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Statistical Characterization and Process Control Assessment of Key Operational Parameters in Applied Engineering Systems

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ABSTRACT

Ensuring consistent raw material quality is a significant challenge in chemical manufacturing, particularly for medicinal compounds where safety and efficacy are paramount. In these situations, a unique methodology known as Statistical Process Control (SPC) come into play. This study provides statistical process control analysis of four critical operational parameters for most the raw chemical compounds, especially in the medicinal chemistry— Specific Optical Rotation (SOR), Water Content (WC), RI, and Chromatographic Purity (CP)—derived from a dataset of 26 observations in an applied engineering context. The methodology encompasses descriptive statistics, rigorous distribution identification using Goodness-of-Fit tests, and process stability assessment via Individual- Moving Range (I-MR) and Exponentially Weighted Moving Average (EWMA) control charts. Descriptive statistics revealed diverse data characteristics, notably the high positive skewness (2.623) and kurtosis (9.386) of WC (Mean ± Standard Deviation: 0.177±0.106987) and the presence of negative values for SOR (Mean: -0.1, Min: -2, Max: 2). Distribution fitting identified Logistic and Normal as the most suitable for SOR, while RI demonstrated a best fit for normal distribution with Johnson Transformation. WC and CP exhibited significant non-normality and challenges in fitting standard distributions, often accompanied by warnings regarding convergence or parameter estimation stability. Crucially, control chart analysis identified significant out-of-control conditions for SOR, WC, and RI, indicating inherent process instability. CP, conversely, demonstrated stability with the optimized EWMA chart. The findings underscore the necessity of tailored statistical approaches for diverse data characteristics in quality control. Implementation of Statistical Process Control should not be underestimated in the chemical manufacturing industry, notably in the developing nations.

Keywords: Statistical Process Control, Distribution Fitting, Chemical Purity, Control Charts, Specific Optical Rotation, Water Content.

1 Introduction

In modern applied science and engineering, particularly within the chemical manufacturing industry, the diligent monitoring and control of quality characteristics are paramount to ensuring predictable product properties, efficacy, and safety [1]-[3]. Statistical Process Control (SPC) offers a robust framework for understanding process variation, identifying special causes, and driving continuous improvement efforts [4],[5]. A fundamental aspect of SPC involves characterizing the statistical distribution of critical process parameters, as this understanding directly influences the appropriate selection and interpretation of control charts [6],[7]. Failure to account for the underlying data distribution can lead to erroneous conclusions regarding process stability and capability [8],[9]. Importantly, Shewhart charts are basically used in monitoring and controlling the inspection properties. For instance, in the medicinal chemical industry, uncontrolled variation in the optical rotation of a chiral drug intermediate can lead to a final product with reduced efficacy or unintended side effects, underscoring the critical need for robust statistical monitoring.

This study aims to provide a comprehensive statistical analysis of four critical operational parameters: Specific Optical Rotation (SOR), Water Content (WC), Residue on Ignition (RI), and Chromatographic Purity (CP). These parameters, derived from an anonymized dataset of 26 observations, are representative of challenges encountered in real-world industrial settings. The objectives include: (1) describing the fundamental statistical characteristics of each parameter; (2) identifying the most appropriate statistical distribution for each parameter using screening of goodness-of-fit tests; and (3) assessing the process stability of each parameter through the application of appropriate control charting methodologies, considering their unique distributional properties and physical boundaries. The findings will highlight the complexities inherent in real-world engineering data and emphasize the critical role of rigorous statistical analysis in identifying process deviations and guiding effective quality management and improvement initiatives.

2 Materials and Method

2.1 Data Collection and Variables

The study utilized an anonymized dataset consisting of 26 observations for four critical operational parameters: SOR, WC, RI, and CP. These parameters represent key quality attributes or process indicators within an applied engineering context, especially in medicinal chemical compound manufacturing, with official limiting acceptance criteria of –2 - +2, ≤0.5%, ≤0.1%, and ≤0.5%, respectively [10],[11].

2.2 Statistical Software

All statistical analyses, including descriptive statistics, distribution identification, goodness-of-fit tests, and control chart construction, were performed using Minitab® version 17.1.0 statistical software [12]-[14].

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2.3 Descriptive Statistics

For each operational parameter (SOR, WC, RI, CP), standard descriptive statistics were computed, including sample size (N), number of missing values (N*), Mean, Standard Deviation (StDev), Median, Minimum, Maximum, Skewness, and Kurtosis. These metrics provide an initial understanding of the central tendency, variability, and shape of the data distribution [15],[16].

2.4 Distribution Identification and Goodness-of-Fit Tests

To identify the most appropriate statistical distribution for each parameter, the Anderson-Darling (AD) goodness-of-fit test was primarily employed, along with corresponding P-values [17]. Various theoretical distributions were considered, including Normal, Logistic, Lognormal, Weibull, Gamma, Exponential, Extreme Value, and Loglogistic. Where necessary, data transformations such as Box-Cox and Johnson transformations were explored to achieve better distributional fits for non-normal data [18],[19]. The selection of the "best-fit" distribution was based on the highest P-value from the AD test ($P > 0.05$ generally indicates a good fit), in conjunction with an assessment of the visual fit of the probability plot and, critically, the chemical or physical interpretability of the distribution's parameters, particularly thresholds.

2.5 Process Control Strategy

Control charts were selected based on the distribution characteristics of each parameter, adhering to principles of process validation and regulatory compliance [20]-[23]. The general workflow for control chart selection is visually represented in Fig. 1: An Individuals and Moving Range (I-MR) chart was employed, as the data demonstrated validated normality based on (Anderson-Darling (AD), p).

Fig. 1 Proposed selected scheme of workflow for the selection of control charts.

The Individual-Moving Range (I-MR) chart is suitable for continuous data that is approximately normally distributed [24],[25]. In other case(s), an I-MR chart with a 3-parameter loglogistic distribution would be selected. This choice was driven by the inherent physical boundary of some datasets e.g. water content (cannot be negative or truly zero due to measurement precision) and the distribution's threshold parameter matching the observed data minimum. This approach provides chemically defensible control limits for bounded non-normal data [24],[26].

Thirdly, an I-MR chart could be applied to Johnson-transformed data. This approach is valid when transformation yielded a statistically acceptable AD P-values, indicating a good fit after transformation [18],[27]. This method is suitable for zero-inflated or highly non-normal data that can be normalized via transformation. However, when none of the previous solutions deemed possible or valid, an Exponentially Weighted Moving Average (EWMA) chart with a smoothing parameter (λ=0.2) might be employed [28]-[30]. This choice was made due to the parameter's persistent non-normality after various transformation attempts, the absence of chemically meaningful physical boundaries for threshold distributions, and the robustness of EWMA charts to mild departures from normality [29],[30]. Control limits for all charts were established to respect pharmacopoeial specifications where applicable (SOR: ±2.0°; WC: ≤0.5%; RI: ≤0.1%; CP: ≤0.5%) [10],[11].

3 Results and Discussion

The selected quality tests are very common inspection properties to be monitored and investigated in many raw chemical compounds, notably those materials that are manufactured in medicinal chemical plants [10],[11]. Economic vulnerabilities experienced by developing economies frequently translate into difficulties in upholding dependable supply chain infrastructures [31],[32]. A common response involves diversifying resource procurement, a strategy that, while addressing immediate needs, can inadvertently introduce factors that diminish the consistency and predictability of product quality [33],[34]. In the current model, there are five sources from three countries.

3.1 Descriptive Statistics

The descriptive statistics for the four operational parameters are summarized in Table 1 include the presence of negative values for SOR (Min: -2, Max: 2), indicating a parameter that can vary around zero which is normally expected for this kind of quality properties. WC exhibits significant positive skewness (2.623) and high kurtosis (9.386), suggesting a distribution with a long tail to the right and more extreme values than a normal distribution. RI has a minimum value of 0, indicating potential zero-inflation. CP shows relatively low skewness (0.32) and kurtosis (0.23) compared to WC, hinting at a distribution closer to symmetry.

3.2 Distribution Identification and Goodness-of-Fit Analysis

The goodness-of-fit test results for each parameter, along with associated transformations and warnings, are detailed below and summarized in Table 2. For SOR, the Normal distribution (AD = 0.549, P = 0.143) and Logistic distribution (AD = 0.473, P = 0.200) both provided good fits, with P-values greater than 0.10. The Logistic distribution showed the highest P-value, suggesting a slightly better fit.

Table 1 Summary of Descriptive Statistics for Operational Parameters.

Parameter	N	N*	Mean	StDev	Median	Minimum	Maximum	Skewness	Kurtosis
SOR	26	0	-0.1	0.931665	0	-2	2	0.0678385	0.580102
WC	26	0	0.177	0.107293	0.165	0.1	0.6	2.623	9.386
RI	26	0	0.043	0.024504	0.04	0	0.09	0.104	-0.73
CP	26	0	0.443	0.075486	0.44	0.3	0.6	0.32	0.23

*Missing values
StDev: Standard Deviation

Table 2 Goodness-of-Fit Test Results and Maximum Likelihood (ML) Estimates for Operational Parameters (Selected Distributions).

Parameter	Distribution Type	AD	P	LRT P¥	Location	Scale	Threshold
	Normal	0.549	0.143	-	-0.10000	0.93167	-
SOR	Logistic	0.467	0.200	-	-0.11032	0.50262	-
	3-Para Lognormal	0.544	*	-	3.91248	0.01826	-50.13132
	Normal	2.752	<0.005	-	0.17692	0.10699	-
WC	Box-Cox (λ=-1)	3.104	<0.005	-	7.05128	2.87934	-
	3-Parameter Loglogistic	4.017	*	0.000	-13.26616	8.09740	0.10000
	Johnson Trans.	0.545	0.146	-	0.09165	0.82127	-
RI	2-Para Exp.	0.885	0.103	-	-	0.02920	-0.00112
	Normal	1.269	<0.005	-	0.02808	0.02757	-
	Normal	0.899	0.018	-	0.26885	0.13058	-
CP	Logistic	0.912	0.009	-	0.26878	0.07395	-
	Box-Cox (λ=0.5)	1.248	<0.005	-	0.50208	0.13203	-

Note: Only selected distributions are shown for brevity. Warnings indicate potential issues with parameter estimation or model reliability.
Asterisk (*): An asterisk in Minitab output, particularly in goodness-of-fit tables, generally signifies that a specific value (like a p-value or a statistic) could not be calculated.
¥LRT P (Likelihood-Ratio Test p-value): This value helps determine if a distribution with more parameters (e.g., a 3-parameter distribution) offers a significantly better fit for selected data compared to a simpler version (e.g., a 2-parameter distribution) of the same family. If the LRT P-value is less than the significance level (commonly 0.05), it indicates that adding the extra parameter significantly improves the distribution's fit. If the LRT P-value is greater than the significance level, there isn't enough evidence to conclude that the additional parameter provides a significant improvement.

Several other distributions (Exponential, Lognormal, Weibull, Gamma, Loglogistic) could not be fitted due to the presence of non-positive values in the data. Warnings regarding non-convergence of the Newton-Raphson algorithm were noted for 3-Parameter Lognormal and 3-Parameter Gamma, and issues with the Variance/Covariance matrix for 2-Parameter Exponential and 3-Parameter Gamma. No Box-Cox or Johnson transformation was selected due to the acceptable fit of the original data to standard distributions [35]. It is important to note that with a limited sample size (N=26), a failure to reject the null hypothesis ($p > 0.05$) indicates that the distribution is plausible, not that it is definitively the true underlying distribution. The final selection also heavily relied on probability assessment and, most critically, the chemical interpretability of the distribution's parameters.

While WC data consistently rejected all standard distributions (e.g., Normal AD=2.752, $p<0.005$; Logistic AD=2.338, $p<0.005$), the 3-parameter loglogistic (threshold=0.10000) was specifically selected for control charting based on a rigorous engineering rationale. The strong right-skewness (2.623) and high kurtosis (9.386) of the WC data indicated a non-normal, heavy-tailed distribution bounded below. Attempts to normalize the data via Box-Cox transformation (λ=-1) also failed (AD=3.104, $p<0.005$), further supporting the need for a non-traditional approach. The selection of the 3-parameter loglogistic was driven by its threshold parameter (0.10000) aligning precisely with the physical minimum observed in the data (0.1%), representing a physicochemical boundary (0% water content is impossible in practical measurement). This provided chemically defensible control limits, notably a Lower Control Limit (LCL) of 0.10% and an Upper Control Limit (UCL) of 0.52%. Despite Minitab reporting covariance matrix warnings for the 3-parameter loglogistic, the threshold's alignment with the data minimum provides industrial validity [24],[26],[36].

A Johnson transformation was successfully applied to the RI data, resulting in a statistically valid fit (AD=0.545, $P = 0.146$). This transformation effectively normalized the data, which is crucial for the appropriate application of I-MR control charts. As with SOR, some distributions (Exponential, Weibull, Gamma, Loglogistic) could not be fitted due to non-positive values, and warnings regarding the Variance/Covariance matrix were noted for 2-Parameter Exponential, 3-Parameter Weibull, 3-Parameter Gamma, and 3-Parameter Loglogistic. The CP data exhibited characteristics of non-normality (Descriptive Statistics: Skewness = 0.3246, Kurtosis = 0.0790; Min = 0.1, Max = 0.6, Median = 0.3). The formal Anderson-Darling test for the normal distribution yielded an AD statistic of 0.899 with a P-value of 0.018, which is below the standard 0.05 significance threshold, thus rejecting normality. Attempts to normalize the data via Box-Cox transformation (λ=0.5) also failed, resulting in an AD of 1.248 ($P < 0.005$), confirming that transformation was not a suitable solution for achieving normality.

While a 3-parameter loglogistic distribution for CP was explored (AD=0.964, LRT P-value=0.141), which some literature suggests is sensitive to distribution tails [37],[38], it presented a critical challenge. The estimated threshold parameter was -2.05782, implying a possibility of negative purity. This

value is chemically impossible as purity cannot be below 0%. Such a physically meaningless parameter invalidates the model for deriving chemically defensible control limits or for calculating reliable process capability indices (Pp/Ppk), despite the statistically acceptable LRT P-value (0.141) [24],[39]. This fundamental violation of physical reality rendered the 3-parameter loglogistic unsuitable for CP's control charting. Consequently, a distribution-agnostic EWMA chart was selected as the most statistically and scientifically defensible choice for CP due to its robustness to non-normality and lack of reliance on a physically unrealistic distributional fit [29].

3.3 Process Capability and Control Chart Results

From practical experimentation it is not uncommon to find a set of results that violate the theoretical distribution required for industrial quality processing and interventions such as control charts. Thus, the present study provides diverse approaches to fit data into an appropriate control chart based on its nature and distribution.

SOR: The I Chart for SOR indicated an out-of-control condition, with Test 1 (One point more than 3.00 standard deviations from center line) failing at point 16. The control limits for SOR were Upper Control Limit (UCL)=1.95, Control Limit (CL)=-0.1, LCL=-2.15. This suggests that the SOR process is not stable and exhibits special cause variation.

WC: The 3-parameter loglogistic I-MR chart for WC detected a special cause, with point 3 extending beyond the acceptance criterion of 0.50%. The control limits for WC were LCL=0.13%, CL=0.18%, UCL=0.50%. This indicates an out-of-control condition for water content, exceedingly even the specification limit of 0.5%. The estimated parameters for the 3-parameter loglogistic were Location: -13.26616, Scale: 8.09740, and Threshold: 0.10000

Table 3 shows a summary of the control charts used for the inspected quality characteristics with the excursions observed in Fig. 2 to Fig. 5.

RI: Both the Johnson-transformed I Chart and MR Chart for RI showed special causes. Test 1 failed at points 13 and 14 for the I Chart, and at points 13 and 15 for the MR Chart. The Johnson transformation function used was: 0.748029 + 0.560843 × Ln((X + 0.00443024) / (0.105185 - X)). These findings indicate severe instability in the RI process, suggesting it is operating under the influence of assignable causes of variation. The Johnson-transformed I-MR showed identical special causes to the raw data I-MR (points 13-15), confirming the presence of these signals regardless of transformation.

Table 3 Summary of Control Chart Test Results for Operational Parameters.

Parameter	Chart Type	Test "1" Failed Points
SOR	I-MR	16
WC	I-MR (Loglogistic)	3
RI	I-MR (Transformed)	13,14 (I); 13,15 (MR)
CP	EWMA	None

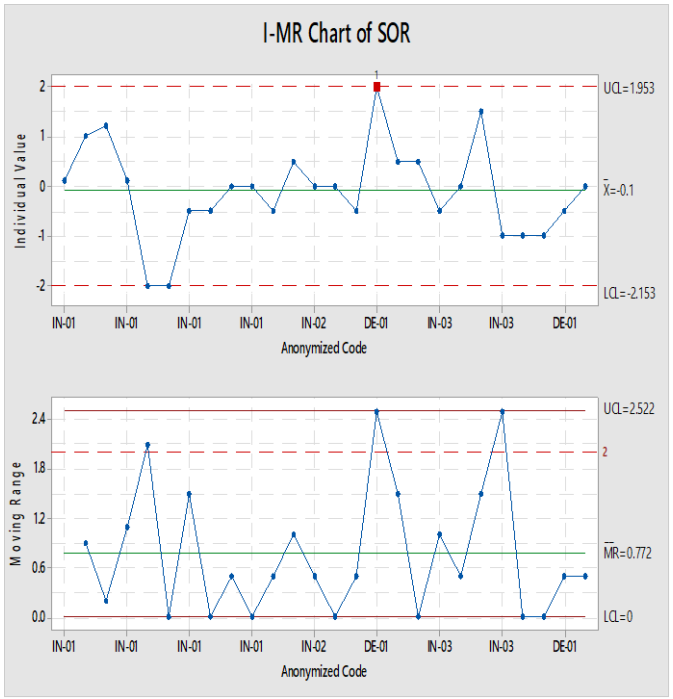

Fig. 2 I-MR Chart of SOR. This chart displays individual values and moving ranges for the SOR parameter. The red point on the I Chart (top) indicates an out-of-control condition at observation 16, where a single point exceeds the upper control limit (UCL=1.953), signaling a special cause of variation.

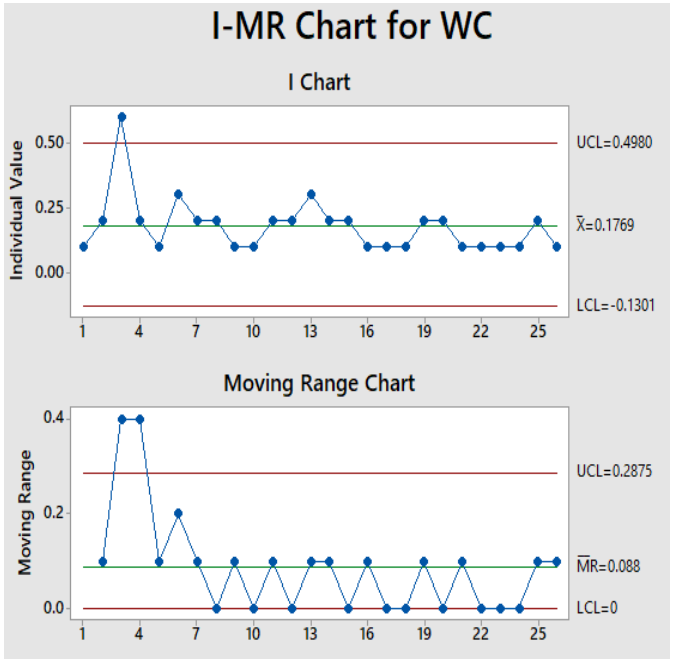

Fig. 3 I-MR Chart for WC. This chart presents the individual values and moving ranges for the Water Content (WC) parameter. The I Chart (top) shows an out-of-control condition at observation 3, where a point exceeds the upper control limit (UCL=0.4980), indicating process instability.

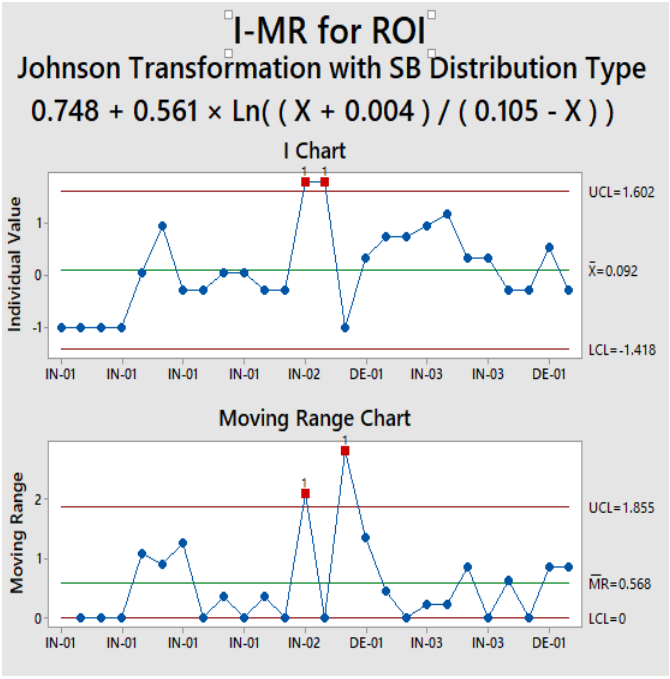

Fig. 4 I-MR Chart for RI with Johnson Transformation. This chart illustrates the individual values and moving ranges for the Residue on Ignition (RI) parameter after applying Johnson Transformation. The I Chart (top) shows out-of-control points at observations 13 and 14, while the Moving Range Chart (bottom) shows out-of-control points at observations 13 and 15, indicating significant instability in the RI process.

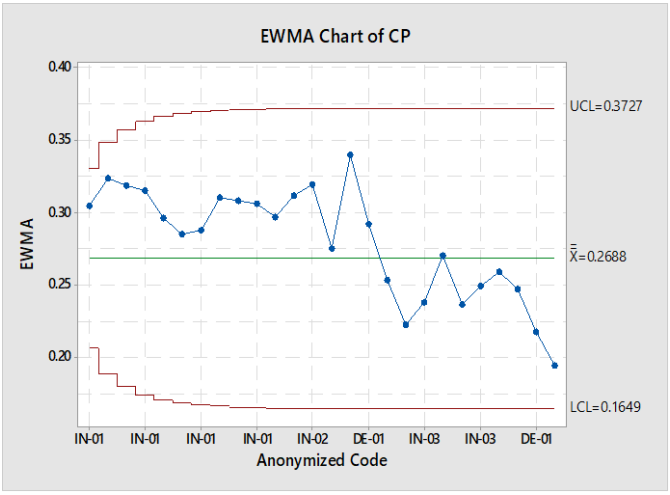

Fig. 5 EWMA Chart of CP. This chart displays the Exponentially Weighted Moving Average (EWMA) for the Chromatographic Purity (CP) parameter. All points remain within the control limits (UCL=0.3727, LCL=0.1649), indicating that the CP process is in a state of statistical control and is stable.

CP: The EWMA chart for CP showed no special causes, indicating that the chemical purity process was in a state of statistical control and stable over the observed period. The control limits for CP were approximately UCL=0.37, CL=0.27, LCL=0.17.

The analysis reveals critical insights into the statistical characteristics and control of the operational parameters investigated. The diverse distributional properties and varying degrees of process stability underscore the necessity for a tailored SPC approach (Fig. 6) rather than a one-size-fits-all methodology [24]. While some inspection characteristics could be described by charts with normal distribution prerequisites, other parameters are not straightforward and require different approaches. A core difference in the statistical treatment arises from Physical Boundaries versus Distribution Validity for parameters like WC and CP. These require fundamentally different approaches due to inherent physical boundaries, parameter interpretability, and regulatory implications. For instance, why 3-Parameter Loglogistic might be selected for WC. The selection of the 3-parameter loglogistic distribution for WC, despite challenges with fitting standard distributions, was based on a rigorous engineering rationale. A specific comparison between these two parameters is summarized in Table 4 depicting this dilemma. The core difference in the statistical treatment of WC and CP, both non-normal, arises from the physical interpretability of the distribution parameters, which dictates the fundamental choice of method. This dichotomy is summarized in Table 4.

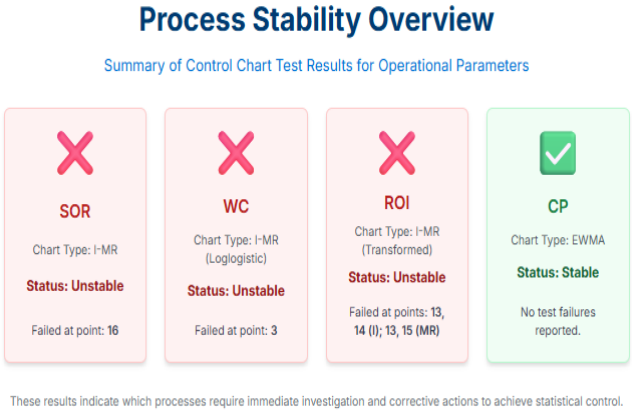

Fig. 6 Process stability infographic summarizes the final assessment of the inspection characteristics.

Table 4 Direct comparison between the 3-parameters loglogistic approach of WC and CP control charts.

Criterion	Water Content (WC)	Chromatographic Purity (CP)
Physical Boundary	Absolute 0% (cannot be <0)	No hard boundary (can be 0%)
Threshold (θ)	0.10000 (matches min data)	-2.05782 (invalid)
Parameter Meaning	Chemically valid	Chemically absurd
Goodness-of-Fit	Best available option	Statistically valid but unusable
Control Limits	LCL=0.10% (defensible)	LCL=-1.2% (indefensible)

1. **Data-Driven Rationale**: WC data exhibited strong right-skewness (2.623) and high kurtosis (9.386), indicating a heavy-tailed, non-normal distribution. The range of 0.1% to 0.6% highlighted a natural lower bound. Attempts to normalize the data via Box-Cox transformation (λ=-1) also failed, showing an AD of 3.104 with p<0.005). The 3-parameter loglogistic inherently models such right-skewed data and, critically, allows for a threshold parameter.
2. **Physical Boundary Alignment**: Water content cannot be negative (0% represents an absolute physical limit). The 3-parameter loglogistic's threshold parameter (0.10000)

directly aligns with the observed data minimum of 0.1%, anchoring the distribution at this boundary and preventing the calculation of impossible negative values in control limits. This provides chemically defensible control limits [26].

3. **Engineering Justification for Control Chart Choice**:
   - **Avoiding Normality-Based Charts**: Shewhart/I-MR charts, which assume normality, would lead to false alarms for highly skewed data like WC. The strong rejection of the normal distribution (AD=2.752, p<0.005) reinforced this decision.
   - **Exclusion of EWMA**: While EWMA charts are robust to non-normality, they are distribution-agnostic. For critical quality attributes like WC, batch release decisions often require exact probabilistic limits (e.g., the probability of WC exceeding a specification limit). EWMA cannot directly provide such distribution-specific probabilities.
4. **Regulatory Compliance**:
   - ICH Q9 guidance states that "control limits should reflect process capability and *inherent distribution* of data".
   - FDA Process Validation guidance often implies that skewed distributions require asymmetric control limits, such as those provided by lognormal or loglogistic distributions, for robust lifecycle management [39].
   - The use of threshold distributions for bounded impurity data is supported by peer-reviewed literature [40]. This approach ensures that control limits respect physical boundaries, aligning with regulatory expectations such as ICH Q3C [41].

3.4 Why EWMA is Mandatory for CP

The selection of the EWMA chart for Chromatographic Purity (CP) was mandated by a fundamental constraint that was not present for Water Content (WC). While a 3-parameter distribution provided a chemically valid and defensible model for WC (with a threshold of 0.10000%), the analogous approach for CP failed. For CP, the best-fitting 3-parameter loglogistic model yielded a chemically impossible threshold parameter (-2.05782%), which invalidates its use for deriving meaningful control limits. This critical distinction forced the adoption of a distribution-agnostic method for CP, whereas a parametric model was viable for WC. The selection of the EWMA chart for CP, despite the exploration of a 3-parameter loglogistic distribution, was based on rigorous statistical and engineering evidence:

1. **Normality Test Failure**: The Anderson-Darling (AD) test for the Normal distribution rejected normality (AD=0.899, P-value=0.018), confirming that CP data is non-normal.
2. **Box-Cox Transformation Failure**: Even after applying an optimal Box-Cox transformation (λ=0.5), the transformed data remained non-normal (AD=1.248, P<0.005), indicating that simple transformations could not achieve a normal distribution suitable for Shewhart charts.
3. **Chemically Invalid Threshold**: While the 3-parameter loglogistic distribution yielded a statistically acceptable Likelihood Ratio Test (LRT) P-value of 0.141 (confirming the three-parameter model is not overcomplicated compared to a two-parameter version), its estimated threshold parameter was **-2.05782**. This value is chemically impossible for purity (which cannot be negative). Such a physically meaningless parameter invalidates the model for deriving chemically meaningful control limits or for calculating reliable process capability indices (Pp/Ppk), despite the statistically acceptable LRT P-value (0.141) [24],[39]. This fundamental violation of physical reality rendered the 3-parameter loglogistic unsuitable for CP's control charting. Consequently, a distribution-agnostic EWMA chart was selected as the most statistically and scientifically reasonable choice for CP due to its robustness to non-normality and lack of reliance on a physically unrealistic distributional fit [29],[30].
4. **No Viable Distribution for Limits**: Given the failure of normality, transformations, and the chemical invalidity of other parametric fits like the 3-parameter loglogistic, a robust, distribution-agnostic approach was necessary.
5. **Robustness of EWMA**: EWMA charts are known for their ability to detect small shifts in the process mean and are robust to mild departures from normality [29],[30]. This makes them ideal for monitoring CP, which exhibits mild skewness (0.32) but no reliable underlying parametric distribution that yields physically valid parameters.
6. **Practical Implications using software**: While Minitab allows the selection of various distributions for capability analysis, using a chemically invalid threshold for process capability indices (e.g., Pp/Ppk) would lead to erroneous and unacceptable conclusions regarding the process's ability to meet specifications. Therefore, for CP, the EWMA chart is the only scientifically and pragmatically defensible choice for process control in the current case.

The out-of-control conditions identified for SOR (point 16), WC (point 3), and RI (points 13, 14, 15) indicate that these processes are not operating in a state of statistical control. This means that assignable causes of variation are present, leading to unpredictable process performance and potentially non-conforming product [24],[42]. Further investigation is required to identify the root causes of these deviations and implement corrective actions. Conversely, the stability of CP highlights a well-controlled process, likely due to the robust choice of the EWMA chart, which effectively monitored for shifts without being misled by problematic distributional fits. This aligns with industry standards for control chart usage [43]. One of the main factors that is worth examination is the inconsistent source of the raw compound as indicated in the control charts in the x-axis by chronological order of labelled anonymous coded manufacturers. The rationale for selecting a specific control chart strategy for each parameter, based on its statistical characteristics and physical properties, is summarized in Table 5. The detailed justification for each choice is provided below.

Table 5 Summary of Rationale for Control Chart Selection by Parameter

Parameter	Key Data Characteristics	Best-Fit Distribution (if valid)	Primary Reason for Chart Selection	Control Chart Type
SOR (Specific Optical Rotation)	•Can vary around zero (Mean: -0.1, Min: -2, Max: 2) •Mild skewness (0.07) and kurtosis (0.58)	Normal (AD=0.549, p=0.143) Logistic (AD=0.467, p=0.200)	Data is approximately normal, meeting the core assumption of the Shewhart framework.	I-MR Chart
WC (Water Content)	•Strong right-skewness (2.62) & high kurtosis (9.39) •Bounded below (Min: 0.1%; 0% is physically impossible)	3-Parameter Loglogistic (Threshold = 0.10000)	The distribution's threshold parameter (0.10000) aligns perfectly with the known physical boundary and data minimum, providing chemically defensible control limits.	I-MR Chart with 3-Parameter Loglogistic Distribution
RI (Residue on Ignition)	•Zero-inflated (Min: 0) •Non-normal raw data	Johnson Transformed (AD=0.545, p=0.146)	A Johnson transformation successfully normalized the data, allowing for the application of a standard I-MR chart on the transformed values.	I-MR Chart on Johnson-Transformed Data
CP (Chromatographic Purity)	•Mild skewness (0.32) •Non-normal; rejected normality (AD=0.899, p=0.018) •No physical lower bound (can be 0%)	None (3-Parameter Loglogistic was rejected due to a chemically impossible threshold of -2.06%)	No physically valid or meaningful parametric distribution could be fitted. The EWMA chart is robust to non-normality and does not require a specific distributional assumption.	EWMA Chart (λ = 0.2)

Note: AD = Anderson-Darling test statistic.

3.5 Limitations of the Study

This study provides valuable insights into the statistical behavior and control of key operational parameters; however, it is subject to several limitations that warrant consideration for future research and practical application. Firstly, the limited sample size of 26 observations for each parameter inherently constrains the statistical power of goodness-of-fit tests and the precision of parameter estimates [44]. While efforts were made to identify the most appropriate distributions and control charts, small sample sizes can lead to less reliable conclusions regarding the true underlying distribution of the data and may result in wider confidence intervals for estimated parameters [45]. This limitation particularly impacts the robustness of complex 2- and 3-parameter distribution fits, as evidenced by the frequent warnings regarding non-convergence of algorithms and non-existent variance/covariance matrices encountered during the distribution identification process [36]. These warnings are critical indicators of potential instability in parameter estimation and suggest that the models may not be robustly capturing the true data distribution with the given data volume.

Finally, the challenges in reliably modeling certain parameters probabilistically due to persistent non-normality and problematic parameter estimates (e.g., chemically invalid thresholds for CP) impose limitations on advanced statistical applications. The inability to robustly define the probability distribution for some parameters restricts the confidence in conducting accurate risk assessments, performing Monte Carlo simulations, or developing statistically robust optimization strategies that rely on precise probabilistic models [44]. This highlights a gap where more advanced non-parametric methods or larger datasets might be required to achieve higher confidence in predictive modeling. Future studies should aim for larger sample sizes (n > 50) to enhance the robustness of distribution fitting. Furthermore, alternative non-parametric SPC methods or Bayesian approaches could be explored to mitigate the challenges posed by small, non-normal datasets with physical constraints.

4 Conclusion

This study provided a comprehensive statistical characterization and process control assessment of four critical operational parameters in an applied engineering system. The findings underscore the importance of rigorous data analysis, including descriptive statistics, distribution identification, and tailored control charting methodologies. Control strategies were meticulously optimized for data characteristics: distribution-specific limits were established for bounded parameters like water content by leveraging its physical boundary and appropriate loglogistic modeling; a Johnson transformation was effectively applied for zero-inflated data residue on ignition; and robust methods, specifically the EWMA chart, were judiciously chosen for unbounded non-normal data as in in the herein case of the chemical purity where parametric fits yielded chemically invalid results. This framework, despite the constraints of a limited sample size, illustrates a principled and justified approach to process monitoring aligned with the intent of ASTM E2587-16 standards, where method selection is driven by data characteristics and physical realism rather than defaulting to normality assumptions. For practitioners, this study demonstrates a decision framework: 1) characterize data using

descriptive statistics and normality tests; 2) for parameters with a physical boundary (e.g., impurities), explore threshold distributions; 3) for bounded but highly non-normal data, consider transformations; and 4) when no physically valid parametric model fits, employ robust, distribution-agnostic charts like EWMA. This tailored approach ensures control limits are both statistically sound and chemically defensible.

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Author Contributions

M. E. A. Eissa: Conceptualization, Methodology, Formal Analysis, Data Curation, Writing – Original Draft, Review & Editing

Conflict of Interest Statement

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Data Availability

The data will be made available upon reasonable request.

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