value is 2.29. This value represents the process is capable and meeting its requirements. But from the dashboard it is depicted that range of value is pretty high and it is not that much good for the process. The variation in the length can happen because of the following reasons: Mould is not fixed properly in the holder so that the latex will stick more than the specified length. It can also happen because of the level of latex in the DT.

5.3 Average Weight and Thickness Correlation

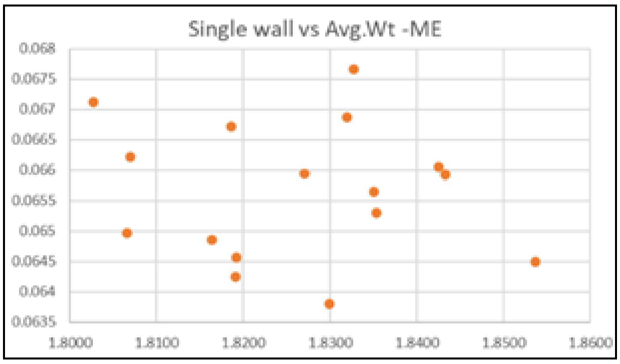

Figure 4.6: Correlation for ME

Table 4.3: Correlation ME

	Single Wall	Avg. Wt
Single Wall	1	
Avg. Wt	-0.102960954	1

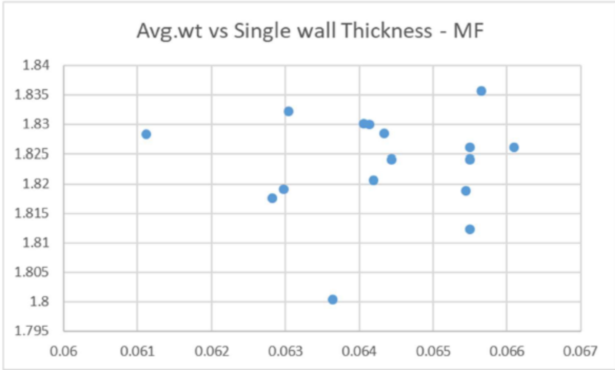

Figure 4.7: Correlation for MF

Table 4.4: Correlation MF

	Single Wall	Avg. Wt
Single Wall	1	
Avg. Wt	0.045552	1

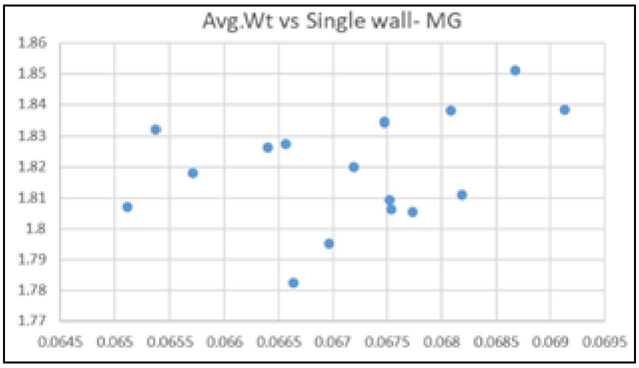

Figure 4.8: Correlation for MG

Table 4.5: Correlation Table – MG

	Single Wall	Avg. Wt
Single Wall	1	
Avg. Wt	0.326125	1

The analysis shows there is small correlation exist between Average weight and single wall thickness. From the correlation table and scatter plot it is clearly evident. For machines MF and MG it shows a small positive correlation and for ME it shows a negative correlation exist. The other factors like width, length also matters that is why this shows a negligible correlation.

5.4 Average Weight and Thickness Independency Test with Machines

Contingency table for average weight

Table 4.6: Contingency table Avg.wt

		Average Weight		
		1.80-1.82	1.82-1.85	
Machines	Machine E	7	9	16
	Machine F	5	10	15
	Machine G	6	8	14
		18	27	45

Hypothesize:
Step 1:
Ho: Average weight is independent of machines.
Ha: Average weight is dependent of machines.
Test:
Step 2:
The appropriate statistical test is

$$X^2 = \sum \frac{(f - fe)^2}{fe}$$

f= observed frequency
fe= expected frequency
Step 3:
Alpha is 0.05
Step 4:
Rows, r = 3
Columns, c=3
Therefore, degrees of freedom = (3-1) (3-1) = 4
Alpha, α= 0.05
The critical value of chi-square is, $X^2_{0.05,4}$ = 9.49 (from chi-square table) [1]
Step 5:
To determine the observed value of chi-square we should find the expected frequency,

$$e_{ij} = \frac{n_i n_J}{N}$$

Table 4.7: Contingency table 2 Avg.wt

		Average Weight		
		1.80-1.82	1.82-1.85	
Machines	Machine E	7 (6)	9 (9)	16
	Machine F	5 (6)	10 (9)	15
	Machine G	6 (6)	8 (9)	14
		18	27	45

Therefore, observed chi-square is,

$$X^2 = \sum \frac{(f - fe)^2}{fe}$$

$$x^2 = \frac{1}{6} + \frac{0}{9} + \frac{1}{6} + \frac{1}{9} + \frac{1}{6} + \frac{1}{9} = 0.722$$

Action:
Step 7:
The Calculated value of chi-square is less than critical value of chi-square so the decision is to accept null hypothesis.

Business Inference:
The Average weight is independent of machines i.e. the variations in the measurements doesn't depend on machines.

Contingency table for thickness

Table 4.8: Contingency table Thickness

		Thickness		
		0.126-0.130	0.130-0.134	
Machines	Machine E	6	9	15
	Machine F	9	6	15
	Machine G	1	9	10
		16	24	40

Hypothesize:
Step 1:
Ho: Average weight is independent of machines.
Ha: Average weight is dependent of machines.
Test:
Step 2:
The appropriate statistical test is

$$X^2 = \sum \frac{(f - fe)^2}{fe}$$

f= observed frequency
fe= expected frequency
Step 3:
Alpha is 0.05
Step 4:
Rows, r = 3
Columns, c=3
Therefore, degrees of freedom = (3-1) (3-1) = 4
Alpha, α= 0.05
The critical value of chi-square is, $X^2_{0.05,4}$ = 9.49 (from chi-square table) [1]
Step 5:
To determine the observed value of chi-square we should find the expected frequency,

$$e_{ij} = \frac{n_i n_J}{N}$$

Table 4.9: Contingency table 2 Thickness

		Thickness		
		0.126-0.130	0.130-0.134	
Machines	Machine E	6 (5.853)	9 (8.780)	15
	Machine F	9 (6.243)	6 (9.365)	15
	Machine G	1 (3.902)	9 (5.853)	10
		16	24	40

Therefore, observed chi-square is,

$$X^2 = \sum \frac{(f - fe)^2}{fe}$$

X^2 Calculated= 6.2861
X^2 Critical= 9.49 (From chi-square table)
Action:
Step 7:
The Calculated value of chi-square is less than critical value of chi-square so the decision is to accept null hypothesis.

Business Inference:
Single wall thickness is independent of machines. i.e. the variations in the measurements doesn't depend on machines.

5.5 Average Weight

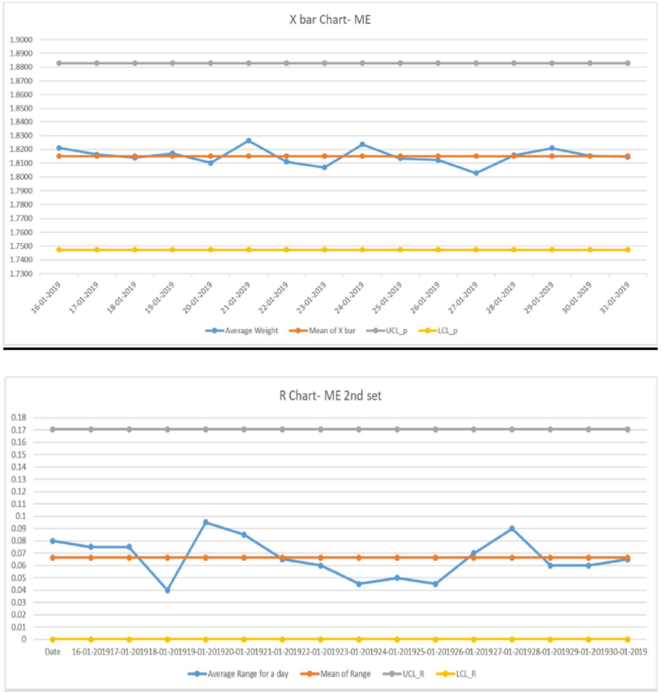

Figure 6.9: X bar chart & R chart- ME

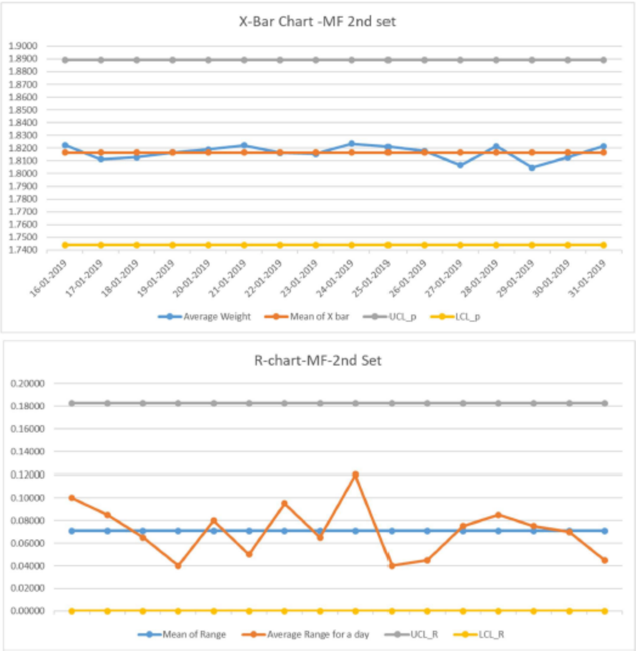

Figure 6.10: X bar & R-Chart – MF

X-bar and R-chart for the machines ME, MF, MG is plotted. From the above picture it is clearly seen that the average weight recorded online is in control limit. That means it met all the specification. But in the range chart it is seen that the range of average weight is little high. This condition is not suitable for production, maximum range noted is 0.07. The varying range can be due to Latex temperature, varying drying condition, problem in the beading unit, etc…

Figure 6.11: X bar & R-Chart – MG

6. Findings and Recommendations

Fish bone diagram in the previous chapter reveals root cause for pinhole. It can be due to Foam, Dust particles, water drops in the mould, etc… Even though the root cause is known, it is very difficult to categorize it, i.e. the defect cannot be categorized based on the cause. HPQA department will give warning to the production department if they spotted JIS out, then the operators in the plant will generally do corrective action in a generous way like bracing of latex, ensuring the latex temperature, ensure the sponge used for cleaning the mould is in proper condition, and clean the place for dust particles and chemicals that is being used for production. By doing all this action the defect will be rectified. Based on the data 70 lots (Table 5.3) are rejected for foam in the month of January, so it is clearly depicted that the main reason for pinhole is Foam and dust particles. So approximately about 60% of the pinhole can be due to this reason. Shrinkage of latex can also happen after it is being adhered into the mould. Because latex is mixture of Natural rubber (Cis-1, 4 Polyisoprene) and compounding mixtures. Rubber generally have the property of shrinkage, so this can also be a cause.

Process capability for the measurement of Length is carried out and Cpk value of 2.29 is obtained. It is analysed that process is capable and meeting the production and customer specification. This Cpk value is an indication of the ability of process to consistently provide output of required specification. But in the month of December 50% of the defect is due to length over. The root cause can be latex is not mixed properly i.e. quantity of ammonia will be high so this lead to dripping of latex after it is being adhered to mould, mould is not fixed properly after clarification, level of latex may be more than the specified quantity in the DT. Even though the Cpk value is high, this defect is mainly dependent on human errors during clarification or due to machine errors.

The study of average weight and thickness is carried out and found out that there is a correlation exist between them. If average weight is varied it should reflect in thickness or other parameter like length or width must vary because it is directly related to each other. Here correlation parameter "r" is very small that means there isonly negligible relation between average weight and thickness, and there are some other factors intervening them. So Length can be the other factor since there is no chance for width to vary. After this correlation study it is necessary to know whether there is any dependency exist between machines and product measurements. So it is carried out using Chi-square test and analysed that measurements thickness and weight are independent of machines produced. i.e. we can say that the measurements doesn't vary with the machines but it may vary with process condition or materials.

The control charts for Average weight is drawn and analysed whether the process is in control limit or not. The study shows that the process is in control limit but the range of values for average weight is more. The reasons for varying average weight or range can be high latex level maintained in the DT and beading unit rolls up the end of the product this will result in increasing the edge roll thickness and average weight. The DT level measuring device should install to maintain proper level. Viscosity of latex can be another factor, if TS is high then the latex will be thicker and causing increased weight, it is very difficult to maintain the viscosity of latex all the time. But the installation of viscosity measuring device into the DT will drastically reduce this problem.

7. Conclusion

This study discussed about the application of statistical quality control techniques in a condom manufacturing industry. The working and performance of various departments, mainly production department can be studied by this thesis. The kinds of defects on the quality of product can be identified and various quality parameters like pinhole, length, thickness and average weight are analyzed and the correlation of each parameter with the machines where calculated. From the data collected in 14 days, and the dependency test and correlation parameter it is clear that the measurements will not change with respect to the machineries, but it only depends on the process parameters and materials, also the process capability index of most defect occurring machines where calculated and the calculated value was within limit.

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