A new method for controlling the quality of technological products

A M Karmishin\textsuperscript{1}, L K Orlik\textsuperscript{1} and G S Zhukova\textsuperscript{2}

\textsuperscript{1} Russian State Social University, Moscow, Russia
\textsuperscript{2} Financial University under the Government of the Russian Federation, Moscow, Russia

E-mail: vaxzk8chif@mail.ru, lubov.orlik@gmail.com, galsevzhukova@mail.ru

Abstract. The problem of conformity of products to the requirements of technical control or between products of different batches puts the methods of experimental determination of product properties high on the agenda. The measurement of the parameters of these properties is stochastic. Some product properties can only be determined in specially designed experiments. Thus, in the production of powders, their dispersion can be normalized, the specific charge of condenser powders can increase, the location of magnetic granules of nanoparticles on information carriers can be controlled, the content of physiologically active substances in drugs can be controlled, and the spectrum of mobilities of atmospheric particles can be analyzed. Possible approaches to solving the problem of checking a batch of products for compliance with the requirements of technical specifications (TS) are considered using the example of powder dispersion. For the first time, a method has been proposed for comparing product properties, which are continuous random variables, by determining the joint area under their differential curves. The decision on the conformity of the measured product properties to the requirements of technical specifications is based on a comparative assessment with the directive established joint area under the distribution density curves. The technique of determining the probability of correspondence of normal distribution laws to each other is described. A final analytical solution is obtained for two exponential distribution laws.

1. Introduction

In the production of products in practice, the question arises of its compliance with the requirements of technical specifications or the correspondence between products of various lots. Some product properties can only be determined in specially designed experiments. In the production of powders, their dispersion can be normalized, when information is placed on special magnetic media, the location of magnetic granules of nanoparticles of the same size, shape and orientation can be controlled, in the manufacture of drugs, the content of physiologically active substances can be controlled, while studying natural and anthropogenic factors involved in the formation aerodispersion systems, the spectrum of mobility of atmospheric particles can be analyzed; in the production of tantalum electrolytic x capacitors the specific charge capacitor powders can be increased [1–6]. The experimental determination of product properties should be measured using scientifically justified methods.

Depending on the physical meaning of a product property, on a quantitative level it can be described in two different ways: in the form of a determinate value (the product property must be
greater or less than a given value); in the form of a distribution law (for properties that are discrete or continuous random variables). If the controlled property of products varies from batch to batch slightly, then we can talk about high quality, otherwise the quality of the process is low and measures must be taken to improve it.

Despite the fact that some product properties are a deterministic quantity, in practice they are judged by the measurement results, which, as is well known, are random in nature.

In this regard, one can speak of the conditional determinism of these properties.

2. Methods and materials

2.1. Methods for experimental determination of product properties that are discrete random variables

The task of evaluating an unknown parameter of the studied product property with a given reliability \( \gamma = 1 - \alpha \) is solved using the confidence interval taking into account the additional condition for confidence boundaries, based on the essence of the quantitative characteristics. If the accuracy of the parameter should be no more than a given value, then the additional requirement to the boundaries is usually due to the fact that the probability of deviation of the measured quantity is greater than the specified one, that is, to the left or to the right of the confidence limits should be the same and equal to \( (1-\alpha)/2 \) [7].

If, according to the condition of the problem, the measured value, for example, the content of the reagent in the sample, should be not less than a certain minimum admissible value \( C_{\min} \), then the condition for estimating the confidence probability is as follows:

\[
P\{C > C_{\min}\} = \alpha
\]

If we assume that the measurement errors of the relative content of the substance in the sample are small, then, due to the large number of commensurate random errors affecting the measurement, it can be assumed with sufficient accuracy for practice that the result of measuring the relative content of the active principle in the sample is a continuous random variable distributed over normal law. Then, to estimate the probabilities, one can use an integral function with an unknown mean square deviation \( s_1 \), which is estimated from the results of measurements. So, the probability that a random value of the measured quantity, for example, the concentration of the active principle in the sample \( C \) will be less than a certain value \( C_{\min} \) determined by the requirements of TU, can be found as follows:

\[
P = 0.5 \left[ 1 + \text{erf} \left( \frac{C_{\min} - \bar{C}}{\sqrt{2}s_1} \right) \right],
\]

where \( \bar{C} \) is the average value of the measured substance content in the sample.

The probability that the random value of the measured concentration of the active principle in the sample \( C \) will be not less than a certain value \( C_{\min} \) determined by the requirements can be found by the formula:

\[
P = 0.5 \left[ 1 - \text{erf} \left( \frac{C_{\min} - \bar{C}}{\sqrt{2}s_1} \right) \right],
\]

while the probability that the substance content in the sample is in the range from \( C_1 \) to \( C_2 \) will be equal to:

\[
P = 0.5 \left[ \text{erf} \left( \frac{C_2 - \bar{C}}{\sqrt{2}s_1} \right) - \text{erf} \left( \frac{C_1 - \bar{C}}{\sqrt{2}s_1} \right) \right].
\]

It follows from the foregoing that there will always be some likelihood that the studied product property will not meet the requirements of technical specification. It follows that the requirements of
technical specifications should be set based on the guaranteed value of the studied quantitative characteristics of the product, which in practice is not always observed.

2.2. Methods for experimental determination of product properties that are continuous random variables

The most complete characteristic of a continuous random variable is the law of its distribution, which is given as a function of the probability density function, or as a distribution function. Note that the law is considered given if its type and its parameters are known.

So, for example, the distribution of the mass of powder particles or the mass of aerosol particles by their size is described by a logarithmically normal law, which has the following form [8]:

$$\varphi_m(d) = \frac{1}{\sqrt{2\pi} d \sigma_{ln d}} e^{\frac{-(ln d - ln d_{em})^2}{2\sigma_{ln d}^2}};$$

$$P = 0.5 \left[ 1 + \text{erf} \left( \frac{ln d - ln d_{em}}{\sqrt{2}\sigma_{ln d}} \right) \right],$$

where \(d\) is the particle diameter, \(\mu m; d_{em}\) is a law parameter; median particle mass diameter, \(\mu m; \sigma_{ln d}\) is law parameter: standard deviation of the natural logarithm of a random particle diameter.

Note that a similar distribution has a random dose of the drug that causes a given therapeutic effect (for this, the particle size \(d\) can be replaced by dose \(D\)) [9].

In relation to powder, the question arises whether or not the dispersion of the powder differs significantly from batch to batch and whether it meets the requirements of TS. If the differences from the point of view of mathematical statistics are not significant, then the technological process can be considered high-quality and stable. Otherwise, process improvement will be required.

For a physiologically active substance/drug, the following question can be formulated. Does the physiological activity of the drug differ significantly from batch to batch, the requirements of TS, or compared with another drug? If these differences are not significant, then it is considered that the batch of product meets the requirements of TS. Summarizing the above, it can be noted that in practice, according to the results of experimental studies of a continuous random variable, the distribution law and its parameters are determined, so the question arises of the conformity of the laws of distribution of measured property of a product from batch to batch.

Let us consider possible approaches to solving the problem of checking a batch of products for compliance with the requirements of technical specifications using the example of powder dispersion. Let it be established from the primary measurement data of particle sizes that their mass is located according to a logarithmically normal law and its parameters \(d_{em}\) and \(\sigma_{ln d}\) are determined.

It is necessary to compare this distribution law with the requirements of TS (with another batch), according to which the log-normal law has parameters \(d_{em}\) and \(\sigma_{ln d}\).

Following the ideas of classical mathematical statistics, one can compare the parameters of the laws in question in pairs. For each of the compared parameters, three incompatible events are possible: one of the considered parameters will be less, equal or greater than the other. Then the total number of possible combinations of incompatible events when comparing the two parameters of the laws of distribution will be \(3^2 = 9\):

1) \(d_{em}^* < d_{em}\) and \(\sigma_{ln d}^* < \sigma_{ln d}\);
2) \(d_{em}^* < d_{em}\) and \(\sigma_{ln d}^* = \sigma_{ln d}\);
3) \(d_{em}^* < d_{em}\) and \(\sigma_{ln d}^* > \sigma_{ln d}\);
4) \(d_{em}^* = d_{em}\) and \(\sigma_{ln d}^* < \sigma_{ln d}\);
5) \(d_{em}^* = d_{em}\) and \(\sigma_{ln d}^* = \sigma_{ln d}\);
6) $d_{em}^+ = d_{em}$ and $\sigma_{ln d}^+ > \sigma_{ln d}$;
7) $d_{em}^+ > d_{em}$ and $\sigma_{ln d}^+ < \sigma_{ln d}$;
8) $d_{em}^+ > d_{em}$ and $\sigma_{ln d}^+ = \sigma_{ln d}$;
9) $d_{em}^+ > d_{em}$ and $\sigma_{ln d}^+ > \sigma_{ln d}$.

Similar combinations can be made for the parameters of the law of distribution of random doses of a drug that cause a given therapeutic effect.

It should be borne in mind that when comparing two random variables, the following hypotheses can be formulated:

- hypothesis $H$ is true and is accepted according to the selected criterion (correct decision);
- hypothesis $H$ is false and is rejected according to the selected criterion (correct decision);
- hypothesis $H$ is true, but rejected according to the selected criterion (incorrect decision is an error of the first kind);
- hypothesis $H$ is false, but is accepted according to the selected criterion (incorrect decision is an error of the second kind).

Thus, an error of the first kind is associated with the probability of rejection of the null (true) hypothesis, and a mistake of the second kind is associated with the probability of adopting an alternative null (false) hypothesis [10].

Sometimes, a quantile can be specified as the requirements of a technical specification: a guaranteed particle size and a certain mass, concentrated on particles of smaller or larger sizes. Such a specification of requirements does not fully characterize the law of distribution of a random variable. We illustrate this with the following example: let the particles of one batch have a median mass diameter $d_{em} = 4 \mu m$ and $\sigma_{ln d} = 0.175$, while for other particles $d_{em} = 1 \mu m$ and $\sigma_{ln d} = 1.263$.

For each of the considered distributions, we have: $F(5) = 0.9$ (i.e., 90% of their mass is concentrated on particles up to 5 $\mu m$). However, these are completely different distributions, which is clearly illustrated in Figures 1 and 2.

From the given example it follows that for the properties of products described by continuous random variables, the law parameters or a quantile of order $p$ must not be compared, but their most complete characteristics, i.e. distribution laws.

Figure 1. Two probability densities of logarithmically normal laws of mass distribution by particle size

Figure 2. Two distribution functions of the logarithmically normal laws of mass distribution over particle sizes

As far as the authors of this article know, in mathematical statistics such a question is posed for the first time.
3. Results

As a measure of the correspondence of the two distribution laws to each other, we consider the total (combined) area under two differential curves (Figs. 3a and 3b).

![Figure 3. Illustration to a comparison of two distribution laws. Possible configuration a)](image1)

![Figure 4. Illustration to a comparison of two distribution laws. Possible configuration b)](image2)

Interestingly, the area under the differential curve inherently determines the probability and is normalized to unity. Then, if two differential curves coincide, which is possible only if the parameters of the distribution laws are completely equal, then the laws themselves coincide with a probability equal to unity. If the total area under the differential curves of the distribution laws tends to zero, then they coincide with the probability tending to zero and do not coincide, that is, they are different, with the probability tending to unity.

To find the total area under two differential curves, we need to find the points of their intersection. So, for example, equating two logarithmically normal densities and solving the quadratic equation, we get two roots, respectively, two intersection points:

\[ d_{1,2} = e^{-\frac{b+\sqrt{b^2-4ac}}{2a}}, \]

where

\[ a = \frac{1}{2} \left( \frac{1}{\sigma_{ln1}^2} - \frac{1}{\sigma_{ln2}^2} \right); \quad b = \ln \frac{d_{em1}^*}{\sigma_{ln1}^2} + \frac{\ln d_{em2}}{\sigma_{ln2}^2}; \quad c = \frac{(\ln d_{em1}^*)^2}{\sigma_{ln1}^2} - \frac{(\ln d_{em2})^2}{\sigma_{ln2}^2} - 0.5 \ln \frac{\sigma_{ln1}^*}{\sigma_{ln2}^*}. \]

After the intersection points of two differential curves are found, determining the total area under them is not difficult.

In computer-assisted probability calculations for Figs. 3 and 4, four situations are possible. However, if the distribution laws are arranged in such a way that the parameters of a law which median particle diameter is smaller to be the first to be input (less than the median dose for a physiologically active substance), then only two situations can be considered.

For the case when the parameters of the distribution laws for computer calculations are introduced in exactly this sequence, that is, for \( d_{em1} < d_{em2} \), the total area under two differential curves is calculated as follows:

\[ \text{if } \sigma_{ln1} > \sigma_{ln2} \left( \sqrt{k_1} < \sqrt{k_2} \right), \text{ then} \]
\[ P_s = P_1(d_1) + [P_2(d_2) - P_2(d_1)] + [1 - P_1(d_2)]. \]

If \( \sigma_{ln d_1} < \sigma_{ln d_2} \left( \sqrt{k_1} > \sqrt{k_2} \right) \), then

\[ P_s = P_2(d_1) + [P_1(d_2) - P_1(d_1)] + [1 - P_2(d_2)]. \]

Here \( P_1(d) \) and \( P_2(d) \) are integral functions of mass distribution over particle sizes, calculated by the following equation:

\[ P(d) = \frac{1}{2} \left[ 1 + \text{erf} \left( \sqrt{k} \ln \frac{d}{d_{em}} \right) \right], \quad \sqrt{k} = \frac{1}{\sqrt{2} \sigma}. \]

We obtain similar equations when comparing the physiological activity of two batches of a product or two different substances, for which it is sufficient to replace the particle size symbol \( d \) with the dose symbol \( D \).

For the final decision on the conformity or divergence of the two laws of distribution or the conformity of the measured product properties to the requirements of TS, it is necessary to establish the level of probability of compliance of the two distribution laws. If as a result of the calculations it is established that the joint area under the two distribution curves is not less than the directive established, then the hypothesis of the equality of the two distribution laws is accepted, otherwise the laws do not match.

Figs. 5 and 6 show the correspondence of two distribution laws having the following parameters:

- \( d_{em1} = 0.3 \mu m \) and \( \sqrt{k_1} = 1.0 \);
- \( d_{em2} = 0.5 \mu m \) and \( \sqrt{k_2} = 1.5 \) (a);
- \( d_{em1} = 0.3 \mu m \) and \( \sqrt{k_1} = 1.0 \);
- \( d_{em2} = 0.325 \mu m \) and \( \sqrt{k_2} = 0.94 \).

**Figure 5.** Illustration of the case of a low probability of coincidence of two distribution laws

**Figure 6.** Illustration of the case of high probability of coincidence of two distribution laws

Similar considerations apply to product properties, which are continuous random variables distributed according to the normal law.

The presented idea of determining the probability of correspondence of the exponential laws of the distribution of random variables allowed obtaining the final analytical solution.
Let there be two exponential distribution laws with parameters $\lambda_1$ and $\lambda_2$. Let us specify $\lambda_1 < \lambda_2$ (Figure 7).

From the analysis of the two densities of the exponential distribution laws presented in Figure 7, it follows that the joint area under two differential curves is found as

$$P_s = F(\lambda_1, x_1) + [1 - F(\lambda_2, x_1)]$$

(1)

where $x_1$ is the intersection point of two densities of exponential distribution laws

$$x_1 = \frac{1}{\lambda_2 - \lambda_1} \ln \frac{\lambda_1}{\lambda_2}; \quad F(\lambda, x) = 1 - e^{-\lambda x}.$$

Substituting $x_1$ into (1), we find the probability of coincidence of two exponential distribution laws:

$$P_s = 1 - \left( \frac{\lambda_1}{\lambda_2} \right)^{\lambda_1 - \lambda_2} + \left( \frac{\lambda_1}{\lambda_2} \right)^{\lambda_2 - \lambda_1}.$$

(2)

An analysis of formula (2) shows that it is correct in limiting cases. If $\lambda_1 = \lambda_2$, then $P_s = 1$. Thus, the laws of distribution coincide with a probability of unity. If $\lambda_1 \ll \lambda_2$, then $P_s$ tends to zero, which means that the laws in question do not coincide.

Let us introduce dimensionless criterion $k_{ov}$ [0, 1]:

$$k_{ov} = \frac{\lambda_1}{\lambda_2}.$$

Then the probability of coincidence of distribution laws (2) through the criterion $k_{ov}$ can be written as

$$P_s = 1 - k_{ov}^{1-k_{ov}} + k_{ov}^{1-k_{ov}}.$$

(3)

Table 1 contains calculated by relation (3) probabilities of coincidence of the laws of distribution of two exponentially distributed random variables.

**Table 1. Probabilities of coincidence of laws of distribution**

| Complex $k_{ov}$ | Probability $P_s$ | Complex $k_{ov}$ | Probability $P_s$ |
|------------------|-------------------|------------------|-------------------|
| 0                | 0.55              | 0.783            |
| 0.05             | 0.189             | 0.60             | 0.814             |
| 0.10             | 0.303             | 0.65             | 0.843             |
| 0.15             | 0.392             | 0.70             | 0.869             |
| 0.20             | 0.465             | 0.75             | 0.895             |
| 0.25             | 0.528             | 0.80             | 0.918             |
| 0.30             | 0.582             | 0.85             | 0.940             |
| 0.35             | 0.631             | 0.90             | 0.961             |
| 0.40             | 0.674             | 0.95             | 0.981             |
| 0.45             | 0.714             | 1.00             | 1.00              |
| 0.50             | 0.750             |                  |                   |

Figure 8 shows a graph of the probability of coincidence of two exponential laws depending on the dimensionless complex $k_{ov}$.
Figure 7. Illustration to comparison of two exponential distribution laws

Figure 8. Probability of coincidence of two exponential laws depending on the dimensionless complex $k_{ov}$

Obviously, similar calculations can be made for other distribution laws, for example, for the law of equal density.

4. Conclusion
The requirements of technical specifications for the level of certain quantitative characteristics should be formulated on the basis of statistical, not deterministic, ideas about these properties of products.

For the first time, a method has been proposed for comparing the properties of products that are continuous random variables by determining the combined area under their differential curves, which, in essence, is nothing more than the probability of coincidence of the laws of distribution of random variables under consideration.

Using the developed method for comparing the two distribution laws, various practically important applied problems can be solved. For example, an analysis of the professional training of specialists performing experimental research. If the results of measuring the properties of products from the same batch, carried out by two different employees, do not differ from the point of view of mathematical statistics, then the level of their professional training is the same, otherwise the level of their professional training is different.

In a similar way, process stability can be compared.

References
[1] Melichov E Z and Farzetdinova R M 2014 Maximum Density of Magnetic Recording and Distribution of Switching Fields Solid Body Phys. 56 2326–34
[2] Laakso L, Gagne S, Petäja T et al 2007 Detecting charging state of ultra-fine particles: instrumental development and ambient measurements Atmos. Chem. Phys. 7 1333–45
[3] Varekhov A G 2014 Spectral analysis mobility of atmospheric particles Sci. instrum. Making 24(4) 51–8
[4] Edward M C 2000 Tantalum and Niobium A Review of Worldwide Industry Statistics TIC Bui 102 2–3
[5] Kolov V N, Miroshnenko M N, Orlov V M and Prokhorov T Y 2005 Kalietermic production of tantalum powders ZHPC 78(4) 545–7
[6] Libenson G A, Lopatin V J and Komarnicki G V 2001 Powder metallurgy processes. Production of metal powders Textbook for univer. vol 1 (Moscow: MISIS)
[7] Kramer G 2003 Mathematical methods of statistics (Moscow; Izhevsk: Res. Center Regular and stochastic dynamics)
[8] Kobsar A I 2006 Applied mathematical statistics. For engineers and researchers (Moscow: Phys. Math. Lit.)
[9] Karmishin A M and Kireev A A 2011 *Mathematical methods of pharmacology, toxicology and radiology* 2nd ed (Moscow: APR) 330 p

[10] Orlik L.K., Semenov S.A., Guseva S.V et al 2009 *Terrorism: problems, models, scenarios* (Moscow)