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Construction of Equipment Standardized Maintenance System and Practice of Fuzzy Comprehensive Evaluation and Analytical Hierarchy Process in Pharmaceutical Plant

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Abstract

It is an inevitable trend to establish standardized maintenance system based on GMP. In order to promote the standardization construction of equipment maintenance, a pharmaceutical factory introduced a standard method to solve problems. The method consists of five standard stages for the analysis and repair of faulty equipment. In order to confirm whether to start standardized maintenance procedures, fuzzy evaluation model and hierarchical analysis process are used to transform multiple fuzzy factors into quantitative indicators, and calculate the weight of quantitative indicators, when obtaining satisfactory consistency through consistency check, scientific and reasonable decision-making can be used to verify the reliability of maintenance decisions. The practice of factory case verification proves that the model can meet the decision requirements and can be used as the basis for decision making.

Keywords

GMP Pharmaceutical Factory; Standardized Maintenance; Fuzzy Comprehensive Evaluation(FCE) Method; Analytical Hierarchy Process (AHP); Practice Verification.

1. Foreword

With the promotion of GMP (Good Manufacturing Practice of Medical Products) in the Pharmaceutical industry, the management of production-oriented pharmaceutical plants is more scientific and standardized, but in the equipment maintenance management, they are trying and exploring, hoping that according to the actual situation of the factory, Establish a set of standardized maintenance system in line with its own feature to improve maintenance efficiency and sustainable development.

In this paper, the feasibility of maintenance standardization was analyzed and discussed in order to solve the problem of "failure of suction carton from Carton-Magazine". After investigation review, it was found that the malfunction was a high-frequency problem. These issues mainly include such as carton adhesion, insufficient vacuum, and failure of the carton to form after being suctioned by the suction cup. The top three highest frequency equipment malfunctions for the cartoning-machine were: failure to pick up cartons, improper sealing of the carton lid, and leaflet folding. These problems lead leaflets to damage to blister, making them non-recyclable, resulting in waste. In order to find a reliable and effective solution, the engineering team decided to establish a set standardized Problem-Solving Based (PSB) maintenance process. In order to ensure that the PSB method had scientificity and reliability, at the same time, a decision model based on fuzzy evaluation and hierarchical analysis system was established to better ensure the correct decision, it was the first implemented in the fault-maintenance of the Cartoning-Machine to verify the feasibility and reliability of PSB.

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2. Standardized Maintenance based on PSB

The philosophy of the maintenance standardization practice project is to establish and optimize the equipment maintenance process as the starting point, analyze the structure of the Cartoning-Machine, define the procedure involved in operation, compile the performance summary table, assess the loss and impact of the malfunction parts on the production line, and evaluate the malfunction parts by resetting standard parameters, to improve the reliability and work efficiency, and reduce the labor strength for production department.

The PSB standard approach is to perform a relational matrix structured analysis of the root cause of problems, to discriminate problem which previously worked well but now fault, and recover the "variable" problem to its original state. Using PSB method to carry out practical activities can further explore and optimize the standardized maintenance process.

Standardized maintenance process was divided into five stages: preliminary preparation, Machine Function Matrix (MFM) Analysis, Machine Action Analysis (MAA), verification training, Acceptance Archiving.

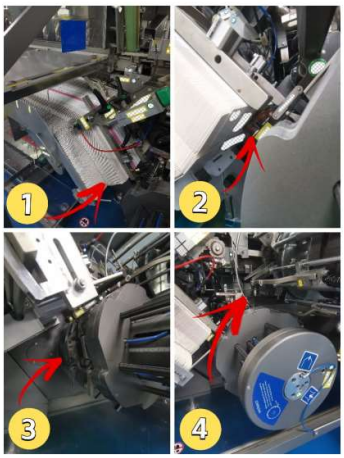
2.1 Stage 1: Preparatory Work

When receive a fault report, maintenance personnel need to consult the equipment manual to understand the working principle of the equipment. The analysis shows that for the Cartoning-Machine, the cartons download process can be divide into four actions: extracting the carton from the Carton-Magazine, extracting the carton from the sucker to the drum, opening the carton on the drum and transporting the carton to the locator.

2.2 Stage 2: Establish MFM (Machine Function Matrix)

In this stage, it's need to be focus on the following queries: What changes have taken place in the material and shape of the material on the production line, what is the purpose of the change, what mechanical actions can be broken down into during the operation of the equipment, how the setting of machine parameters affects the production of drugs, whether the equipment operates in a normal state, what are the high frequency failures in historical experience and suggestions for improvement, etc. With these important data, the MFM can be established. See Table 1 for an example. Through matrix analysis, engineers can easily understand which functional modules of mechanical equipment may have changed and which equipment data needs to be corrected.

Table 1. MFM of Cartoning-Machine

Product			Transformation		Equipment	
Product Characteristic	Product Procedure	Product Feature Diagram	Machine Function Module	Transformation Point Target	Machine setting parameter	Set-Point Standard (CL)
The cartons were picked up smoothly, then opened(blister & leaflets are able to pushed into cartons smoothly without obstruction)	(1) The position of the cartons matches the cup. (2) Dancing and erecting arm pick up the carton into the drum unit. (3) The cartons gradually open on the drum unit. (4) The cartons are fully opened on the shifter. The execution mechanisms of the above four devices are accurate error		Position of the Carton Magazine	When the carton is picked up, the slope position matches the position of the suction cup action is 29.5cm from the ground. And the top of the carton is 35.5cm from the ground.	Carton magazine height	A4 height
					Carton magazine Width	B1(width) B3(assisted width)
			Position of the Suction Cup	The raised edge of the drum is 1mm away from the folding line of the carton.	The suction cup rod length	C1:12cm C2:42cm
				The folding line of the carton is located inside the "L" of the drum.	Carton magazine height	A4:9752cm B2:9947cm
				The suction cup on the displacement sensor is located at 1/2 of the width of the carton	The mechanical position o the carton exchanged between the drum and the displacement sensor	D6:0019cm
			Vacuum	Vacuum negative pressure is -95kpa	Vacuum degree	P= -95kpa

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For a cartoning-machine MFM, the table is designed into three title: "Product", "transportation" and "equipment".

In the "Product" title, the column of "Product Characteristic" describes the engineers' purpose for troubleshooting - to ensure that no errors occur when the carton is extracted from the Carton-Magazine to the drum. The column of the "Product Procedure" contains four actions involving (1) the position of the cartons matches the cup. (2) Dancing and erecting arm pick up the carton into the drum unit. (3) The cartons gradually open on the drum unit. (4) The cartons are fully opened on the shifter. The column of the "Product Feature Diagram" contains detailed drawings of the four suction box-actions.

In the "Transformation " title, The column of "equipment function module" involved in transportation. Through process analysis and inquiry of the instruction manual of the Cartoning-Machine, it can be found the position parameters of the Carton-Magazine, the position of the suction cup on the magazine, extraction arm and the vacuum system are the three key parameters. The column of "Transformation Point Target" gives the specific requirements to achieve the function of the module - to ensure the smooth operation of the suction-carton. There are the following points:

- To ensure that the carton and the suction-cup can be extracted and matched at the optimal position, it is necessary to ensure that the raised edge of the drum is at a moderate distance from the fold line of the carton, and the position of the cup cannot be suction-ed into the fold line of the carton. Since the position and Angle of the sucker rod are fixed and locked, it is believed that the height of the Carton-Magazine determines the location of the carton.
- The position of the suction-cup on the mechanical arm and the position of the suction-cup on the rotating drum of the next action affect each other, therefore, it is also necessary to adjust the position of the suction-cup so that the carton can fall into the "L" carton-opener of the rotating drum. In addition, the position of the displacer suction-cup is also related to the position of the previous suction-cup, so the suction-cup on the displacer should be accurately fixed to 1/2 the width of the carton.
- The negative pressure of the suction-cup is provided by the vacuum generation system and almost participates in the entire process, so the vacuum degree, sensitivity, cleanliness and other factors are also crucial.

In the "Equipment" title, the column of "Machine setting parameter" is the list of parameters that maintenance team need to adjust in order to achieve the "functional module objective" to verify that the machine value is consistent with the "initial standard value". For example, by simply adjusting certain equipment parameters, it is possible to quickly adapt to the production of new products.

2.3 Stage 3: Establishing and Analyzing the MAA

The Machine Action Analysis(MAA) is more detailed analysis than MFM, as shown in Table 2. The definition of the working point of the equipment is that the position or shape of the material has changed, for the Cartoning-Machine, the machine action can be that the Carton is extracted from the Carton-Magazine to the drum, or the Carton be folded to complete an edge. In the "Draw Work Point" column, it's need to be provided a diagram showing the action from the download-carton to the suction-carton.

The "System category" provided by the maintenance team has six categories, of which the "System category" defined refers to the parts that can be separated out of each system, such as "fasteners", fasteners that can be subdivided into the width of the Carton-Magazine, and fasteners that can be restricted to the height of the Carton-Magazine. For example, "pneumatic system" can be subdivided into the vacuum control system and the vacuum conveying system at the end of the extraction mechanism; A defined "Component" column is a breakdown of the finer parts, For example, the sucker rod transmission mechanism can be further subdivided into connecting rod and swing arm; The vacuum system can even be divided into vacuum solenoid valves, vacuum dispensers and vacuum pressure gauges.

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Table 2. MAA of Cartoning-Machine

Define Work Point	Draw Work Point	System category	Component/System list	Subcomponent list	Find defect	(Target)	Fix & Old Standardize	Fix & New Standardize
The carton was picked up into the drum unit		Fasteners	Adjust the fastening bolts of the width of the carton magazine	N/A	No defect	Lock nut, no looseness, no change in value/scale	A1: 9440 ; A2: 12-20 ; A3: 6-9	
			Adjust the fastening bolts of the height of the carton storage area	N/A	No defect	Lock nut, no looseness, no change in value/scale	A4: 9752	
			Adjust the fastening bolts of the width of the carton storage area	N/A	No defect	Lock nut, no looseness, no change in value/scale	B2	
			Adjust fastening bolts of the drive device of the suction-cup rod	Linkage rod mechanism	No defect	Lock nut, no looseness	N/A	Establish new standards CIL and characterize assembly lines in the future
			Adjust the fastening bolts of the fixed position of the suction cup rod	N/A	No defect	Lock nut, no looseness, no change in value/scale	C1: 12 ; C2: 42	
		Pneumatic System	Vacuum control at the end of the extraction mechanism	Suction cup rod	The lengths of the two suction cup rods are inconsistent	The suction cup rod is consistent	N/A	Establish new change over confirmation in the future
				Vacuum tube	Broken, blocked and has foreign substance	No broken, no blockage	CIL monthly disassembly inspection and cleaning	
				Suction cup fixed on the rod	Broken/wear and tear	No broken, no falling	CIL two-week disassembly inspection and cleaning	
				Check valve	Blocked and has foreign substance	No blockage, no blow-by	CIL monthly disassembly inspection and cleaning	
			Vacuum system	Vacuum solenoid valve (valve body)	Has foreign substance	No blockage, no foreign substance	CIL monthly disassembly inspection and cleaning	
				Vacuum distributor	Wear on the inner surface	No wear, the gap between the distributor body and the friction ring, the wear loss does not exceed 0.1mm	Clean or replace, change PM cycle to one year, wear loss≤ 0.1mm	➡ Opt std
				Vacuum pressure at the end of action point	Insufficient pressure	Maintain the negative pressure to the corresponding value, -95kPa	Negative pressure = -95KPa	
		Drives & Transmission	Vacuum generator	Vacuum generator	Blocked	No blockage, maintain positive pressure to the corresponding value, 0.65MPa	PM half-year disassembly inspection and cleaning, positive pressure = 0.65MPa	
			Rotary-vane vacuum pump	Motor	Strange sound	No missing phase, no damage to motor bearings, vibration measurement reaches 0.2m/ms	PM yearly disassembly inspection and cleaning, vibration volume reaches 0.2m/ms	
				Graphite Slide	Wear and tear	No wear, the wear loss of the width does not exceed 1/4	Replace, wear loss ≤ 1/4	
				filter	Blocked	No blockage	PM quarterly cleaning every three months	
			Suction cup rod transmission mechanism	Linkage rod	No defect	Correct specifications	N/A	
				Swing arm	No defect	Operating angle 0°~30°	N/A	
		Sensors	N/A	N/A	N/A	N/A	N/A	N/A
		Lubrication	N/A	N/A	N/A	N/A	N/A	N/A
		Hydraulic System	N/A	N/A	N/A	N/A	N/A	N/A

In the MAA table, the "Sub-component list" column describes the basic requirements for a part to be in good condition, how the part appears, and so on. For example, for fasteners, the goal is to expect the nut to be locked, not loose, and the value and scale do not change; For the vacuum tube, there should be no damage and no blockage. For the "Find defect" column, when it is used for on-site operation, maintenance personnel will check and report the actual fault. The "Fix & Old Standardize" column gives historical data or standards for reference. As with MAA, maintenance personnel need to check whether the actual value is consistent with the Standard value in the "Fix & Old Standardize", if not, it need to be adjust according to the Standard Operating Procedure (SOP) requirements and update it in the "Fix & New Standardize".

2.4 Stage 4: Verification Training

The purpose of the verification training is to ensure that each engineer and operator has a clear grasp of the standardized maintenance process, improve the knowledge of the equipment structure, and gain maintenance experience.

The Verification Training should be combined with maintenance summary, focusing on MFM and MAA methods, reviewing and improving the ability to solve practical problems, completing PDCA(Plan, Do, Check, Act) closed-loop management, and providing experience accumulation for future maintenance.

The training methods include experience sharing, divergent discussion, key comments and other forms, focusing on creating a good ambient to improve the enthusiasm of personnel participation.

2.5 Stage 5: Acceptance Archiving

Acceptance archiving needs to review the whole process, sort out and categorize relevant information. The focus is on ensuring the integrity, accuracy, timeliness and accessibility of data for subsequent tracking, management and use. In this stage, it is also necessary to "look back" at all aspects of standardized maintenance, and make necessary updates or optimization according to the actual situation to better adapt to the development of the factory.

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3. Use FCE and AHP for Maintenance Decision-Making

Standardized maintenance of equipment plays an important role in production operations, however, in practical applications, maintenance personnel can not determine whether the failure and frequency of equipment has improved after the implementation of maintenance standard procedures, or whether the operating state of equipment has further deteriorated. The traditional evaluation methods are often difficult to fully take into account various influencing factors, so the introduction of fuzzy comprehensive evaluation method can be more flexible in comprehensive evaluation and decision-making.

Fuzzy-Comprehensive-Evaluation(FCE) is an evaluation method based on Fuzzy-Set-Theory, and it is a method to solve multi-factor, multi-level and fuzzy evaluation problems [1][2]. For the evaluation and judgment of equipment maintenance, there are many influencing factors, both qualitative and quantitative, and they are often fuzzy. Therefore, the introduction of Fuzzy-Set-Theory into the evaluation system can make the evaluation results more flexible and closer to the actual complex scene.

Analytic Hierarchy Process (AHP) is mostly used to combine quantitative analysis and qualitative analysis, evaluate the relative importance of each factor according to the experience of decision makers, reasonably give the weight of each factor in the decision scheme, and use the weight to find out the order of pros and cons of each scheme. For those scenarios that are difficult to judge quantitatively, AHP has unique advantages [3].

The model in this paper combines the FCE method and the AHP method, combines the qualitative and quantitative multi-factor fuzzy decision, and adopts the two-layer FCE to provide the decision basis for the implementation of SOP.

3.1 Implementation of FCE

3.1.1 Set Factor Set and Evaluation Set

1) Set the Factor Set

Factor set, also known as "evaluation indicator", is a set of factors that affect the evaluation object. Suppose $[U = \{u_1, u_2, u_3, \dots, u_m\}]$, that it contains “m” objects to be evaluated, which $\boldsymbol{u_i}$ represents the ith factor affecting the evaluation object. By consulting the cartoning-machine ID and its maintenance characteristics, the maintenance team has comprehensively evaluated and investigated various aspects, and agreed that the reliability, maintainability and economy of the cartoning-machine are three important influencing factors, and these influencing factors are subdivided into two levels:

The first layer is the criterion layer, there are 3 objects to be evaluated;

$U = \{$Reliability u_1, Maintainability u_2, Economy $u_3\}$, m=3

The second layer is the sub-criterion layer:

$u_1 = \{FEDF\ u_{11}$, SLE $u_{12}\}$; $u_2 = \{MD\ u_{21}$, ASP $u_{22}\}$; $u_3 = \{PC\ u_{31}$, MC $u_{32}\}$;

NOTE:

FEDF: Frequency of Equipment Downtime Failure

SLE: Service Life of Equipment

MD: Maintenance Difficulty

ASP: Availability of Spare Parts

PC: Production Costs

MC: Maintenance Costs

2) Evaluation Set

Evaluation set, also known as "evaluation result", is a set of rating levels set for the objects to be evaluated[4], which are generally divided into 3 to 5 levels. What is to be evaluated and decided here

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is "whether to implement standardized maintenance process", that is, the evaluation set here is the set composed of various results of possible decisions, and this layer is determined to be the plan layer:

$V = \{Do\ v_1$, Abandon $v_2\}$

Do: Implement standardized maintenance;

Abandon: Non following standardized maintenance.

3.1.2 Establishing a Layer Structure

Through the analysis in the previous section, the decision hierarchy structure is established as shown in Figure 1.

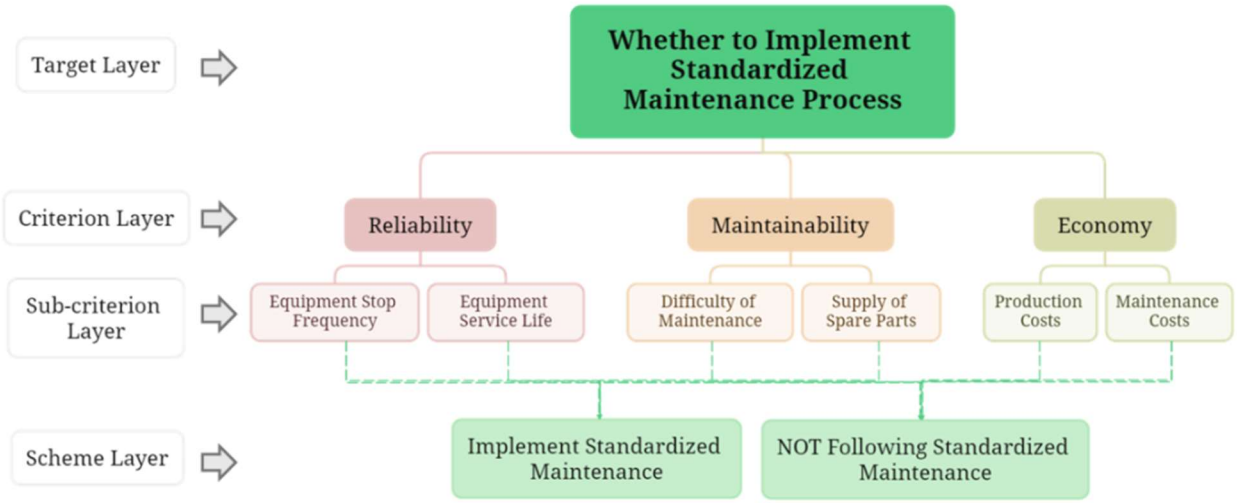

Figure 1. Hierarchical Structure of Evaluate Model

3.1.3 Constructing a Judgment Matrix Using AHP to Determine Weights

Due to the varying importance of each factor, it is necessary to assign different weights to represent the importance. Methods for determining weights include Expert Estimation, Delphi Method, and Analytical Hierarchy Process (AHP)[5]. This thesis uses the AHP's to calculate the weight vector.

Let $A = (a_1, a_2, \cdots, a_m)$ be the vector assigned to the weights,

where $\boldsymbol{a_i}$ represents the weight of the $\boldsymbol{i^{th}}$ factor, and $0 \leq a_i \leq 1$, and $\sum_{i=1}^{m} a_i = 1$.

1) Factor Comparison

From the second layer of the layer structure model, for each factor subordinate to (or influencing) the factors in the layer above, judgment matrices are constructed, extending to the lowest level. When determining the weights between factors at each level, if the results are purely qualitative, they are often not easily accepted by others. Therefore, Saaty et al. proposed the consistency matrix method, which involves:

- Comparing factors pairwise rather than comparing all factors together;
- Using a relative scale to minimize the difficulty of comparing factors with different characteristics, in order to improve accuracy.

The judgment matrix represents the relative importance of all factors at the current level with respect to a factor at the level above. The elements of the judgment matrix are given using Saaty's 1-9 scale method. The scale method of judging matrix elements $\boldsymbol{a_{ij}}$ is shown in Table 3.

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Table 3. Judging Matrix Elements a_{ij} Scale

Scale	Definition
1	The two factors are equally important
3	When comparing, one factor is slightly more important than the other
5	When comparing, one factor is significantly more important than the other
7	When comparing, one factor is strongly more important than the other
9	When comparing, one factor is extremely more important than the other
2,4,6,8	The mid-value of the two adjacent judgments mentioned above
Reciprocal	a_{ij} is the comparison between factor i and j, then $a_{ji} = 1/a_{ij}$ is the comparison between factor j and i.

2) Seeking Expert Opinions

In order to make decisions in a scientific manner, pairwise comparisons were made for the criteria of reliability, maintainability, and economy. Based on the evaluation by the maintenance team, the comparison results of the judgment matrix have been established, see Table 4.

Table 4. Comparison of Judgment Matrices

Influence Factor	Reliability(u_1)	Maintainability(u_2)	Economy(u_3)
Reliability(u_1)	1	3	4
Maintainability(u_2)	1/3	1	4/3
Economy(u_3)	1/4	3/4	1

Then the judgment matrix of the first layer (criterion layer) : $P = \begin{bmatrix} 1 & 3 & 4 \\ \frac{1}{3} & 1 & 2 \\ \frac{1}{4} & \frac{1}{2} & 1 \end{bmatrix}$,

Using Matlab to calculate the judgment matrix, it was found that the eigenvector $w = (0.62501, 0.23849, 0.1365)$.

3.1.4 Consistency Test

1) Criteria Layer Consistency Test

In order to better assess whether the characteristic vector represents a reasonable allocation of weights, it is necessary to conduct a consistency test on the judgment matrix.

Firstly, let's examine the consistency index (CI) : $CI = \frac{\lambda_{max} - n}{n-1}$

Where: λ_{max} is the maximum eigenvalue, and nis the order of the matrix.

Next, we will examine the consistency ratio (CR) : $CR = \frac{CI}{RI}$

Where: RI is the average random index for consistency.

The table of random index (RI) values obtained from 1000 simulations by Saaty, see Table 5:

Table 5. Random Consistency Index (RI)

n	1	2	3	4	5	6	7	8	9	10
RI	0	0	0.58	0.9	1.12	1.24	1.32	1.41	1.45	1.49

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When the consistency index $CI = 0$ or λ_{max}, it indicates that the judgment matrix P is completely consistent. The larger the CI, the more severe the inconsistency of the judgment matrix, at which point $\lambda_{max} > n$.

When $CR < 0.1$ *or* $\begin{cases} CI = 0 \\ \lambda_{max} = 0 \end{cases}$, it indicates that the judgment matrix $\boldsymbol{P}$ exhibits satisfactory consistency. At this point, the normalized eigenvector corresponding to the largest eigenvalue can be used as the weight vector[6].

By using Matlab to calculate, the maximum eigenvalue of the judgment matrix $\boldsymbol{P}$ is determined to be $\begin{cases} \lambda_{max} = 3.0183 \\ n = 3 \\ RI = 0.58 \end{cases}$, it is found that $CR = 0.015771 \ll 0.1$, indicating that the judgment matrix $\boldsymbol{P}$ exhibits satisfactory consistency. Therefore, its eigenvector $w = (0.62501, 0.23849, 0.1365)$, can be used as the weight for the first level, so $A = (0.62501, 0.23849, 0.1365)$.

2) Sub-Criteria Layer Consistency Test

Similarly, according to the decision layer, it is evident that the second layer (sub-criterion layer) should have 3 judgment matrices. Based on the evaluation by the maintenance team supervisor, the judgment matrices for the second layer (sub-criterion layer) are as follows:

$$P_1 = \begin{bmatrix} 1 & 5 \\ \frac{1}{5} & 1 \end{bmatrix}, P_2 = \begin{bmatrix} 1 & \frac{1}{2} \\ 2 & 1 \end{bmatrix}, P_3 = \begin{bmatrix} 1 & 6 \\ \frac{1}{6} & 1 \end{bmatrix}.$$

The weight result of the second layer (sub criterion layer) is:

$$A_1 = (0.83333, 0.16667),\ \lambda_{1max} = 2,\ CR_1 = 0;$$
$$A_2 = (0.33333, 0.66667),\ \lambda_{2max} = 2,\ CR_2 = 0;$$
$$A_3 = (0.85714, 0.14286),\ \lambda_{3max} = 2,\ CR_3 = 0.$$

It is clear that the weight allocation of the second layer has passed the consistency test.

3.1.5 Establishing Fuzzy Relation Matrix for Single Factor Fuzzy Evaluation

Table 6. Second Layer Fuzzy Relation Matrix

Factors	Implement Standardized Maintenance	NOT Following Standardized Maintenance
Equipment Stop Frequency	0.7	0.3
Equipment Service Life	0.6	0.4
Difficulty of Maintenance	0.6	0.4
Supply of Spare Parts	0.3	0.7
Production Costs	0.8	0.2
Maintenance Costs	0.7	0.3

Evaluating a single factor independently to determine the degree of membership of the evaluation object to the evaluation set $\boldsymbol{V}$ is known as one-way evaluation. After constructing the fuzzy subsets, it is necessary to quantitatively assess each evaluation object with respect to each factor $\boldsymbol{U_i}$, that is,

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from the perspective of a single factor, to determine the degree of membership of the evaluation object to each fuzzy subset. This process yields the fuzzy relation matrix between the factor set-U and the evaluation set-V (Table 6). Here, r_{ij} represents the degree of subjection of the ith factor to the jth evaluation[7].

So the fuzzy relation matrix are : $R_1 = \begin{bmatrix} 0.7 & 0.3 \\ 0.6 & 0.4 \end{bmatrix}$, $R_2 = \begin{bmatrix} 0.6 & 0.4 \\ 0.3 & 0.7 \end{bmatrix}$, $R_3 = \begin{bmatrix} 0.8 & 0.2 \\ 0.7 & 0.3 \end{bmatrix}$.

3.2 Evaluation Result

3.2.1 Comprehensive Evaluation of Sub-Criteria Layer

Using an appropriate fuzzy synthesis operator to combine the fuzzy weight vector A with the fuzzy relationship matrix R yields the fuzzy comprehensive evaluation result vector B for each evaluation object[8]. The calculation formula for the model is:

$$B = AR = (a_1, a_2, \cdots, a_m) \begin{bmatrix} r_{11} & r_{12} & \cdots & r_{1n} \\ r_{21} & r_{22} & \cdots & r_{2n} \\ \vdots & \vdots & \vdots & \vdots \\ r_{m1} & r_{m2} & \cdots & r_{mn} \end{bmatrix} = (b_1, b_2, \cdots, b_n).$$

Upon substituting the weight vector and the fuzzy relationship matrix for the second level, the following results are obtained:

$$A_1R_1 = (0.83333, 0.16667) \begin{bmatrix} 0.7 & 0.3 \\ 0.6 & 0.4 \end{bmatrix} = (0.6833, 0.3167);$$
$$A_2R_2 = (0.33333, 0.66667) \begin{bmatrix} 0.6 & 0.4 \\ 0.3 & 0.7 \end{bmatrix} = (0.4000, 0.6000);$$
$$A_3R_3 = (0.85714, 0.14286) \begin{bmatrix} 0.8 & 0.2 \\ 0.7 & 0.3 \end{bmatrix} = (0.7857, 0.2143).$$

3.2.2 Comprehensive Evaluation of Criteria Layer

The fuzzy relation matrix R at a higher level is obtained from the comprehensive evaluation output B_i at the lower level:

$$B = AR = (0.62501, 0.23849, 0.1365) \begin{bmatrix} 0.6833 & 0.3167 \\ 0.4000 & 0.6000 \\ 0.7857 & 0.2143 \end{bmatrix} = (0.62974, 0.37026).$$

3.2.3 Result Judging

According to the evaluation results B of the criterion layer, and the principle of maximum subjection degree, $0.62974 > 0.37026$, maintenance team should implement a standardized maintenance process to perform fault repair on the cartoning-machine[9].

3.3 Limitation Discussion

The FCE method transforms qualitative assessments into quantitative values, enabling a more scientific, rational, and practical quantitative assessment from fuzzy information.

From the evaluation results, it appears reasonable to implement the standardized maintenance process on cartoning-machine. This decision is closely related to the basic status of the cartoning-machine, which known for its good quality and high reliability. Factors such as the machine's stop frequency and service life are related to the equipment's condition. If a machine has been in use for a long time and experiences frequent failures, the scores for the subjection to the standardized maintenance process in the judgment of the fuzzy relation matrix will be lower, ultimately affecting the evaluation results.

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There is a certain subjectivity in judging the fuzzy relation matrix, and the calculation method is relatively complex. Even with reference to the actual situation of the equipment, production data, and financial conditions, it is still difficult to avoid deviations.

4. Conclusion

The use of FCE for decision-making is influenced by a variety of fuzzy factors. In order to make relatively scientific and rational decisions, it is necessary to quantify these fuzzy factors through certain conditional means. Currently, the establishment of a standardized maintenance system needs to be implemented as soon as possible, as standardized maintenance processes can significantly address equipment failures, leading to more stable equipment operation, improved efficiency and profitability of pharmaceutical production lines, and reduced losses.

As a pharmaceutical production industry, the construction of maintenance standardization system is a process of continuous improvement, which cannot be achieved overnight. The practical project of the cartoning-machine is only a practice to standardize the maintenance system and fuzzy evaluation decision-making, and there is still a lot of space for improvement in the subsequent business process. In addition, on the basis of improving the level of maintenance management, it is recommended that the maintenance team do strictly check all aspects of the whole life of the equipment, starting from the selection and procurement of the equipment, and participate in the whole process to achieve the control of the whole time and the whole quality. In the follow-up management, it should be also pay attention to the establishment of rules and systems, strengthen standard maintenance procedure, optimize the maintenance management scheme, and pay attention to performance assessment of maintenance standardization.

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