Sumerianz Journal of Scientific Research, 2018, Vol. 1, No. 3, pp. 75-79
ISSN(e): 2617-6955, ISSN(p): 2617-765X
Website: https://www.sumerianz.com

Original Article Open Access

Microbiological Quality of Purified Water Assessment Using Two Different Trending Approaches: A Case Study

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Abstract

Statistical process control (SPC) is of prime importance for the evaluation of inspected characteristics of the monitored product or process. Microbiological quality of water that supplies healthcare facilities and plants is crucial to ensure the safety of its use in consumption and application. The current case aimed to investigate the microbiological stability and value of purified water produced from city water supply source that feeds water processing station through multiple purification stages. This study is part of monitoring project of water quality at different time periods from water treatment plant. Purified water (PW) produced from the processing of the water plant was assessed microbiologically using conventional culture technique on daily basis during working days in the facility. The results of the laboratory analysis were saved, interpreted statistically and trended using two different types of control charts. Statistical analysis and trending charts were interpreted using commercial statistical software programs. The analysis showed that microbiological results have met the acceptance criteria for bioburden limit with no fungi or waterborne pathogens were detected during the testing period of the third quarter period of the year (Q3). However, statistical interpretation demonstrated the non-Gaussian distribution of data. Moreover, the results did not follow even Poisson or negative binomial type of distribution. Interestingly, omitting aberrant results, square root and logarithmic transformations did not improve the normalization of data significantly. In such instances, Laney correction for overdispersion or underdispersion of data was considered. In parallel, Individual-Moving Range (I-MR) chart was constructed showing similarity with control limit parameters for the Laney-modified attribute Shewhart chart indicating that I-MR chart is robust with non-normal data with the advantage of greater sensitivity in detecting out-of-control alarm signals. In conclusion, both types of control charts may be considered for non-normal microbiological count data that resist the normalization process and does not follow Poisson or negative binomial distributions.
Keywords: SPC; Purified water; I-MR; Poisson; Negative binomial; Normal distribution.

1. Introduction

The microbiological quality of raw materials for manufacturing and processing of consumable products for human consumption is critical for health and safety of people exposed to these subjects such as medicinal products. Among the crucial components that are used in healthcare industries is water [1]. According to the final manufacturing goal, the water is processed and purified to the level required [2]. One of the important aspects of quality control monitoring of water is the qualitative and quantitative microbiological content [3]. This could be considered as a delicate issue as the microbial community of water is highly dynamic and the quality state can be easily changed from controlled condition to catastrophic chaos if the controlling parameters during water processing are underestimated and not appropriately implemented.

Statistical process control (SPC) is a useful tool to characterize, monitor, control and investigate the inspected process and/or properties of the manufactured product. Shewhart control charts are one of the prominent tools that help to visualize and assess the process quantitatively [4]. It helps to determine the efficiency and stability of the inspected process or characteristic. The value of the application of SPC will be described in details in the following studied case.

2. Case Study

A healthcare facility in an African country is supplied with purified water (PW) through water treatment station that processes municipal water supply to the plant. Initial assessment of PW was started from July till September i.e. third quarter of the year (Q3). The representative port for water sampling was the return of the distribution loop of the purified water (loop return). Loop return was sampled daily on regular basis except for weekends and shutdown periods. Microbiological water sampling, processing and analysis were done as described previously in other works [4, 5]. Application of the statistical software for SPC and trending chart analysis was constructed using programs like those mentioned before in previous researches [1, 6]. All microbiological results met the acceptance criterion limit of the microbial count with no pathogens were detected in water samples. Interpretation of results showed that microbial count distribution failed to follow Poisson or negative binomial distributions of the microbial community in water as reported by previous authors [7, 8]. Instead, the distribution was closest to what is called Weibull (3) as determined by the statistical program in Figure 1. On the other hand, Table1 shows the results and parameters of the distribution while Table 2 shows the statistical significance of the distribution using Kolmogorov-Smirnov (KS) test.

Table 3 demonstrates the normality test on bioburden data by Shapiro-Wilk (SW) and Anderson-Darling (AD) methods where the result did not follow Gaussian distribution. Probability–probability (P-P) plot in Figure 2 illustrates the degree of departure of the results from theoretically assumed normality. Figure 3 provided a visual evaluation by the statistical software package of the suitability of using conventional attribute control chart otherwise changing to Laney modification would be the most appropriate to correct for overdispersion or underdispersion of data [9].

Figure-1. Graphical comparison between the actual and the expected distribution

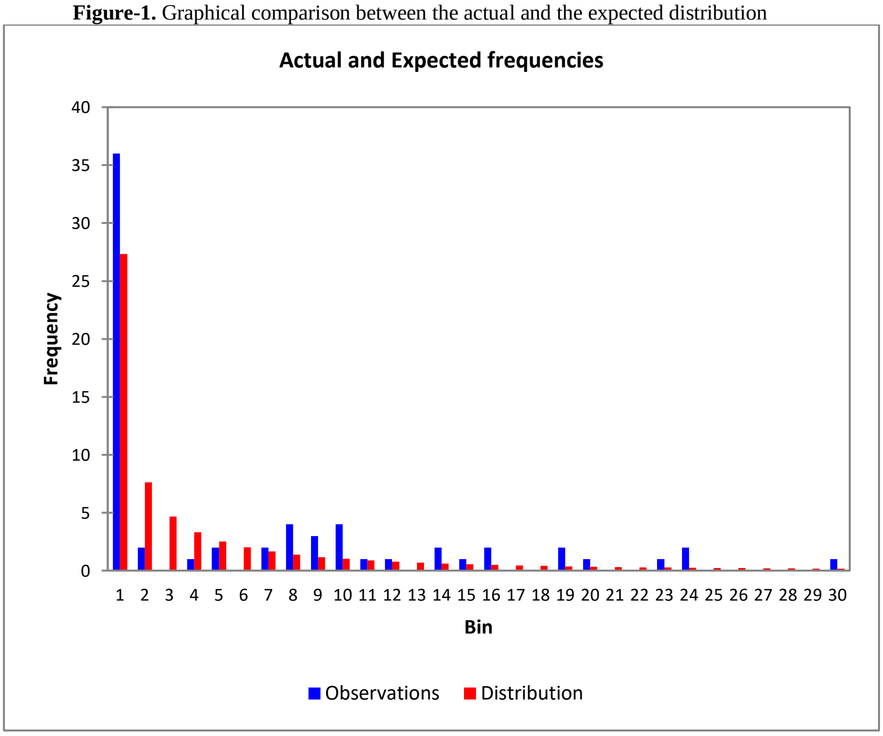


Table-1. Statistics expected on the results and computed using the estimated parameters of the Weibull (3) distribution using statistical software

Statistic	Results	Parameters
Average	29.62	35.53
S^2	1535.91	7792.16
Skewness (Pearson)	1.3	7.79
Kurtosis (Pearson)	0.77	122.25

Table-2. Kolmogorov-Smirnov test to verify null hypothesis using statistical program

D	**0.15**
p-value	0.079
α (significance level)	0.0005
Verification of distribution fitting:	
Ho: The sample comply with a Weibull (3) distribution	
Ha: The sample does not comply with a Weibull (3) distribution	

As the calculated p-value > the significance level α =0.0005, one cannot reject the null hypothesis H_o. The risk to reject the null hypothesis H_o while it is true is 7.86%.

Table-3. Normality test on bioburden data by Shapiro-Wilk (SW) and Anderson-Darling (AD) methods

Shapiro-Wilk test for loop return (PW) using statistical software		**Anderson-Darling test for loop return (PW) using statistical software**	
W	0.7688	A²	6.0916
p-value	< 0.0001	p-value	< 0.0001
α (significance level)	0.01	α (significance level)	0.01
Verification of distribution fitting:			
H_o: The variable from which the sample was extracted follows a Normal distribution.			
H_a: The variable from which the sample was extracted does not follow a Normal distribution.			

As the computed p-value < significance level α=0.01, one should reject the null hypothesis H_a, and accept the alternative hypothesis H_a. The risk to reject the null hypothesis H_o while it is true is lower than 0.01%.

Figure-2. Percent–percent plot (P-value plot) of observed results against theoretical normal distribution

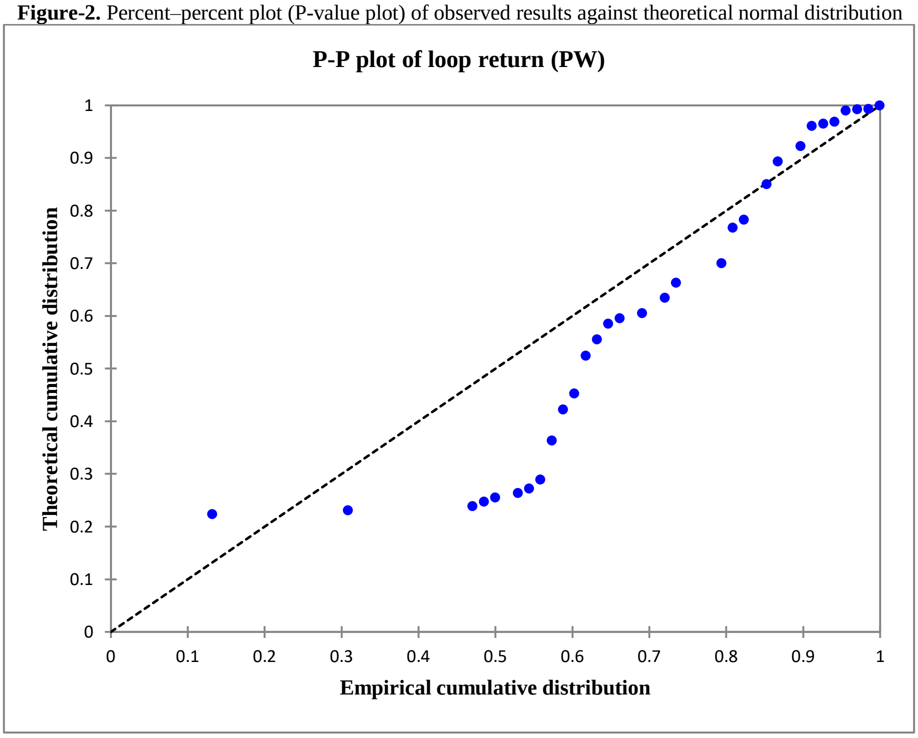
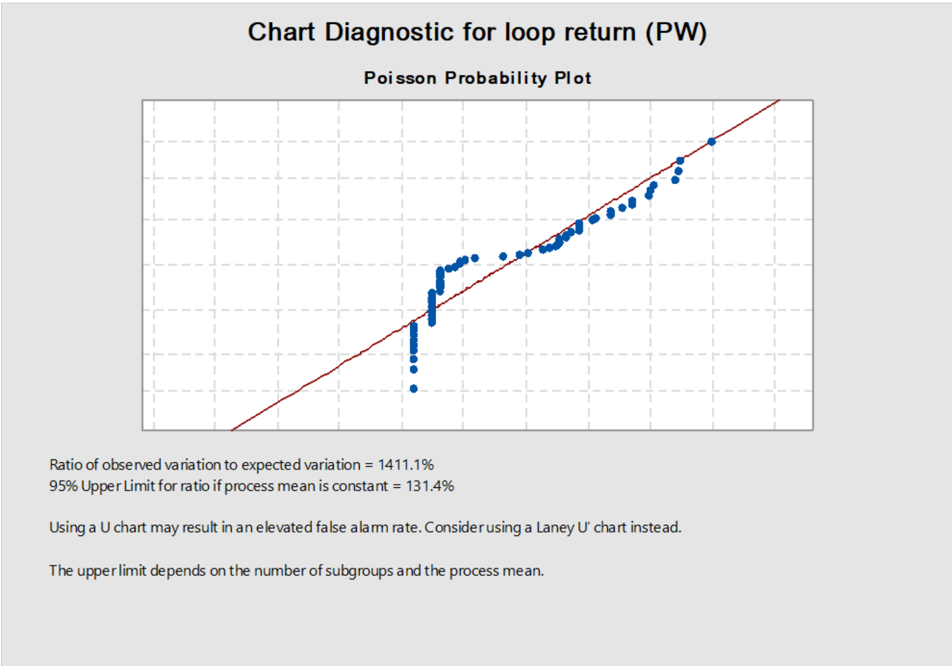


Figure-3. Evaluation test for suitability of conventional attribute chart for microbiological count data of water samples or switching to Lany corrected charts



It should be noted that the modification of results using methods such as omitting aberrant results (with justification to remove), square root and logarithmic transformations did not improve the normalization of data significantly and the outcome still did not pass normality test in contrast with previously published research article [10]. Individual-Moving Range (I-MR) chart was applied the present study to evaluate and compare it against its attribute analog as there was previous evidence of similarity of both in several aspects [11]. Laney chart was found to be similar to I chart in terms of 1 and 2 alarm types. But variable control charts possess the advantage of detecting other types of alarms (5 to 8 as indicated by Minitab). However, since microbiological count specification is one-sided criterion with an only upper limit, the alarms of the upper side of the chart are brought to the focus [12]. Accordingly, Mean and upper control limit (UCL) are only concerned here which are similar in Laney and I chart. MR chart provides an additional advantage of showing the stability of the process variation. Thus, the last month of the study showed freak variations in bioburden that require further investigation to avoid such undesirable pattern in the future which may predispose chaotic out-of-limit due to further control measures required in the process.

Figure-4. Laney attribute control chart of PW bioburden result

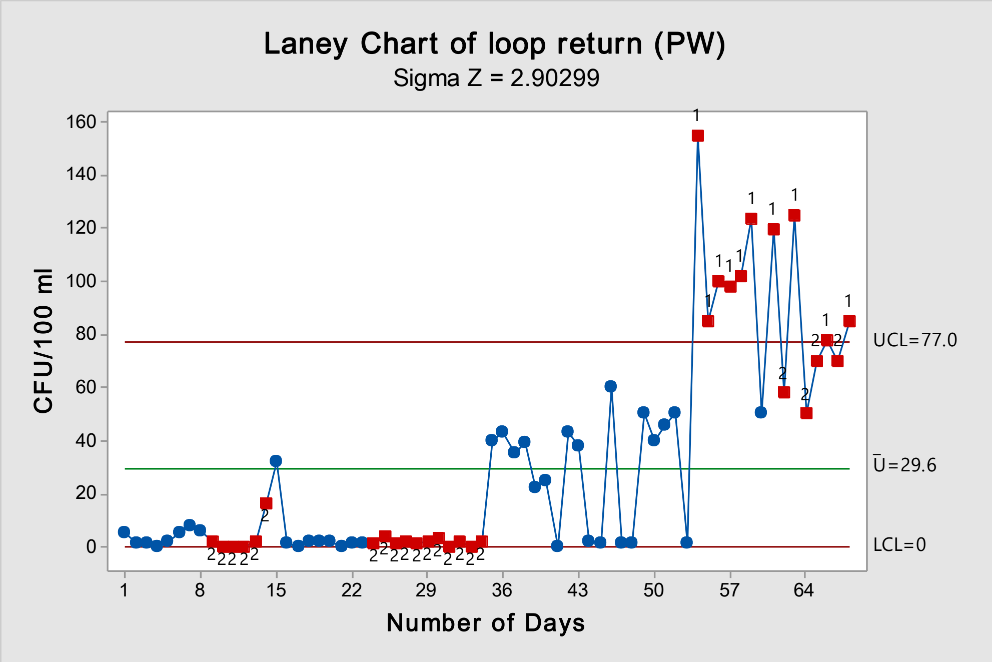
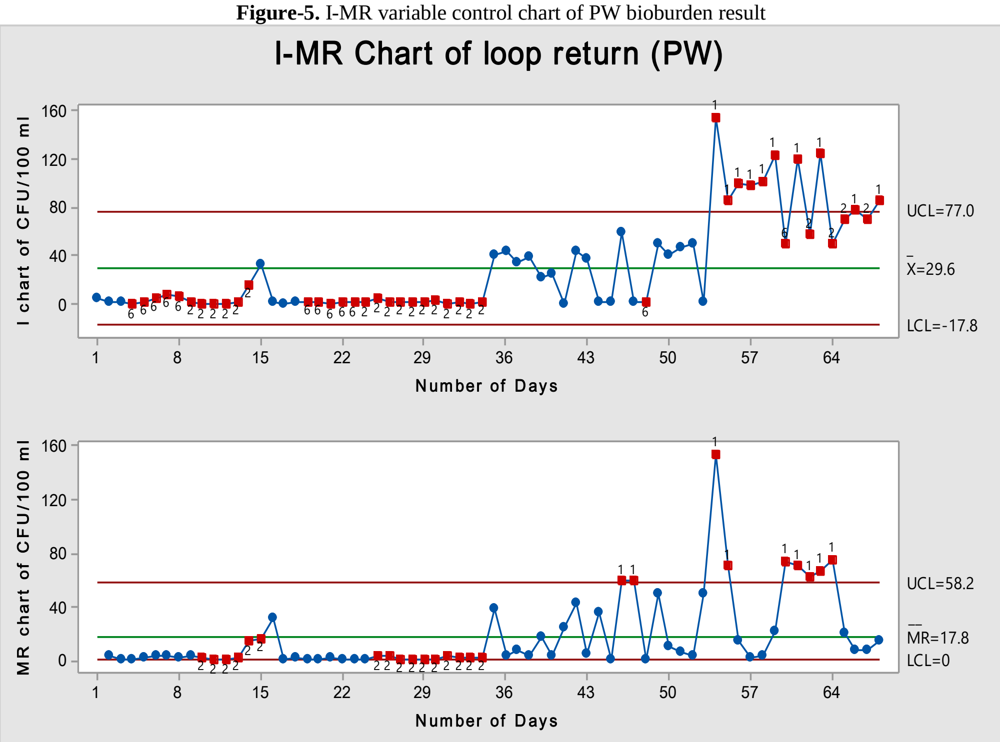


Figure-5. I-MR variable control chart of PW bioburden result



3. Conclusion

SPC provides insight into the stability and efficiency of the inspected characteristic or process. Monitoring of the process behavior may show deviations that cannot be visualized or sensed upon reliance only on the usual acceptance criteria limits of pass/fail only. Control charts showed that abnormal increase in the microbial count - although not out-of-specification (OOS) - in the about last third period of the study is due to assignable cause variation that does not pertain to the normal process fluctuations. Using statistical software in the construction of control charts demonstrated that variable control charts are more sensitive in alarm signals detection than their attribute counterparts. However, in the current case, both charts may be considered effective in the process monitoring and detection of aberrant points and I-MR chart showed to a great extent that it is effective and robust with non-normal data.

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