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ASSESSMENT OF TUYIL PARACETAMOL PRODUCTION PROCESS: A STATISTICAL QUALITY CONTROL TECHNIQUES

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ABSTRACT

This research deals with the application of statistical quality control techniques on process control of paracetamol production of Tuyil Pharmaceutical Company with the aim of estimating the control limits and investigate whether the production process is under statistical control. The data used in this research was collected on two measurable quality characteristics of content and weight of paracetamol from 2015-2018. The Mean, Range and EWMA-chart together with process capability analysis were employed for measuring the production process. The result obtained from the analysis on the content of paracetamol, it was observed that for X-bar and R-Chart one point from the observations is out of the control limits while for the EWMA chart all the observations are within control and capable of improving the production process. The analysis also reveals that on the weight of paracetamol, the Mean, Range and EWMA-chart together with process capability analysis are within control and capable of improving the process of production. it was concluded that for the weight of paracetamol is statistically stable and under control while that of the content is partially stable as one point from the observations fall outside the control limits and this could be due to a small shift in the production process which is caused by chance causes of variation such as temperature, room vibration and so on. It is recommended that the company needs to take proper caution so as to improve their production process in order to meet up with consumer's requirement.

Keywords: Paracetamol, Tuyil Pharmaceutical Company, statistical control

INTRODUCTION

The development of a drug product is a lengthy process involving drug discovery, laboratory testing, animal studies, clinical trials, processing control and regulatory registration. The core value around which pharmaceutical industry is basically centered is the delivery of medicinal products which fulfill five criteria namely: Safety - Identity -Strength - Purity - and Quality (SISPQ) (Welty, 2009). There has been an increase in the circulation of counterfeit drugs worldwide in the recent few decades which has been attributed to the lack of effective monitoring of the quality of products being sold in the markets (Chow,1997). Despite several effort being made by the relevant authorities in Nigeria such as National agency for food and drug administration (NAFDAC), there has been reports of drug counterfeiting in the country which is attributed to lack of resources control for effective monitoring of the quality of drug products in the pharmaceutical industries. Pharmaceutical industry is very critical and delicate industrial field that affects the health of the final consumers through the properties of manufactured products (Mostafa & Hassan, 2019). Paracetamol is one of the most widely used as analgesic and antipyretic pharmaceutical compound, it belongs to the class of drugs known as aniline analgesics which is commonly used for the relief of headache, other minor aches, pains, inflammations and a major ingredient in numerous cold and flu remedial combination drugs (Pound, 2009). Likewise, Orji *et al.*, (2020) Studied the effect of chronic exposure to paracetamol and hibiscus extract on the kidney of mice, the analysis reveals that paracetamol toxicity was confirmed to be significantly increase and creatinine. Paracetamol is generally safe and well tolerated for human use at recommended doses. This also depends on their formulation and manufacturing process variables adopted by the different manufacturing companies in the quality of some dosage forms with reference to the pharmacopoeia standard of quality. Imrana *et al.*, (2017) assessed the quality of paracetamol tablet brands sold in Katsina metropolitan dispensaries using spectrophotometry and qualitative analysis techniques. The average active content of the paracetamol tablets samples assayed was found to be 463.108mg and the results obtained from the spectrophotometric analysis were compared with the British Pharmacopeia's permissible range of active content (450-500mg), and world health organization's quality assessment guidelines on qualitative analysis results for paracetamol tablets. Also Eichie and Kudehinbu (2009) performed tests to investigate the effect of particles size distribution of paracetamol granules on some tablet mechanical properties of paracetamol tablets. Granules were formed by wet massing paracetamol powder (200g) with 20% (w/w) of maize starch mucilage as binder.

In every business organization, the target is to attain maximum profit level and minimum loss by monitoring the production process. Therefore, employees have been considered to be the backbone of most organization irrespective of its size and structure. Organizations around the globe invest on employees because of the strategic importance they play in achieving the organization goals (Ojokuku, 2012). Businessmen and government officials at all levels are forced to make plan for future quality assurance and this is achieved through statistical quality control and operational performance. For any firm to work with high-quality standards level, an efficient Quality Control (QC) system must be implemented (Spiridonică, 2011). In Nigeria today, there are few companies that handle their industrial transformation processes in the best way and this affects the quality of products that lose competitiveness compared to similar products or processes that come from foreign companies that use better technologies and apply better tools for the control of its processes (Ieren *et al.*, 2020).

The scientific method of managing quality products is through Statistical Quality Control Process, however quality of products depends on the production process, it is obvious to know that the statistical process control can be applied to industrial processes through the control of the variables in accordance to the characteristics of the products. Quality control is a process aimed at ensuring that a manufactured product adhere to a set of define quality criteria and statistical quality control is a technique which make use of statistical tools and methods in controlling quality of manufactured products (Salimu, 2012). Operational performance is the capacity of a manufacturing firm to fulfill its mission through a prescribed indicators of productivity, capacity utilization, effectiveness efficiency, waste management and regulatory compliance. Demirbag (2006) notes that quality control and improvement is one of the most important factors in every organization. Hence many competitive companies constantly enhance their quality standard by introducing total quality control departments in their organizations whose policies are aimed at satisfying customers by giving them standard quality products, excellent services and timely delivery. Mostafa and Ahmedy (2018) applied statistical process control for spotting compliance to good pharmaceutical practice. The average weight and hardness of 31 batches of anti-bacterial tablet were considered for the analysis using X bar and R charts together with process capability analysis, the result reveals the process mean and range in the variable control chart were not in state of control and require strong action to correct the noncompliance to good manufacturing and laboratory practice. Due to aforementioned challenges, the aim of the present study is to evaluate the quality control process of paracetamol tablets at Tuyil pharmaceutical company, kwara tsate-Nigeria.

MATERIAL AND METHODS

The data for this research study is on the content (mg) and weight (g) of paracetamol products of Tuyil pharmaceutical company obtained from kwara state ministry of health between year 2015 to 2018. Statistical quality control techniques such as $\bar{X}$, R and EWMA charts together with process capability Analysis were employed for the analysis with the help of SPSS and Minitab software package.

X-bar and R-Control Charts

The X-bar and R-Control Charts are one of the Statistical Process Control (SPC) methods used for monitoring and improving company's quality and productivity. The X-bar chart is used to monitor the average value of a process over time while R-Chart on the other hand is used to monitor process variation on the variable of interest. According to (Montgomery,2009)

The control limits for X- bar chart becomes:

$$UCL = \overline{\overline{X}} + A_2\overline{R} \quad (1)$$

$$CL = \overline{\overline{X}} \quad (2)$$

$$LCL = \overline{\overline{X}} - A_2\overline{R} \quad (3)$$

where $A_2 = 3/d_2\sqrt{n}$ is tabulated for various sample sizes in the appropriate SQC table.

A typical control chart is a graphical display that is used to estimate the parameters of a production process in order to determine the quality characteristic hat has been measured or computed from a sample statistic versus the sample number or time. The chart contains a center line (CL) that represents the average value of the quality characteristic together with two other horizontal lines called the Upper Control Limit (UCL) and Lower Control Limit (LCL). These control limits are chosen so that if the process is in control, nearly all of the sample points will be within the center line in a random pattern. Even if all the points are inside the control limits and they behave in a non-random manner, then this could be an indication that the process is abnormal.

For the R chart control limits is presented as:

$$UCL = \bar{R}D_4 \quad (4)$$

$$CL = \bar{R} \quad (5)$$

$$LCL = \bar{R}D_3 \quad (6)$$

The constant D_3 and D_4 are tabulated for various values of n in the appropriate SQC table.

While for the R Control chart, the range of a sample of n-item is computed and plotted. If the sample does not fall outside the control limits and there is no indication of non-randomness within the control limits, then the process is said to be under control otherwise the process is said to be out-of-control with respect to its variability.

Exponential Weighted Moving Average (EWMA) Chart

The EWMA chart is used to detect small shifts in the process mean. EWMA charts are used to monitor the mean of a process based on the samples considering at a given time that constitute a subgroup. The EWMA chart relies on the specification of a target value and a known or reliable estimate of the standard deviation. The control limit of EWMA control charts is presented as follows;

$$UCL = \mu + L\sigma\sqrt{\frac{\lambda}{(2-\lambda)}\left[1-(1-\lambda)^{2i}\right]} \quad (7)$$

$$CL = \mu \quad (8)$$

$$LCL = \mu - L\sigma\sqrt{\frac{\lambda}{(2-\lambda)}\left[1-(1-\lambda)^{2i}\right]} \quad (9)$$

Where L = 2.7 is called multiplier or width of the control limit, λ is the exponential smoothing constant and *i* is the period.

Process Capability Analysis

Process capability analysis is a measure that estimates the ability of a production process to meets specifications. It also helps to quantify, monitor and eventually reduce production process variability which is determined by using the process capability index C_p. The process capability index is defined as the ratio of the specification width over the width of the process variability (Montgomery, 2009). Mathematically, the process capability index C_p is given by:

$$C_P = \frac{USL - LSL}{6\sigma within}$$

where: USL = upper specification limit,
LSL = lower specification limit

$6\sigma within$ = standard deviation of the samples that fall within the specification limits

The output of this measurement is usually illustrated by a histogram and the value of Cp helps to better understand process performance. Generally, if

$C_p \leq 1$, it means the process variation exceeds the range of specification (the process is not capable)

$C_p = 1$, it means the process is just meets specification.

$C_p \geq 1$, it means that the process variation is within specification (the process is capable).

Data Presentation

The following tables present data collected based on content (mg) and weight (g) of paracetamol at Tuyil pharmaceutical company Ilorin between the year 2015 to 2018.

Table 1: Content (mg)of Paracetamol of Tuyil Company from 2015 to 2018

months	C_{015}	C_{016}	C_{017}	C_{018}
1.	498.84	500.00	501.03	503.49
2.	499.10	502.01	494.53	499.18
3.	500.01	504.03	509.01	506.40
4.	501.00	497.45	496.72	502.51
5.	502.06	500.10	493.81	500.08
6.	497.98	509.11	488.57	500.11
7.	489.94	439.43	500.01	501.82
8.	498.79	500.10	493.92	500.10
9.	503.01	501.34	493.92	489.66
10.	500.01	500.21	496.78	508.34
11.	510.00	512.10	498.49	503.82
12.	507.01	499.45	500.06	500.11
Total	6007.75	6019.32	5966.85	6015.62

Source: kwara state ministry of health, 2019

Table 2: Weight (g)of Paracetamol of Tuyil Company from 2015 To 2018

months	W_{015}	W_{016}	W_{017}	C_{018}
1.	0.6010	0.6144	0.6311	0.6121
2.	0.6001	0.6215	0.6310	0.6123
3.	0.6100	0.6133	0.6027	0.6211
4.	0.6110	0.6251	0.6118	0.6105
5.	0.6212	0.6143	0.6042	0.6050
6.	0.6301	0.6048	0.6126	0.6022
7.	0.6281	0.6123	0.6111	0.6031
8.	0.6290	0.6055	0.5891	0.6066
9.	0.6187	0.6026	0.6081	0.6249
10.	0.6198	0.6143	0.6215	0.6113
11.	0.6201	0.6127	0.5637	0.6094
12.	0.6196	0.6099	0.5903	0.6219
Total	7.4087	7.3507	7.3072	7.3404

Source: kwara state ministry of health, 2019

RESULTS AND DISCUSSION

The paracetamol production process of Tuyil pharmaceutical company Ilorin from 2015 to 2018 was examined using statistical quality control modelling approach. The $\bar{X}$, R and EWMA charts together with process capability Analysis on the content (mg) and weight (g) of paracetamol at Tuyil pharmaceutical company were employed for the analysis as follows;

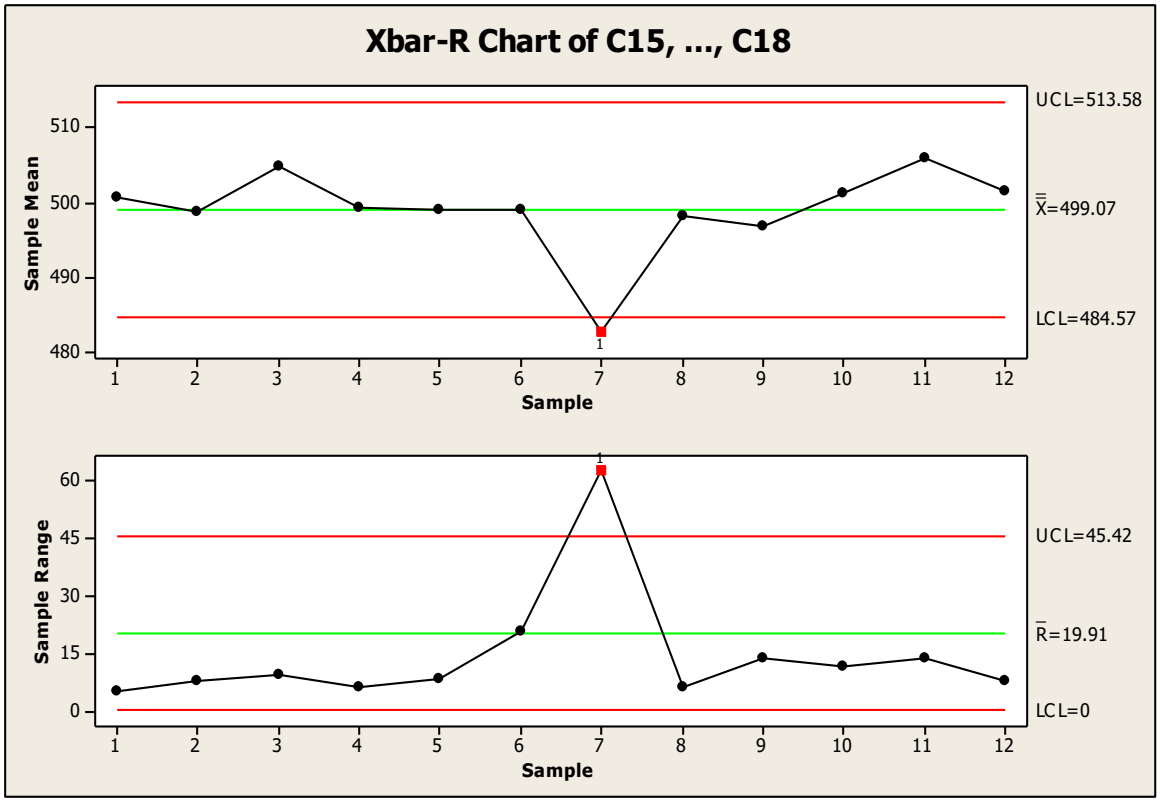

Figure 1: The Mean and Range charts for the content of Paracetamol of Tuyil Pharmaceutical Company.

It was observed that one point from the observations fall outside the control limits in Figure 1 above, it therefore indicates that a small shift occurs in the process control and this could be due to chance causes of variation such changing in temperature, backlash in machine, room vibration etc. this shows that proper caution should be taken in the production process as it tends to be out of control.

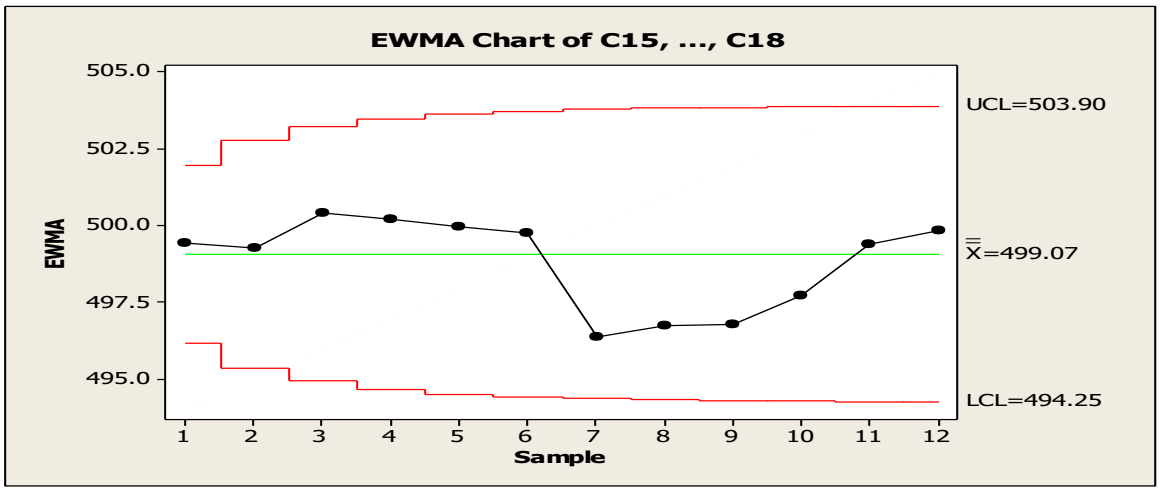

Figure 2: The Exponential Weighted Moving Average for content of paracetamol of Tuyil pharmaceutical company.

This implies that the EWMA control chart try to minimize variation in the production process on the content of paracetamol at Tuyil pharmaceutical company as the production process is statistically in control.

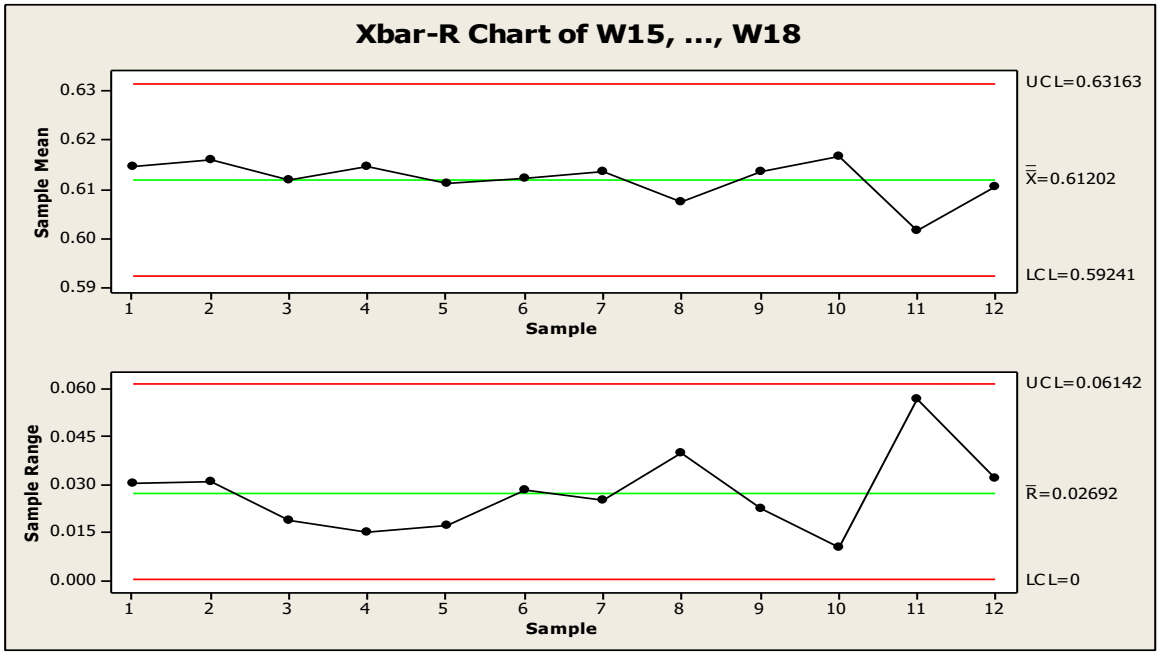

Figure 3: The Mean and Range chart for the weight of Paracetamol of Tuyil Pharmaceutical Company.

From the result in Figure 3 above, none of the observations falls outside the control limits and therefore the process is in statistical control.

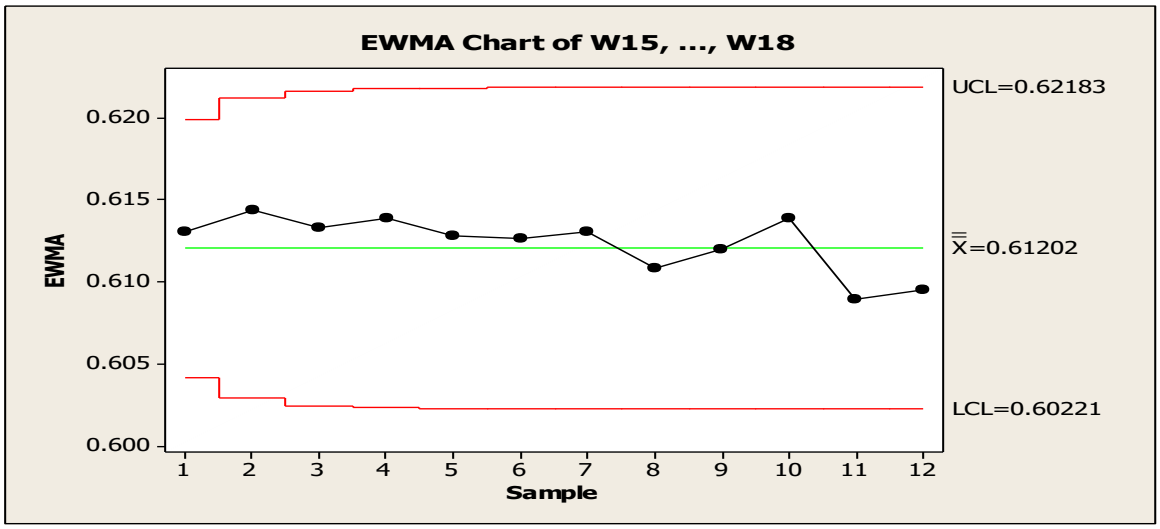

Figure 4: The Exponential Weighted Moving Average for weight of paracetamol of Tuyil pharmaceutical company.

Result from Figure 4 shows that the production process is in statistical control. This indicates that a proper attention and care was taking during the production process.

Process Capability

Process capability values C_p are used to determine if the production process is capable of producing Paracetamol with respect to the weight at the given specification limit.

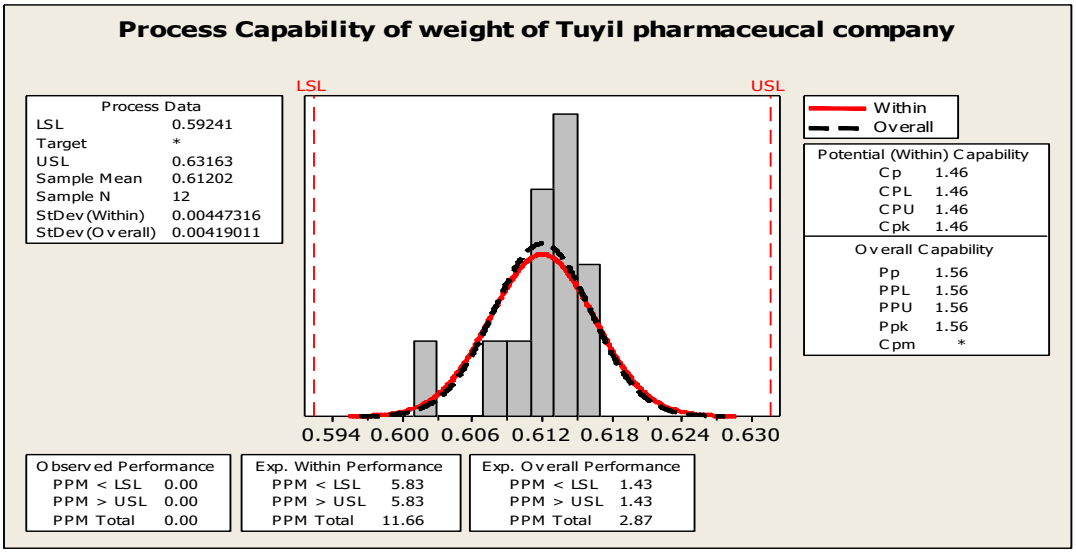

Figure 5: Process capability chart on weight of Paracetamol at Tuyil Pharmaceutical Company.

A process capability value C_p of (1.46), means that the capability index is at satisfactory stage and this implies that the production process is satisfactory and capable of producing Paracetamol with respect to weight at the given specification limits.

CONCLUSION

Based on the result obtained from the analysis, it was concluded that the weight of paracetamol at Tuyil pharmaceutical company is statistically stable and under control while that of the content is partially statistically stable as one point from the observations fall outside the control limits and this could be due to a small shift in the production process which is caused by chance causes of variation such as temperature, room vibration and so on. It is recommended that the company needs to take proper caution so as to improve on their production process in order to increases their profit margin and meet up with consumer's requirement.

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