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Application of FMEA based on fuzzy multi-criteria decision-making for HVAC in a pharmaceutical plant

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ABSTRACT

FMEA (Failure mode and effects analysis) is one of the most popular risk assessment tools which has been used for continuous improvement of product quality. FMEA was formally introduced to cGMP (current Good Manufacturing Practice of China) for the first time in 2010. In order to achieve the requirement of quality risk management under revised 2010 cGMP certification, the in-depth study of FMEA is conducted to evaluate the risk of HVAC in a pharmaceutical plant located in south China. To solve the problems presenting in traditional risk assessment methods such as non-differential evaluation parameters, impossibility of risk evaluation with equal risk priority numbers (RPN) and low accuracy of evaluation results, our research has proposed a modified assessment method based on entropy method and the theory of fuzzy multi-criteria decision-making. On the basis the FMEA of HVAC(Heating, ventilation and air-conditioning), the occurrence, severity and detectability were chosen as the risk evaluating parameters in this method; the values of these three parameters were respectively fuzzed by using triangular fuzzy number; the weights of the parameters indicating their relative importance are obtained by using entropy method; and the fault modes were sorted by means of fuzzy multi-criteria decision-making; finally, the result of risk assessment has be achieved. The assessment results indicated that our method can not only effectively overcome the defects of traditional FMEA methods that are non-differential analysis of evaluation parameters and impossibility of risk evaluation with equal RPN, but also effectively improve the accuracy of the assessment results.

Key words: FMEA, fuzzy number, entropy weight, multi-criteria decision-making, HVAC

INTRODUCTION

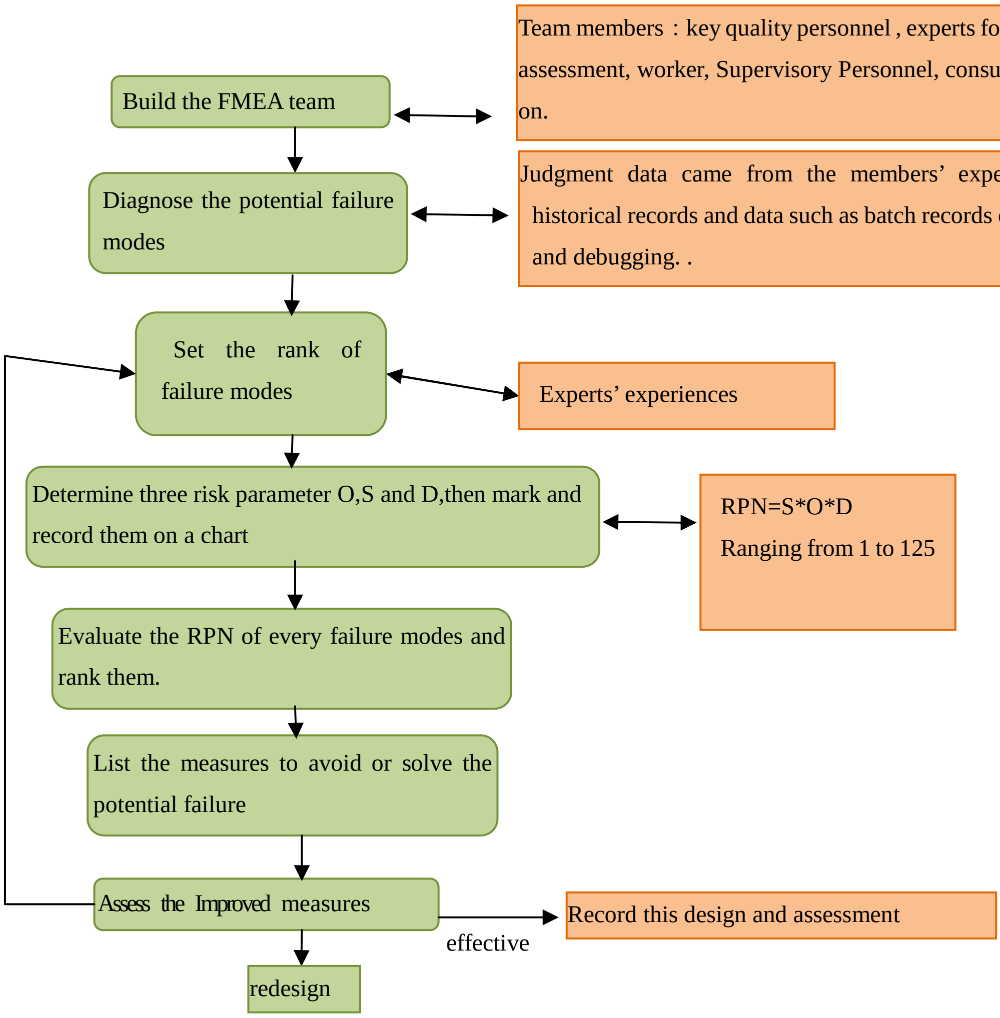
The technique of Failure Mode and Effect Analysis (FMEA) was originally developed for systematic analysis of the failures modes and its subsequent effects for the defects related products particularly in the aviation and automobile sector [1].In these years, the importance of quality system and risk management approaches have been recognized in the pharmaceutical industry and it is becoming evident that FMEA is a valuable component of an effective quality system. FDA(Food and Drug Administration) put forward to use FMEA in drug's launch in 1999 for the first time .Then in 2005, ICH (International conference on harmonization of technical requirements for registration of pharmaceuticals for human use)expert working group developed the guideline named ICH-Q9 in order to offer a systematic approach to drug quality risk management. Additionally, risk management was firstly applied in drugs production in 2010 revised cGMP in China's pharmaceutical industry. FMEA is becoming widely used in pharmaceutical projects to assure drugs quality and as a mean to improve operational performance and reduce the risk in quality system of drug. At the same time, the defects of FMEA exposed gradually.

In the following sections, the FMEA based on fuzzy multi-criteria decision making is to be applied firstly in HVAC system to better ensure the clean environment in clean workshop of pharmaceutical plant. The paper is organized in such a way that traditional FMEA is introduced in Sections 2, then literature review is given in Section 3, the definition and process of modified FMEA are introduced in Section4, and the application ofmodified FMEA in HVAC is given thoroughly in Section 5. The paper ends with remarks of the conclusion.

1. Traditional Failure Mode and Effect Analysis tool

Traditional FMEA is a listing of potential failures modes, each of which will have at least one (or many) potential effects or consequences of the failure.Decisions on how to improve the quality of productionsare based on RPN (Risk Priority Number) which is a very normal method for risk assessment. RPN is evaluated by three components,i.e. the potential causes of the failure (O), the severity of the failure(S)and the detectability of the failure(D). As the cGMP guidance for pharmaceutical plantdirectedin china, these three components are all rated on a scale of 1 to 5.Higher the risk of the failure higher is the value of the RPN.RPN canbe calculated mathematically as RPN=O×D×S. The design and process of traditional FMEA is as figure 1.

Figure 1: The process of traditional FMEA



However, with the development of FMEA in many field. Several defects of this approach of the RPN value calculation have been concerned and queried. The drawbacks of traditional FMEA are as follows:

(1) We define the occurrence, severity and detectability as a crisp number,
because of which the RPN value is also crisp.But the risk parameter itself comes from intuition or experience of experts or production operators. It is controversial to rank the three risk factors as a crisp number mainly through experiences because that it is very difficult for the experts to give precise numerical inputs for the three risk parameters as required in crisp model approach [2-4].

(2) The traditional FMEA adopts to achieve a risk ranking is debated critically.
Various combination of O, S and D may produce an identical value of RPN which in reality may have very different risk implication altogether [5-6]. For example, two different failure modes are equal in one system, that is 24 (RPN_1= 3(O)×2(D)×4(S), RPN_2= 4×2×3).

(3) The three parameters are weighted equally to every application of FMEA process. The relative importance among the risk parameters are not taken into account while calculating the RPN value[7].

In order to overcome the aforementioned weaknesses associated with the traditional RPN ranking system, we introduced the theory of fuzzy multi-criteria decision-making into FMEA.

2. Literature review

Fuzzy set theory was firstly proposed by Zadeh(1965) and fuzzy logic has applied into various fields. One of the major apply set theory has been in the area of modelling where epistemic uncertainty comes into play. Yang et al. proposed the fuzzy if–then rule for FMEA purpose [2]. Although fuzzy if–then rule solve the problems encountered in the crisp RPN to some degree, but the time and cost involved in building rule would beexcessive[8].Tay proposed a generic method to simplify the fuzzy logic-based FMEA methodology by reducing the number of rules that needs to be provided by FMEA users for the fuzzy RPN modeling process [9]. Some other researchers proposed the numerical approach by using fuzzy numbers to calculate fuzzy RPN. Chang et al.showed the application of data DEA(envelopment analysis)technique to improve theassessment accuracy of the FMEA[10]. However, they found that the model was not capable to deal with the inherent vagueness of the input values[10]. Apart from DEA, researchers were trying to use the mathematical programming approach for FMEA. Tay et al proposed a generic method to simplify the fuzzy logic-based FMEA methodology by reducing the number of rules that needs to be provided by FMEA users for the fuzzy RPN modeling process[10]. Wang et alintroducedthe use of linear programming approach using alpha level sets to calculate the RPN values [11]. Zhang et al used the concept of fuzzy preference relations using hamming distance concept to partially order the FRPN values [6]. This concept required pairwise comparison of each of the FRPN values as a result it becomes computationally inefficient with increase in number of failure modes. Researches about modifying the FMEA were applied in many fileds. Chin et al. developed a fuzzy FMEA-based product design system [12]. Abdelgawad and Fayek combined fuzzy FMEA and fuzzy AHP in the construction industry [13].Tay and Lim introduced generic method into the test handler process in a semiconductor manufacturing plant[10]. Hassan et al. used FMEA to improve the conceptual process planning.

To our knowledge, we found that no research has been conducted for Fuzzy FMEA application in drug quality management system. Furthermore, there was little research has combined the theory of fuzzy and entropy. Therefore, this study on modified FMEA might be the first one in pharmaceutical industry.

3. Method of fuzzy multi-criteria decision-making

Fuzzy multi-criteria decision-making is a fuzzy logic derived from fuzzy set theory. This method deals with reasoning that approximate rather than precise. Before application, we view the process of this fuzzy method firstly.Fuzzy multi-criteria decision-making method is based on fuzzy positive-ideal solution and fuzzy negative-ideal solution. The positive-ideal solution consists of the maximum of the fuzzy parameter values in every attribution; and the negative-ideal solution is the minimum. Then the hamming distance measure tool is used to measure the discrepancy between the decision scheme and the ideal solution. The basic frame is: first to weight the fuzzy parameter values, and then determine the fuzzy positive and negative-ideal solutions, then calculating the distance between the failure mode and ideal solution. At last, rearrange the risk priority of failure mode and make the final choice to reduce the highest-risk failure mode at first.

4.1 The relevant definitions

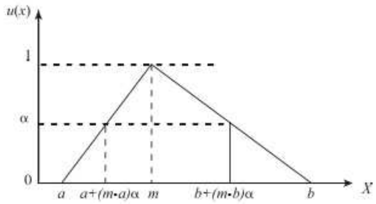
Definition1: Triangular fuzzy number

Let X be a nonempty set. A fuzzy set A in X is characterized by its membership function μ_A: $X \to [0, 1]$ and $\mu_A(x)$ is interpreted as the degree of membership of element x in fuzzy set A for each $x \in X$. Themembership function is to be exemplified as below:

$$\mu_A(x) \begin{cases} 0 & x \le a \\ (x-a)/(m-a) & a < x \le m \\ (b-x)/(b-m) & m < x \le b \\ 0 & x > b \end{cases}$$

If the membership function is determined by a,m,b, denote it as (a,m,b),and a is the membership degree $\mu_A(x)$ when x=m. [14]

Figure 2 schematic diagram of triangular fuzzy number



Definition 2: Haiming distance
Given:

$$M_p: F(X) \times F(X) \rightarrow [0,+\infty), P \in R+, \forall (A,B) \in F(X) \times F(X),$$

$$when \quad X = [a,b], \quad M_p(A,B) = \left[\int_a^b |A(x) - B(x)|^p dx \right]^{\frac{1}{p}}$$

Particularly, when P=1,then $M_1(A,B) = \int_a^b |A(x) - B(x)| \, dx$

And M1(A,B) is the Haiming distance between A and B [15].

Definition 3: Entropy weight
Entropy method is always applied to determine the weight coefficients when evaluating and ranking the different parameters in one system.

According to the basic theory of entropy method, the entropy weight of parameter is exemplified as follow [16]:

$$W_j = (1 - E_j) / \sum_{j=1}^{n} (1 - E_j)$$

Where, E_j is the entropy of parameter, can be exemplified as:

$$E_j = -k \sum_{i=1}^{m} p_{ij} \times In(p_{ij})$$

Where, m means the number of the failure modes in FMEA, and n means the number of risk parameters[17];

k=1/In(m); $p_{ij} = x_{ij} / \sum_{i=1}^{m} x_{ij}$

X_{ij} is the element of decision matrix, which means the value of jth（risk parameters）under the ith(failure modes)

4.2 The process of these method
Step1: Determine $\tilde{x}_i$ (triangular fuzzy number) as fuzzy parameter value, m means the number of failure modes, i=1,2 , … , m; and n means the number of fuzzy attributions.Normalizing the matrix of fuzzy parameter values as follow[17]:

$$\tilde{r}_i = (\frac{a_i}{c_i^{\max}}, \frac{b_i}{b_i^{\max}}, \frac{c_i}{a_i^{\max}} \wedge 1)$$

Step2: weighting thematrix of fuzzy parameter values as follow:

$$\tilde{r}_i = \tilde{W}_j \tilde{X}_{ij}$$

Step3: determining the fuzzy positive-ideal solution and fuzzy negative-ideal solution as follows:

$$\tilde{M}^+ = (\tilde{M}_1, \tilde{M}_2, \ldots, \tilde{M}_n)$$

$$\tilde{M}^- = (\tilde{m}_1, \tilde{m}_2, \ldots, \tilde{m}_n)$$

Where, $\tilde{M}_j = \max\{\tilde{r}_{1j}, \tilde{r}_{2j}, \ldots, \tilde{r}_{mj}\}$, ($j$=1,2…n) and $\tilde{m}_j = \min\{\tilde{r}_{1j}, \tilde{r}_{2j}, \ldots, \tilde{r}_{mj}\}$ represent the fuzzy maximum and minimum of the weighted fuzzy parameter values.

Step4: Calculating the Haiming distance between $\tilde{r}_{ijL}$ and $\tilde{M}_{jL}$; $\tilde{r}_{ijR}$ and $\tilde{M}_{jR}$; $\tilde{r}_{ijL}$ and $\tilde{m}_{jL}$; and $\tilde{r}_{ijR}$ and $\tilde{m}_{jR}$ as following two formulas:

$$d(\tilde{r}_{ij}, \tilde{M}_i) = \int_{S(\tilde{r}_{ij} \cup \tilde{M}_i)} \left|\mu_{\tilde{r}_{ij}}(x) - \mu_{\tilde{M}_i}(x)\right| dx$$

$$d(\tilde{r}_{ij}, \tilde{m}_i) = \int_{S(\tilde{r}_{ij} \cup \tilde{m}_i)} \left|\mu_{\tilde{r}_{ij}}(x) - \mu_{\tilde{m}_i}(x)\right| dx$$

Step5: Calculating the discrepancy D_i^+ and D_i^- between the original assessment scheme A_i and $\tilde{M}^-$ and $\tilde{M}^+$ as following formulas:

$$D_i^+ = \sqrt{\sum_{j=1}^{n} [d(\tilde{r}_{ijL}, \tilde{M}_{jL}) + d(\tilde{r}_{ijR}, \tilde{M}_{jR})]^2}$$

$$D_i^- = \sqrt{\sum_{j=1}^{n} [d(\tilde{r}_{ijL}, \tilde{m}_{jL}) + d(\tilde{r}_{ijR}, \tilde{m}_{jR})]^2}$$

Step6: Calculating the relative similarity degree between original assessment scheme and fuzzy ideal solution by the following formula:

$$D_i = \frac{D^-}{D^+ + D^-}\text{; i=1,2, , …, m}$$

Step7: Finally rank the new risk priority according to the value of $D_i$from step6.

4. Application of FMEA based on fuzzy multi-criteria decision-making

Heating, ventilation and air-conditioning (HVAC) play an important role in ensuring the manufacture of quality pharmaceutical products. A well designed HVAC system will also provide comfortable conditions for operators.Temperature, relative humidity and ventilation should be appropriate and should not adversely affect the quality of pharmaceutical products during their manufacture and storage, or the accurate functioning of equipment. The HVAC system is the most critical aspect to prevent contamination and cross-contamination particularly in sterile pharmaceutical plant. As anessential part of quality system, HVAC play an important role in three primary aspects: product protection, personnel protection and environmental protection.During the daily operation phase of HVAC for a sterile pharmaceutical plant located in China a functional and proposed FMEA was applied in.The purpose of the study was to improve the air purification of HAVC in cGMP clean workshop and reduce contamination and cross-contamination caused by possible failure modes of HVAC. We examined the process itself and determined the measures which would reduce the procurement times and costs and eliminate the burden of unnecessary work.

5.1 Analyze the failure modes by traditional FMEA and find the original RPN numbers

Referring to historic records of HVAC, expert advice and the guidelines of risk control implementation, we divided the three parameters (severity,occurrence and detectability) into 5 grades as represented in Table3:

Table 3: Grades of three parameters

parameter	Ⅰ	Ⅱ	Ⅲ	Ⅳ	Ⅴ
Severity	Almost none	Low	Medium	High	Very high
detectability	Very high	High	Medium	Low	Almost none
occurrence	Almost none	Low	Medium	High	Very high

We defined this grading as follows:

Table 4: The definition of Severity

Degree	**Definition**
Almost none	Appear defects, almost no influence to the whole, no need to cut off the power and repair
Low	Apper defects, slightly influence to the whole, remain to be seen
Medium	Apparent defects, need to strengthen the monitoring and arrange maintenance
High	HVAC is significantly impaired, need to halt production and inspect in one day, monitor every now and then
Very high	HVAC is badly damaged , have stagnation of production, have a long time to inspect and repair

Table 5: The definition of detectability

Degree	Definition
Very high	Can be judged intuitively by appearance、sound、temperature, humidity
High	Can be judged by the test of special detecting instrument
Medium	Can be judged by the analysis of the detecting results and group discussion.
Low	Halt production in one day and invite the engineering department and experts to inspect
Almost none	Inspection must be carried out in equipment supplier

Table 6: The definition of occurrence

Degree	Definition
Almost none	Once every four to five years
Low	Once every two to three years
Medium	Once every year or two
High	Once every 6-12 months
Very high	Less than once a month

We utilized traditional FMEA assessment tool to identify the potential failure modes of the HVAC in a sterile pharmaceutical plant. By means of brainstorming, expert discussion and reference to historical records, we found out 24 failure modes. In order to better prove the effect of this new fuzzy method, we excluded human risk and insignificant risk. Then we focused on 5 risk factors which are not only difficult to be evaluated but have a direct impact on production. The original results of assessment as shown in Table 6.

Table 7: The failure mode and effect analysis of original risk assessment of HVAC

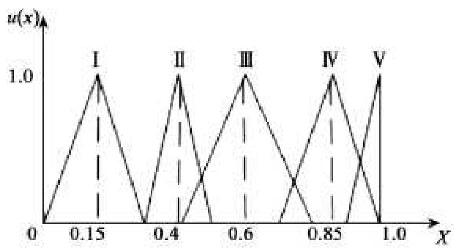
Failure mode	Effect	Failure cause	S	D	O	RPN	Degree
HEPA filter	Level of clean area would be destroyed and drugs would be contaminated	Leak & damaged	5	2	3	30	Very high
Fresh air	The service life of primary efficiency filter would be shortened	The quality of fresh air is low	3	1	2	6	Low
Heating and humidifying zone	Temperature and humidity would be in excess of limit; the useful life of high-performance filters would be shortened	Unstable steam pressure;	3	1	4	12	High
Air duct	Clean area would be contaminated ;dust is not easy to clean	Leak &/ bending	4	1	3	12	high
Air blower	Bearing would be weared; wind leaf deformation would appear	Too much burden	2	1	4	8	Medium

Where, we found that among these five failure modes, air duct and heating and humidifying zone (short for HHZ) had the same value of RPN which was 12. However, the distribution of these three parameters was different (RPN of air duct = 4(S) ×1(D) ×3(O); RPN of HHZ= 3(S) ×1(D) ×4(O)). Then we would figure out the possible difference of this two parts.

5.2 Fuzzifying the risk parameter

According to the method of triangular fuzzy number (see to definition1) in combination with the characteristics of three parameters, we can determine the membership function of triangular fuzzy number used in fuzzifying the risk three parameter(severity,detectability and occurrence) as below:

Table 8: Class evaluation



As shown in Table 8 the membership function of degrees are: Ⅰ—（0,0.15,0.3）；Ⅱ—（0.3,0.4,0.5）；Ⅲ—（0.4,0.6,0.8）;Ⅳ—（0.7,0.85,1.0）； Ⅴ—（0.9,1.0,1.0）

From the Table 6, we got three parameters(O,D,and S)and five failure modes (fresh air, HEPA filter, air duct , heating and humidifying zone and air blower), we let these be a decision-making matrix D:

$$D = \begin{bmatrix} 5 & 2 & 3 \\ 3 & 1 & 2 \\ 3 & 1 & 4 \\ 4 & 1 & 3 \\ 2 & 1 & 4 \end{bmatrix}$$

Where we got the "m" and "n". According to above definition3, we calculated the results of entropy (E_j) and weight (W_j) as follows:

Table 9: calculation results of entropy and weight

	S	**D**	**O**
$\mathbf{E_j}$	0.9720	0.9697	0.9822
$\mathbf{w_j}$	0.368	0.398	0.234

Represent the elements of decision-making matrix D, and normalize them as step1:

$$D = \begin{bmatrix} (0.9,1,1) & (0.6,1,1) & (0.4,0.71,1) \\ (0.4,0.6,0.89) & (0,0.38,1) & (0.3,0.47,0.71) \\ (0.4,0.6,0.89) & (0,0.38,1) & (0.7,1,1) \\ (0.7,0.85,1) & (0,0.38,1) & (0.4,0.71,1) \\ (0.3,0.4,0.56) & (0,0.38,1) & (0.7,1,1) \end{bmatrix}$$

Then we weighted thematrix of fuzzy parameter values as step2:

$$D = \begin{bmatrix} (0.331,0.368,0.368) & (0.239,0,398,0.398) & (0.094,0.166,0.234) \\ (0.147,0.221,0.328) & (0,0.151,0.398) & (0.07,0.11,0.166) \\ (0.147,0.221,0.328) & (0,0.151,0.398) & (0.164,0.234,0.234) \\ (0.258,0.313,0.368) & (0,0.151,0.398) & (0.094,0.166,0.234) \\ (0.110,0.147,0.206) & (0,0.151,0.398) & (0.164,0.234,0.234) \end{bmatrix}$$

Determine the fuzzy positive-ideal solution and fuzzy negative-ideal solution as follows:

$$\widetilde{M}^{+} = [(0.331, 0.368, 0.368) \quad (0.239, 0, 398, 0.398) \quad (0.164, 0.234, 0.234)]$$

$$\widetilde{M}^{-} = [(0.110, 0.147, 0.206) \quad (0,0.151,0.398) \quad (0.07,0.11,0.166)]$$

Then we calculated the Haiming distance of original assessment scheme and fuzzy ideal solution as step4:

Table 10: Calculation results of Hamming distance

	I=1			I=2			I=3			I=4			I=5		
	J=1	J=2	J=3	J=1	J=2	J=3	J=1	J=2	J=3	J=1	J=2	J=3	J=1	J=2	J=3
$d(\tilde{r}_{ijL}, \widetilde{M}_{jL})$	0	0	0.18	0.23	0.17	0.22	0.23	0.17	0	0.09	0.17	0.18	0.31	0.17	0
$d(\tilde{r}_{ijR}, \widetilde{M}_{jR})$	0	0	0.13	0.14	0.12	0.18	0.14	0.12	0	0.04	0.12	0.13	0.22	0.12	0
$d(\tilde{r}_{ijL}, \tilde{m}_{jL})$	0.25	0.14	0.03	0.07	0	0	0.07	0	0.29	0.14	0	0.03	0	0	0.29
$d(\tilde{r}_{ijR}, \tilde{m}_{jR})$	0.17	0.09	0.02	0.03	0	0	0.03	0	0.24	0.12	0	0.02	0	0	0.24

After that, we calculated the relative closeness between the original assessment scheme A_i and fuzzy ideal solution as step6:

Table 11: The result of relative closeness

	I=1	I=2	I=3	I=4	I=5
D_i^+	0.31	0.617	0.470	0.444	0.631
D_i^-	0.481	0.1	0.539	0.265	0.53
D_i	0.608	0.139	0.534	0.374	0.457

As the original assessment evaluated by traditional FMEA, two failure modes(air duct and HHZ) had the same value of RPN which was 12. It is expressed as $D_1 > D_3 = D_4 > D_5 > D_2$ thus these two modes should be in one degree of risk.However, through the application of fuzzy decision-making and entropy, we reassessed the degree of risk of D_3 and D_4, and the new rank of five failure modes of HVAC was figured out as D_1>D_3>D_5>D_4>D_2.

CONCLUSION

In this article, detailed operating method of the fuzzy multi-criteria decision making was given to the application of HVAC. We reassessed the risk rank of five failure modes of HVAC which was originally expressed as D1>D3=D4>D5>D2.As shown in above results,that assessed risk rank of D3 became higher than D4 and D5 improved the accuracy of assessment after modification. The triangular fuzzy number could reduce the influence of uncertain factors. The entropy method can take relative importance among the risk parameters into consideration.Fuzzy multi-criteria decision-making method can not only make up for the deficiency of traditional FMEA methods that are non-differential analysis of evaluation parameters and impossibility of risk evaluation with equal RPNbut can effectively improve the accuracy of the assessment results. Furthermore, this method can be applied in many other parts of drugs production, such as design of clean shop, process validation, equipment/cleaning validation, mass balance, and so on. We believed that the study in improved method of risk assessment FMEA is still of great research value in quality management of drug production.

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