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DESIGN OF A SANITARY DOSING MACHINE FOR SOLID PARTICLES WITH A DIAMETER SMALLER THAN 300 MICRONS

Jaime Antonio Cancho Guisado, José Moro Pisco, José Julio Rodríguez Figueroa
Federico Villarreal National University

Abstract:
The main objective is to design a sanitary dosing machine that facilitates the precise and sanitary dosing of solid particles with a diameter of less than 300 µm for use in the pharmaceutical, cosmetic, or food industry, where it is necessary to maintain high sanitary conditions to preserve the quality of the product offered to the consumer and ensure accuracy in the weight of the product offered in the packaging. For the creation of parts and pieces, as well as the analysis and simulation of the correct functioning of the machine, Autodesk Inventor 2024 software was used, and for the development and simulation of the electrical control and power system, CADe-SIMU software was utilized. Both design and simulation tools allowed for reduced times and efficient design. The aim is to meet the demand of companies that package powdered products and need exact and consistent dosing over time, while maintaining a high sanitary standard to comply with the regulations required by public health control agencies. The proposed dosing process ensures zero direct transfer of microorganisms, and the technology applied in the electromechanical design ensures precise and semi-automatic dosing. The results obtained confirm that the developed design is suitable for sanitary packaging and ensures exact and sustainable dosing within permissible tolerance standards for dosing solid particles with a diameter of less than 300 µm. Due to the quality of the materials used and the characteristics of the finishes of the parts in contact with the product, the process maintains its safety and consequently guarantees no contamination of the product during packaging.

Key words: automation, sanitary design, powder dosing, food industry, pharmaceutical industry

INTRODUCTION

In the field of engineering, the convergence of mechanical, electronic and control systems have driven the creation of innovative solutions covering a variety of industrial and healthcare applications. One of the areas that has attracted increasing interest is the precise dosing of small solid particles, especially in sectors where precision and hygiene are paramount, such as the pharmaceutical and food industries.

The proposed sanitary dosing machine for solid particles smaller than 300 µm in diameter offers a number of very important benefits for the food and pharmaceutical industry, where accuracy, hygiene and consistency are non-negotiable factors.

BENEFITS FOR THE FOOD INDUSTRY

In food production, accurate dosing of powdered ingredients is critical to the quality, taste and
safety of the final product. This machine provides:

- *Superior Accuracy and Consistency:* Ensures that each batch of product has the exact amount of powdered ingredients, resulting in consistent quality and taste in products such as beverage mixes, condiments, flavorings, additives or powdered bakery and confectionery ingredients. This minimizes variability and ensures repeatability in the formulation. In this way [1], they conducted a study in which they analyzed how the refilling process affects the accuracy of loss-in-weight feeders in the continuous dosing of powders, highlighting the importance of maintaining consistency in the feeding of materials during continuous production. Likewise, [2] present a robotic system that optimizes the preparation of powdered beverages using computer vision and Bayesian optimization, achieving high repeatability and quality in the final product. For their part, [3] propose a model based on the Industrial Internet of Things (IIoT) to monitor and control plant machinery, with the aim of achieving consistency in product quality through real-time predictions and recommendations. In addition, [4] examine the chocolate conching process as a transition from a frictionally stuck solid to a fluid suspension, highlighting how mechanical energy and the addition of surfactants affect the fluidity and homogeneity of the mixture.

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- On the other hand, [5] present a statistical model to predict the uniformity of content in tablets and blends, based on the theory of fluctuations in blends, providing a tool to improve consistency in the dosing of powdered ingredients. Therefore, these research papers offer valuable insights into current technologies and methodologies for achieving accurate and consistent dosing of powdered ingredients in the food industry.
- *Waste and Cost Reduction:* By dosing accurately, overuse of ingredients is avoided, minimizing waste of costly raw materials. This translates directly into operational savings and increased production efficiency. For its part, [6] in his article discusses how precision powder filling machines minimize waste by providing accurate fillings every time, reducing overall production costs. In the same vein, [7] presents six strategies to reduce costs in food processing, highlighting the importance of accurate measurement to reduce ingredient waste. Also, [8] presents a research paper presenting the most advanced solutions in powder dosing systems for 2025, focusing on sustainability features that help reduce energy consumption and material waste. In the same context, [9] describes how the high-precision Inflatek valve maintains consistent dosing, helping to minimize waste and reduce production costs. In addition, [10] discusses common problems in batch dosing of powders and how to solve them to avoid losses and ensure the quality of the final product. All of the above studies offer valuable insights into current technologies and methodologies for achieving accurate and consistent dosing of powdered ingredients in the food industry, with a focus on reducing waste and costs.
- *Optimizing Operational Efficiency:* Automating the dosing process reduces the need for manual intervention, speeding up production and freeing personnel for more complex tasks. This optimizes cycle times and increases productivity. The above is supported by studies such as those of [11] who provide a comprehensive review of the evolution of optimization methodologies in the food industry, highlighting the transition from traditional approaches to advanced techniques integrated with emerging technologies, such as artificial neural networks and Industry 4.0, to improve operational efficiency and sustainability. For their part [12], present a robotic system that optimizes the preparation of powdered beverages using computer vision and Bayesian optimization, achieving high repeatability and quality in the final product. Also, [3] propose a model based on the Industrial Internet of Things (IIoT) to monitor and control plant machinery, with the aim of achieving consistency in product quality through real time predictions and recommendations. The study by [13] combines experiments and discrete element simulations to analyze the dosing of cohesive powders, providing valuable information on powder flow behavior and its impact on operational efficiency. Coincidentally, [14] describes how high-precision powder dosing systems maintain consistent dosing, helping to minimize waste and reduce production costs. Of course, the above literature reviewed offers valuable insights into current technologies and methodologies for achieving accurate and consistent dosing of powdered ingredients in the food industry, with a focus on optimizing operational efficiency.
- *Improved Food Quality and Safety:* The sanitary design of the machine, with materials and finishes that meet hygiene standards, prevents cross-contamination and the growth of microorganisms. This is vital for food safety and compliance with sanitary regulations. Just like, [15] highlights the unique challenges presented by powdered food products in terms of safety and quality, underlining the importance of establishing specific quality assurance and food safety programs tailored to the characteristics of these products. Authors such as [16] address common problems in the handling and processing of food powders, identifying knowledge barriers and research opportunities to improve safety and quality in powdered food production. In a similar context, [17] provide a comprehensive overview of the structure, processing and challenges associated with food powders, including aspects related to food safety and final product quality. In turn, [18] analyze the factors affecting the flowability of food powders, a critical aspect to ensure accurate and safe dosing, which directly impacts the quality and safety of the final product. Also, [19] describes recent research focused on methods to ensure food safety without compromising product quality, especially in low-moisture foods such as powdered products. The aforementioned previous studies offer valuable insights into current technologies and methodologies for achieving accurate and consistent dosing of powdered ingredients in the food industry, with a focus on improving food quality and safety.
- *Adaptability to Different Products and Containers:* The ability to adjust to different container formats and powder types (with varied densities and flow properties) allows for greater flexibility in the production line and the manufacture of a wider range of products. Also, [20] describes how this corporation designs and builds facilities dedicated to the handling of dry bulk products and the dosing of powdered ingredients, offering customized solutions that adapt to various production needs in the food industry. Other industries such as [21] conduct research where they analyze how powder packaging machines play a crucial role in the food industry, ensuring accurate dosing and hermetic sealing that protects product integrity. In their study, [14] presents powder dosing systems that enable accurate and safe automatic dosing operations of ingredients required for food industry preparations, adapting to different dosing requirements and types of packaging. On the other hand, it is found that [22] offers individually adaptable solutions for the dosing of main and secondary ingredients, ensuring accurate and consistent process control in a hygienic design. In

addition, [23] highlights how Syntegon's vertical packaging solutions achieve the highest bag quality thanks to continuous motion and servo technology, adapting to a variety of packaging styles with pure materials. Such research offers valuable insights into current technologies and methodologies for achieving accurate and consistent dosing of powdered ingredients in the food industry, with a focus on adaptability to various products and packaging. If you need more information or additional assistance, please do not hesitate to ask.

BENEFITS FOR THE PHARMACEUTICAL INDUSTRY

In pharmaceutical manufacturing, dosing of active ingredients and excipients in the form of microparticles is critical to the efficacy, safety and bioavailability of drugs. Benefits include:

- *Precise Dosage and Uniformity of Content:* The ability to dose particles smaller than 300 µm with high accuracy is essential to ensure that each dose of a drug contains the precise amount of the active ingredient. This is crucial for therapeutic efficacy and patient safety. Already at the time, [24] analyzed how the particle size of excipients, mixing techniques and processing parameters affect the homogeneity and uniformity of content in low-dose mixtures of active ingredients. The results highlight the importance of optimizing these factors to ensure accurate dosage in pharmaceutical formulations. Other authors such as [5] present a statistical model based on the theory of fluctuations in mixtures to predict content uniformity in tablets and mixtures. This approach provides a theoretical tool to understand and improve dosage uniformity in pharmaceutical products. As well as [25] explore microparticle-based controlled rug release systems, combining experiments with statistical analysis to design efficient systems to ensure uniform and controlled dosing. There are reviews such as [26] that address the mechanisms of powder segregation during tablet manufacturing and how these affect the uniformity of the drug content, providing strategies to minimize these effects and improve the quality of the final product. Another study in the same line is that of [27] which presents uniform biodegradable microparticulate systems for controlled drug release, highlighting manufacturing techniques that ensure homogeneous distribution of the active ingredient and precise dosing. All of the above studies provide valuable insights into current technologies and methodologies for achieving accurate dosing and content uniformity in the manufacture of pharmaceuticals using microparticles.
- *Optimizing Bioavailability and Dissolution:* Particle size directly influences the rate at which a drug dissolves and is absorbed into the body. Precise dosing of microparticles allows the formulation of drugs that maximize their therapeutic efficacy and bioavailability. Already authors such as [28] demonstrate how the spray-drying technique with HP-β-cyclodextrin significantly improves the solubility and dissolution rate of ezetimibe, a drug with low aqueous solubility, increasing its oral bioavailability. In the same line, [29] offer a comprehensive view on the use of microparticles, microspheres and microcapsules in advanced drug delivery systems, highlighting their role in improving the bioavailability and dissolution of drugs. Authors such as Lotter [25], present a microparticle-based model for controlled drug release, combining experiments and statistical analysis to optimize drug bioavailability and dissolution. Likewise, [30] explore the use of mesoporous silica as a carrier in amorphous solid dispersions, improving the solubility and bioavailability of drugs with low aqueous solubility. Authors such as Gupta [31], review various pharmaceutical particulate technologies, such as micronization and solid dispersions, which are used to improve drug solubility, dissolution and bioavailability. The papers reviewed above provide valuable insights into current technologies and methodologies for achieving accurate and consistent dosing of active ingredients and excipients in microparticulate form in the pharmaceutical industry, with a focus on optimizing bioavailability and dissolution. If you need more information or additional assistance, please do not hesitate to ask.
- *Strict Regulatory Compliance:* The pharmaceutical industry is subject to extremely stringent regulations. A machine with sanitary design and validation capabilities ensures compliance with national and international regulations (such as GMP, FDA, etc.), which is indispensable for product approval and marketing. In this regard, [32] introduce the full tolerance coverage method as an approach to evaluate the uniformity of dosage units using large sample sizes, ensuring that no dosage unit exceeds the specification range. There are works such as the one published by [33] that provide information on current Good Manufacturing Practice (CGMP) regulations for drugs, which contain minimum requirements for the methods, facilities, and controls used in the manufacture, processing, and packaging of a pharmaceutical product. On the other hand, [34] discuss several important aspects of particle size specification for solid oral dosage forms from a regulatory perspective, highlighting how particle size distribution can affect the performance of the final drug product. Of importance is the contribution of [35] who discusses how advanced technologies, such as NIR and Raman spectroscopy, enable in-line measurements of mixing and content uniformity in the production of solid dosage forms, improving compliance with regulatory standards. Resources such as [35, 36] were found that provide answers to frequently asked questions about mixing uniformity and content uniformity, addressing critical aspects of regulatory compliance in pharmaceutical manufacturing. The above contributions offer valuable insights into current regulations and methodologies for achieving accurate and consistent dosing of active ingredients and excipients in

microparticulate form in the pharmaceutical industry, with a focus on strict regulatory compliance.

- *Cross Contamination Prevention:* The sanitary design and cleanability of the machine are critical to avoid cross contamination between different batches or products, a critical risk in pharmaceutical production. Pharmaceutical grade materials minimize interaction with products. Therefore, it is important to mention [37] who presents a structured and systematic approach for risk-based identification of the worst-case product and manufacturing process in oral solid form facilities, addressing the high risk of cross-contamination. In addition, [38] analyze contamination trends in medicinal products and propose recommendations for industry and regulatory authorities to address the identified problems. There are papers such as those by [39] where an overview of contamination and cross-contamination in the pharmaceutical industry is provided, highlighting sources of contamination and control strategies. Also [40] discusses cross-contamination control strategies in the manufacture of parenteral and solid oral pharmaceuticals, including examples of product recalls and basic principles for avoiding cross contamination. There are resources such as [41] where the importance of effective equipment cleaning for cross-contamination control in pharmaceutical manufacturing is highlighted. All of the above papers offer valuable insights into current regulations and methodologies for achieving accurate and consistent dosing of active ingredients and excipients in microparticulate form in the pharmaceutical industry, with a focus on preventing cross contamination. If you need more information or additional assistance, please do not hesitate to ask.
- *Reduction of Human Errors and Risks:* Automated batching minimizes human errors associated with the handling of fine powders and reduces the exposure of personnel to potentially hazardous substances, improving occupational safety. This is why [42] discusses how manual visual inspection remains a vital part of ensuring that contaminated products do not enter the supply chain and that injectable drugs are safe for patients. It highlights the importance of effective training and the combination of appropriate technical skills and personality traits to significantly reduce human error in manual visual inspection. In this regard, [43] provides strategies to reduce human errors in the pharmaceutical industry, emphasizing the identification of systemic causes and the implementation of effective solutions to prevent errors and improve product quality. Authors such as [44], in his paper discusses how human error has been a persistent problem in the pharmaceutical industry, accounting for up to 40% of all deviations. He analyzes the common causes and proposes measures to mitigate these errors, including the improvement of quality control systems and processes. Other authors are found such as [45], who investigate how the type of mixer and critical process parameters affect the content uniformity of thin polymeric films loaded with microdoses of drugs, highlighting the importance of properly selecting equipment and mixing parameters to ensure content uniformity and reduce associated risks. Finally [46], elaborate an article where they present an integrated platform for the formulation and manufacturing of pharmaceutical tablets, which combines predictive modeling, optimization algorithms and automation to reduce development time and minimize human errors in the manufacturing process. The research presented offers valuable insights into current technologies and methodologies for achieving accurate and consistent dosing of active ingredients and excipients in microparticulate form in the pharmaceutical industry, with a focus on reducing human error and risk. If you need more information or additional assistance, please do not hesitate to ask.
- *Production Efficiency and Cost Reduction:* As in the food industry, automated and accurate dosing reduces waste of costly ingredients and optimizes production times, resulting in increased profitability. This is why [29] provide a comprehensive review on the use of microparticles, microspheres and microcapsules in advanced drug delivery systems, highlighting their role in improving production efficiency and reducing costs through techniques such as microencapsulation and controlled release. In addition to this, [47] present a "pseudo-homogeneous" catalysis technique using palladium-loaded elastomeric microparticles, combining the speed of homogeneous catalysis with the efficiency of heterogeneous catalysis, resulting in a significant improvement in pharmaceutical production efficiency. As well as, [31] review various pharmaceutical particle technologies, such as micronization and solid dispersions, which are used to improve drug solubility, dissolution and bioavailability, thus contributing to more efficient and cost-effective production. Along the same line, [45] investigate how the type of mixer and critical process parameters affect the content uniformity of polymeric thin films loaded with drug microdoses, highlighting the importance of properly selecting equipment and mixing parameters to ensure content uniformity and reduce associated risks. Researchers such as [46] present an integrated platform for pharmaceutical tablet formulation and manufacturing, which combines predictive modeling, optimization algorithms, and automation to reduce development time and minimize human errors in the manufacturing process. In the above, valuable insights are offered on current technologies and methodologies to achieve accurate and consistent dosing of active ingredients and excipients in microparticulate form in the pharmaceutical industry, focusing on production efficiency and cost reduction.
- *Product Stability:* Uniform particle dosage contributes to the physical and chemical stability of pharmaceutical products, preventing problems such as segregation of components or premature degradation. In this regard, [48] present the manufacture and evaluation of

polymeric microparticles loaded with glipizide, highlighting their stability and efficacy in the controlled release of the drug. Likewise, [49] analyze how different excipients affect the stability of polymeric microparticles used in autoimmune therapies, providing valuable information for the formulation of stable pharmaceutical products. Likewise, [25] demonstrate microparticle-based controlled drug release systems, combining experiments with statistical analysis to design efficient systems that ensure uniform and controlled dosing.

Authors such as [29] provide a comprehensive view on the use of microparticles, microspheres and microcapsules in advanced drug delivery systems, highlighting their role in improving drug stability and efficacy.

The papers shown offer valuable insights into current technologies and methodologies for achieving accurate and consistent dosing of active ingredients and excipients in microparticulate form in the pharmaceutical industry, with a focus on product stability. In both the food and pharmaceutical industries, the ability of this machine to handle microparticles in a sanitary and precise manner is what makes it an invaluable tool, ensuring quality, safety and efficiency in the production of critical products.

TECHNICAL AND SANITARY JUSTIFICATION FOR POWDER DOSING MACHINE

Designing a dosing machine for solid particles with a diameter of less than 300 µm, which guarantees precision and optimal sanitary conditions, is essential to meet the needs of food and pharmaceutical industries that require accurate and consistent dosing processes.

This need is based on several critical aspects:

- Accurate dosing in the form of microparticles is crucial to ensure the efficacy, safety and bioavailability of drugs. Studies have shown that uniformity in dosing significantly improves the quality of the final product and reduces batch-to-batch variability.
- Sanitary compliance in the pharmaceutical industry is subject to strict regulations that demand rigorous sanitary conditions in production processes. The design of equipment that minimizes cross-contamination and facilitates cleaning is essential to comply with Good Manufacturing Practices (GMP) and regulatory agency standards.
- Reducing cross-contamination by implementing closed and automated dosing systems significantly reduces the risk of cross-contamination, a critical aspect in drug and food production. Automation also reduces human intervention, which reduces the possibility of errors and improves process consistency.
- Operational efficiency with the adoption of advanced technologies in the design of dosing machines allows for more efficient production, with less material waste and reduced downtime. This translates into higher productivity and reduced operating costs.

Therefore, the design of such a dosing machine that guarantees precision and optimal sanitary conditions is essential to meet the quality and safety standards required in the pharmaceutical and food industries. The integration of advanced technologies and compliance with sanitary regulations ensure the production of safe products. [50] postulates that there are a large number of dosing machines equipped with outdated systems; however, operator safety and operational efficiency of these machines progressively deteriorate over time. In this context, he explored novel alternative technologies already prevalent in the industry, which could facilitate the assembly of a control system that not only delineates multiple machine features, but also improves overall machine performance [51] notes that dosing systems serve the fundamental function of determining the precise proportions of the product to be packaged or blended, thus ensuring uniform distribution or melting. By maintaining a uniform distribution of the products, these systems not only facilitate the marketing of the product, but also enable the consumer to acquire the necessary quantities adapted to his specific requirements. It also classifies dispensers according to several criteria, including, among others, the type of dispensing, the specific products for which the system is designed and the physical characteristics of the product being dispensed: telescopic cup dispensers, sliding carriage dispensers, tilting dispensers, auger dispensers and rotary gate dispensers. [52] states that a dosing machine is a useful working tool that allows adding a liquid or solid in exact quantities in each of its discharges. They are used in various industries such as food, cosmetics, medical, cleaning, fertilizers and insecticides, etc. [53] states that liquid dosing is an industrial procedure that facilitates the flow of liquid substances. In essence, it regulates the volume of liquid required for the product in various types of containers, including plastic, glass or one-liter containers, allowing the dispenser to calibrate the desired amount for the product application. [54] postulates that solid dosing represents an industrial methodology that allows for fully dynamic weighing, meaning that as the product is weighed, it actively contributes to the overall process, thus requiring varying amounts of solid materials for mixing and selection. He stresses that such an approach produces an optimal dispenser that ensures the required weight, essential to achieve a high-quality end product. [55] indicates that the design of an automatic Bakelite dispenser should aim to improve the process by minimizing processing time and industrial safety risks for the operator. For this purpose, an evaluation of design alternatives was proposed and made based on the dosing systems used in the industry. It then selected the most suitable for the process. [56] points out that the purpose of the design of this machine was to satisfy the industry's requirement for efficient, good quality and competitively priced machinery. This machine was designed to combine, in a single unit, the packaging material and the product to be packaged, where it did it in an efficient way with a minimum of waste of both the product and the packaging material. [57] points out that nowadays the principle of loss-in-weight operation is highly considered, because it offers an accurate and highly reliable method of continuous dosing by weight, taking into account that the gravimetric doser

contains a proven and viable weighing system, with a versatile and reliable measuring mechanism, as well as a built-in control system with the latest technology for optimum performance. The design of a sanitary machine intended for the dosing of solid particles smaller than 300 micrometers (μm) in diameter represents a significant challenge. This challenge arises from the need to guarantee accurate weight control while ensuring that the process remains contaminant-free and meets strict sanitary standards. Dosing accuracy is crucial not only to guarantee the quality of the final product, but also to ensure compliance with safety and quality regulations.

The present research focuses on the development of an advanced mechatronic system that combines sensor, actuator and controller technologies to achieve accurate, efficient and sanitary dosing of solid particles smaller than 300 micrometers (μm) in diameter. This proposed system integrates feeding and dosing mechanisms specifically designed to handle solid particles smaller than 300 micrometers (μm) in diameter. In addition, materials and methodologies are used that minimize the risk of contamination and ensure product integrity throughout the process. The main objective of this research is to design a dosing machine that facilitates the dosing of solid particles with a diameter of less than 300 micrometers (μm). This proposed machine will not only meet the technical and regulatory requirements, but should also be versatile in terms of testing the dosing quantity. To achieve this objective, a detailed analysis will be carried out, as well as an exhaustive study of the design and operation principles of the dosing system, using the theory explained in engineering texts.

A key aspect of the project is the evaluation of the impact of the developed system in terms of efficiency, accuracy and safety. This evaluation will be carried out through experimental tests and simulations, which will serve to validate the proposed design. The results obtained will not only confirm the feasibility of the system, but will also provide a solid basis for future improvements and innovations in the industry.

In summary, this research seeks to make a significant contribution to the field of mechatronic engineering by developing an advanced solution for the sanitary dosing of solid particles smaller than 300 micrometers (μm). The advances achieved through this research have the potential to improve current industrial processes and open new opportunities for the application of mechatronic technologies in sectors where precision and hygiene are critical.

METHODOLOGY

System Design

The design process was carried out using Autodesk Inventor 2024, which allowed the generation of detailed 3D models, including assembly and exploded views. For the simulation of the electrical and control system, CADeSIMU was used, ensuring the efficient integration of sensors, actuators and controls.

Material Selection

FDA-approved materials, such as C-304 sanitary grade stainless steel and high-strength polymers, were used to ensure durability and ease of cleaning. According to ISO 408, the design includes polished finishes with a surface roughness Ra ≤ 0.8 μm, minimizing risks of microbiological contamination for being a surface metrology standard for its required sanitary finish.

Applicable Regulations

The prototype complies with the following regulations:

- NMP 02:2008, regulates the quantity of products in prepackages, data is presented in Table 4.
- NTS 071-MINSA/DIGESA: Establishes the important microbiological criteria for food and beverages, presented in Annex B.
- ISO 468: Specifies surface roughness requirements, presented in Annex C.

Experimental Validation

Tests were carried out with sodium bicarbonate as reference material. The tests included dosing accuracy measurements and particle flow simulations under different humidity and temperature conditions.

PROPOSED PROBLEM

General Problem

To what extent does a dosing machine facilitate accurate and sanitary dosing of solid particles smaller than 300 micrometers (μm) in diameter?

Specific Problems

How can a dosing machine for solid particles with diameters smaller than 300 μm be designed to be versatile in format changeover?

How can a semi-automatic dosing machine for solid particles with diameters smaller than 300 μm be designed?

Results and discussion

By employing theoretical knowledge and practical activities, it was possible to delineate the necessary resources essential for the execution of the project under control; consequently, compliance with the relevant standards was achieved, which served as a fundamental step towards the realization of the prototype design and the expected results were achieved.

Engineering Study

Through the use of academic knowledge and systematic activities, it was possible to delineate the necessary resources essential for the implementation of the project under review; consequently, compliance with the established standards was achieved as a fundamental step towards the realization of the prototype design.

Likewise, such research contributes significantly to the discipline of mechatronics engineering, as it aims to improve industrial methodologies and open up new possibilities in sectors where precision and hygiene are of utmost importance.

Fundamental aspects and key considerations

The conceptualization of the Sanitary Dispensing Machine for solid particles smaller than 300 µm is based on the requirement for accurate and hygienic dispensing in industries such as pharmaceuticals, food production and cosmetics. The main obstacle to be considered is to ensure meticulous control of the particle mass and, at the same time, to ensure that the process remains free of contaminants and, therefore, must comply with stringent sanitary standards. Accurate dosing is also essential to maintain product integrity and ensure compliance with regulatory mandates. Finally, a multifunctional dosing machine has been designed to dispense solid particles of less than 300 µm, evaluating its implications in terms of efficiency, accuracy and safety.

Knowing that: 1 micrometer (µm) = 1 micra (µ) = 1 micrón (µ) = 0.001 mm = 1×10^{-6} m.

Design approach for the prototype of a sanitary dosing machine for solid particles with a diameter of less than 300 µm

Consideration was given to designing a multifunctional dosing machine to dispense solid particles of less than 300 micrometers (µm), evaluating its implications in terms of efficiency, accuracy and safety.

Considering the design and development of the sanitary dosing machine, our functional machine can dose solid particles smaller than 300 µm and complying with the hygiene regulations together with those of metrology, the respective calculations were carried out.

Outlet mass flow rate (Q_s), hopper volume (v) and hopper receiving quantity (m)

Hopper outlet mass flow rate (v):

$Q_s = 25\ g/seg$, considering that the density of the dust is $\rho = 2{,}173 g/cm^3$

Hopper volume (v):

$$v = \frac{1}{3}\pi h[R^2 + r^2 + R.r] \quad (1)$$

$$v = \frac{1}{3} \times 3.14 \times 250\ mm\ [\ (213.5\ mm)^2 + (51\ mm)^2 + (213.5\ mm)(51\ mm)\ ]$$

$$v = 15457107.92\ mm^3 = 15457.10792\ cm^3 = 15.457\ L$$

Amount of powder (m) of reception in the hopper:

$$m = \rho.v \quad (2)$$

$$m = 2.173 \frac{g}{cm^3} \times 15457.10792\ cm^3$$

$$m = 33588.29551\ g = 33.588\ kg$$

Total Hopper Discharge Time (θ)

If the discharge is 50 g/2 seg, then:

$$33588.29551\ g \times \frac{2\ seg}{50\ g} = 1343.53182\ seg = 22.39\ min$$

A versatile design that allows format changes according to the type of powder or container required, where 25 exploded drawings, 01 assembly drawing and 01 explosion drawing were obtained, according to Figure 1.

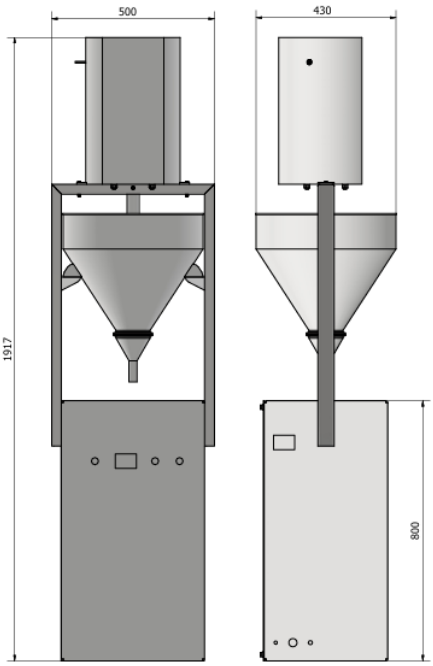


Fig. 1 Powder Dosing Machine

We consider to design an auger packing machine for powders, due to the following characteristics: Accuracy in dosing, it allows to control with precision the powder dispensing, ideal for galenic products. Its precision minimizes overfilling or underfilling, optimizing the use of raw material.

Uniform powder flow, it is possible to dose powders of different granulometries in a continuous way, avoiding lumps or blockages.

Versatility, it can work with dry powders, fine powders, granules or some humidity.

Automation and synchronization, easy and fast integration in automatic packaging lines, allowing quick calibration.

Hygiene and cleanliness, they are designed in stainless steel with smooth and easy to clean surfaces that prevent contamination, it is suitable for application in food products, pharmaceuticals, cosmetics and related products.

Figure 2 shows the worm and with the previous calculations made from Table 1, the respective frequencies are obtained from Table 1.



Fig. 2 Auger dosing system

Table 1

List of Powder Dosing Machine

1	1	CAJA	ACERO INOX. C-304
2	1	BASE DE MOTOR	ACERO INOX. C-304
3	1	SOPORTE MOTOR	ACERO INOX. C-304
4	1	BASE DE REDUCTOR	ACERO INOX. C-304
5	4	DIN 6921 - M8 x 16	Perno hexag. con valona
6	1	CONTENEDOR	ACERO INOX. C-304
7	1	EMBUDO	ACERO INOX. C-304
8	4	DISTANCIADOR	ACERO INOX. C-304
9	1	SELLO	VITON
10	4	M10-1.5 x 45	Perno hexagonal
11	6	ANSI B18.21.1 - 0.375	Arandelas de presión
12	6	M10-1.5 Tipo 8	Tuerca hexagonal
13	2	M10-1.5 x 25	Perno hexagonal
14	2	BOCINA	TEFLON
15	1	EJE	ACERO INOX. C-304
16	1	HELICOIDE	ACERO INOX. C-304
17	1	ENCODER	S50
18	1	FUNDA	ACERO INOX. C-304
19	1	MOTOR ELECTRICO	FRAME 80
20	1	ACOPLE FLEXIBLEiam	ACERO AL CARBONO
21	1	ESTRUCTURA	ACERO INOX. C-304
22	1	REDUCTOR	ALUMINIO
23	4	CNS 5052 - 6	Arandela de presión
24	4	M6-0.8 x 25	Perno hexagonal
25	4	M6-0.8 Tipo 8	Tuerca hexagonal
26	2	BS 1804-2 - 6 x 35	Pasador cilíndrico
27	2	M5-0.6 x 45	Perno hexagonal
28	2	CNS 5052 - 5	Arandela de presión
29	2	M5-0.6 Tipo 5	Tuerca hexagonal
30	2	M10-1.5 x 20	Perno hexagonal
ELEMENTO	CTDAD	Nº DE PIEZA	DESCRIPCIÓN
LISTA DE PIEZAS			
Diseño de: ING CANCHO	Revisado por: ING CANCHO	Aprobado por: ING CANCHO	Fecha: 22/11/2024
UNIVERSIDAD NACIONAL FEDERICO VILLARREAL	ENSAMBLADO DE MAQUINA DOSIFICADORA		
	ENSAMBLADO	Edición	Hoja 1 / 1

Likewise, it has been possible to develop the total exploded view of the machine, the explosion plan, according to Figure 3 and the assembly plan, presented in Figure 4.

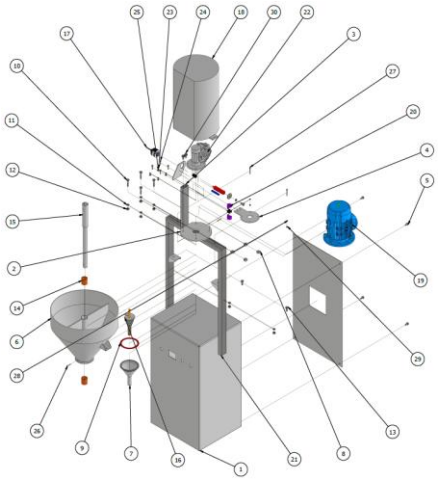


Fig. 3 Exploded Parts of the Powder Dosing Machine

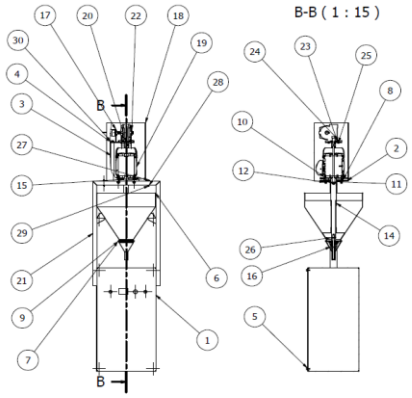


Fig. 4 Powder Dosing Machine Assembly

Considering that it has the adaptation to the incorporation of a semi-automatic system to optimize the operation and guarantee precision according to Box 1 and Table 1.

Box 1

Calculations prior to Descriptive Geometry

PREVIOUS CALCULATIONS	
N° of Data	130
Lower limit	156,35
Upper limit	158,45
Range	2,1
N° of Class	11
Class size	0,191
Standard Deviation	0,471
Variance	0,222
Average	157,3
Median	157,2
Moda	157,0

A list of all the parts that make up the powder packaging machine was also developed, as shown in the following table:

Statistical analysis

The Histogram

With the Frequency data indicated in Table 2, the histogram is drawn with the accumulated frequency curve that helps us analyze the distribution of the data and see how they accumulate in the ranges.

With the previous calculations, the following values are obtained:

Table 2

Frequency data

CLASS	CLASS INTERVAL		BRAND	FREQ.	F. ACCUMUL.	% FREQUENCY.	% ACCUMUL.
1	153,55	153,92	153,73	25	25	19,23%	19,23%
2	153,92	154,29	154,10	15	40	11,54%	30,77%
3	154,29	154,66	154,47	22	62	16,92%	47,69%
4	154,66	155,03	154,84	23	85	17,69%	65,38%
5	155,03	155,39	155,21	14	99	10,77%	76,15%
6	155,39	155,76	155,58	17	116	13,08%	89,23%
7	155,76	156,13	155,95	12	128	9,23%	98,46%
8	156,13	156,50	156,32	2	130	1,54%	100,00%

Likewise, with the data of the brand, frequency, cumulative % and class interval, we have the histogram as shown in Figure 5.

In the histogram, the interval with the highest frequency is in the range of (153.55 to 153.92), which is the most representative of the distribution, indicating that most of the data are in this zone. There is an asymmetric distribution, i.e. the data is skewed to the left. The extreme values (156.13-156.50) have low frequency, indicating that the data are less common in this zone. Two different analyses are shown here, despite including measurements from the same dosing process, taking into account that the

same data structure and statistical objective are not being used.

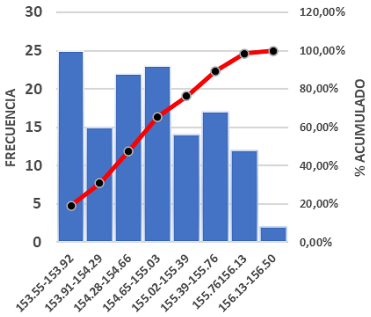


Fig. 5 Histogram of weight analysis

Because of this, the class ranges of the histogram (153.55-153.92, 153.92-154.29, etc.) do not coincide with the control limits (UCL/LCL) or with the means and ranges used in the X̄-R graph.

That is, it is not that different samples were used in the sense of collecting different containers, as these are two levels of statistical treatment on the same population.

Where the Histogram/Descriptives analysis with a database of 130 individual pieces is intended to determine the shape of the distribution, and the Control X-R analysis with a database of 25 subgroups of 5 pieces is intended to determine the stability of the process.

Therefore, the histogram class ranges (153.55-153.92 g, etc.) and the control limits (UCL/LCL) do not match, as they measure different things, with different calculations, even based on the same physical measurements.

As for the cumulative curve, it rises slowly and continuously over the frequencies, indicating that there is a continuous distribution of data between the intervals.

Control charts

Box 2

Limits for the realization of the X-R chart

Control chart type X-R	Límite superior de control (UCL) Línea central (LC) Límite inferior de control (LCL)

For the mean control chart, the limits are calculated with the following formulas:

$$LCS = \overline{x} + A_2\overline{R}$$
$$LC = \overline{x}$$
$$LCI = \overline{x} - A_2\overline{R}$$

The value of $A_2 = 0.577$ is obtained from the Quality Table (Annex A).

For the range control chart, the limits are calculated with the following formulas:

$$LCS = D_4\overline{R}$$
$$LC = \overline{R}$$
$$LCI = D_3\overline{R}$$

Data from $D_3 = 0.0$ and $D_4 = 2.114$ which are obtained from the Quality Table (Annex A).

From Table 3 Control by medians and ranges, the average of the averages is obtained $\overline{x} = 154.76$, the median of the ranges $\overline{R} = 0.14$ and the median of the standard deviations $\overline{\sigma} = 0.753$.

Table 3

Control by medians and ranges, for the elaboration of the X-R graph

							MEDIANS				RANGES			
N°	GRUPO1	GRUPO2	GRUPO3	GRUPO4	GRUPO5	DEV.ESTAN.	MEDIAN	LCS	LC	LCI	RANGE	LCS	LC	LCI
1	155.55	155.95	154.05	155.15	154.00	0.8820	154.94	154.84	154.76	154.68	0.20	0.30	0.14	0
2	155.85	155.85	154.55	155.25	154.40	0.6907	155.18	154.84	154.76	154.68	0.10	0.30	0.14	0
3	154.55	154.60	155.35	154.95	155.55	0.4444	155.00	154.84	154.76	154.68	0.15	0.30	0.14	0
4	154.10	154.60	153.85	154.75	153.95	0.4016	154.25	154.84	154.76	154.68	0.20	0.30	0.14	0
5	154.05	153.65	154.85	154.95	153.60	0.6458	154.22	154.84	154.76	154.68	0.15	0.30	0.14	0
6	153.55	156.00	155.35	156.35	155.00	1.0880	155.25	154.84	154.76	154.68	0.20	0.30	0.14	0
7	153.85	155.65	155.35	156.45	155.25	0.9423	155.31	154.84	154.76	154.68	0.10	0.30	0.14	0
8	154.10	155.80	155.65	155.15	155.35	0.6703	155.21	154.84	154.76	154.68	0.10	0.30	0.14	0
9	154.05	155.45	154.90	155.45	153.55	0.8526	154.68	154.84	154.76	154.68	0.10	0.30	0.14	0
10	154.05	153.55	153.85	153.70	154.90	0.5308	154.01	154.84	154.76	154.68	0.10	0.30	0.14	0
11	153.55	154.95	154.05	154.60	153.55	0.6269	154.14	154.84	154.76	154.68	0.20	0.30	0.14	0
12	156.00	154.55	154.85	154.45	153.90	0.7786	154.75	154.84	154.76	154.68	0.10	0.30	0.14	0
13	154.55	154.55	155.05	154.50	153.90	0.4084	154.51	154.84	154.76	154.68	0.10	0.30	0.14	0
14	154.85	155.50	155.85	155.00	154.05	0.6865	155.05	154.84	154.76	154.68	0.10	0.30	0.14	0
15	155.55	156.00	154.55	154.75	155.50	0.6027	155.27	154.84	154.76	154.68	0.10	0.30	0.14	0
16	155.35	154.95	153.90	154.75	154.05	0.6124	154.60	154.84	154.76	154.68	0.15	0.30	0.14	0
17	154.45	154.85	154.15	154.75	154.05	0.3536	154.45	154.84	154.76	154.68	0.15	0.30	0.14	0
18	154.40	155.75	155.10	155.45	153.55	0.8839	154.85	154.84	154.76	154.68	0.20	0.30	0.14	0
19	155.50	155.45	154.60	155.45	154.75	0.4373	155.15	154.84	154.76	154.68	0.10	0.30	0.14	0
20	153.90	155.85	154.95	156.00	153.95	1.0016	154.93	154.84	154.76	154.68	0.15	0.30	0.14	0
21	153.85	155.05	154.55	155.50	153.85	0.7301	154.56	154.84	154.76	154.68	0.10	0.30	0.14	0
22	155.00	154.55	154.25	154.85	153.85	0.4637	154.50	154.84	154.76	154.68	0.15	0.30	0.14	0
23	153.85	154.45	153.85	153.55	153.65	0.3493	153.87	154.84	154.76	154.68	0.10	0.30	0.14	0
24	153.90	154.55	154.85	154.55	155.10	0.4492	154.59	154.84	154.76	154.68	0.20	0.30	0.14	0
25	153.90	156.00	154.65	155.50	154.95	0.8039	155.00	154.84	154.76	154.68	0.20	0.30	0.14	0
26	154.85	155.45	155.95	154.55	156.50	0.7940	155.46	154.84	154.76	154.68	0.15	0.30	0.14	0
						0.753	154.76				0.14			

The limits were calculated and shown in Fig. 6. The Range Control Chart.

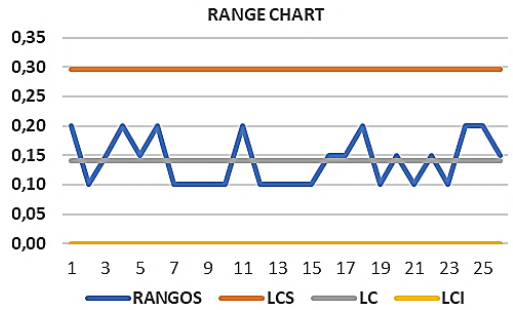


Fig. 6 Range Control Chart

The Range Control Chart is used to monitor process variability in each subgroup, its objective is to detect changes in the dispersion of data that may indicate quality problems.

The blue line represents the ranges, i.e., the difference between the maximum and minimum value of each subgroup shows how the dispersion varies over time.

Center line (LC) also known as the Central Line, represents the mean of the ranges, it is the expected value of variability if the process is under control.

Red line (LCS) called the Upper Control Limit, represents the maximum expected range if the process is under control.

Orange line (LCL) called Lower Control Limit, represents the minimum expected range, if the process is under control.

None of the ranges exceeds the control limits, there are fluctuations in the variability, but within the expected range, therefore it can be stated that the process is under control or the process is stable.

The range chart shows that the process is under control, as all points are within the upper and lower control limits. No unusual behavior or irregular patterns are observed, indicating that the process is stable and consistent in terms of data dispersion.

Determination of C_P and C_{PK} indicators

For the calculation of C_p and C_{pk}, the information in Table 4 is considered, which shows the tolerances of preventive content, where a tolerance is allowed for the packaging according to the nominal weight offered in the package, in our case it is 150 grams.

Table 4

Tolerances for prevéase content – NMP 02:2008

Nominal quantity of product (grams)	Tolerance (grams)
0 a 50	1
50 a 100	4
100 a 200	7
200 a 300	9
300 a 500	10
500 a 1000	15
1000 a 10000	20
10000 a 15000	150
15000 a 50000	200

The customer considers a tolerance of ±3 grams, therefore, the upper specification limit is USL = 157.23 and the lower specification limit is LSL = 151.23, keeping the average value LC = 154.23. According to the customer requirements, the maximum permissible value USL and the minimum permissible value LSL are considered, both in accordance with the technical specifications, LC is considered as the center of the specifications used to analyze the process capability. The data obtained are graphed in Figure 7, a control chart for specific averages, which shows the behavior of the packaging averages according to customer specifications.

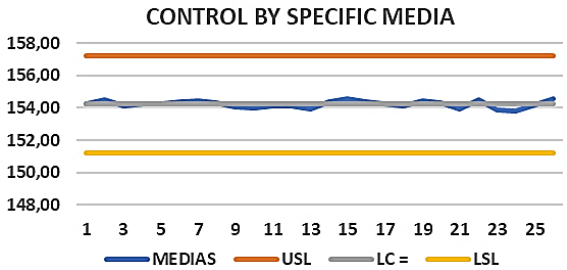


Fig. 7 Control chart by specific averages

This chart is used to monitor process stability over time. It is based on the average of each subgroup in our case, n = 5, given that there are 130 data points distributed across 26 subgroups, and allows for the detection of any unexpected variations. C_p is the Potential Capacity Index and measures whether the process has sufficient capacity to meet specifications, it does not consider whether the process is off-center.

C_{pk} is the True Capability Index, indicating how well the process is centered within the control limits.

For a process to be considered adequate it must be fulfilled that: C_p y $C_{pk} \geq 1.33$.

We use the information:

USL= 157.23

LC = 154.23

LSL = 151.23

$6\sigma = 0.753$

$$C_p = \frac{USL - LSL}{6\sigma} \quad (3)$$

$C_p = \frac{157.23-151.23}{6\times0.753}$

C_p= 1.33

The C_p, found shows that the process is stable and has little variation compared to the allowable tolerance.

The control charts have been worked with n = 5, from the quality table the Factor D3 = 0, D4 = 2.114 and A2 = 0.577.

$$C_{pk} = minimum\left(\frac{USL - \bar{\bar{x}}}{3\sigma}, \frac{\bar{\bar{x}} - LSL}{3\sigma}\right) \quad (4)$$

C_{pk}= minimum $\left(\frac{157.23 - 154.23}{3\times0.517}, \frac{154.23 - 151.23}{3\times0.517}\right)$

C_{pk}= minimum (2.66, 1.33)

The minimum value is taken, then:

C_{pk} = 1.33

The C_{pk}, found demonstrates the process is very good and is meeting its objective of packing within the established tolerance, there is a risk of producing out of specification. The process is centered and very close to the center.

The analysis of the data taken from the production line of powder packaging in bottles x 150 grams, the C_p and C_{pk} indices found indicate that statistically the packaging process is very precise, accurate and highly reliable to operate within the specified tolerance limits with the required accuracy and stability.

Blue line represents the mean of each subset of data taken from the production line and shows how the process mean changes over time.

Lead line or LC, called the Central Line, represents the mean of the process means, it is the reference point for comparing the means of the subgroups.

Red line is the upper limit and specification (USL) indicates the maximum expected value, if the process is under control, if a point of the averages exceeds this line, it indicates that there is a problem in the process.

The orange line is the lower specification limit (LSL), it indicates the minimum expected value if the process is under control, if a point of the averages falls below this line, it indicates that there is a problem in the process.

From the graph it can be deduced that all the subgroup means are within the control limits, there are natural fluctuations, but within the expected range, therefore it can be stated that the process is stable or the process is under control, i.e. the process complies with the established requirements. In addition, the means are quite close to the central line (LC), suggesting consistency and stability.

There are no out-of-specification points or large variations. Therefore, the process is stable and capable, producing results within the acceptable range for the customer, without the need for immediate adjustments.

Practical applications

The machine will have a potential application in various sectors, such as food and pharmaceutical, improving processes and ensuring the required accuracy in critical products. The design complies with the standards required for proper maintenance and sanitary control, ensuring the durability and usability of the equipment.

A. Design of a semi-automatic dosing machine for chocolates and truffles by weight [58] detail the design of a sanitary dosing machine for solid particles smaller than 300 µm, intended for the pharmaceutical and food industries.

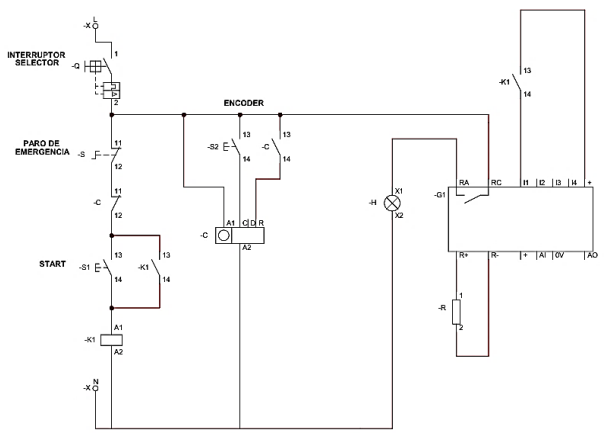


Fig. 8 Control diagram

The main objective is to achieve accurate and sanitary dosing, using software such as [59] and CADe-SIMU for design and simulation. Likewise, they describe the design process, the selection of materials, the applied regulations and the experimental validation, where they present the results of the design, including calculations of mass flow, hopper volume and discharge time. The machine is designed to be versatile, adaptable to different formats and semi-automatic, complying with national and international standards. Finally, the paper concludes by highlighting the practical applications, the contribution to the field of mechatronic engineering and the potential for improving industrial processes.

B. A prototype powder deposition system for an open selective laser sintering machine.

[60] indicate that commercial selective laser sintering (SLS) devices are equipped with their own integrated powder deposition systems (PDS), most of which operate on the principle of a piston containing powder together with a roller designed to distribute it evenly. Furthermore, they state that these systems are calibrated at the manufacturing stage and do not allow any relevant parameters related to powder deposition to be actively modified. Finally, they point out that, to enable such experimental evaluations, they conceptualized and fabricated a prototype of the PDS and in this prototype, the designed system is delineated and its functionalities are clarified.

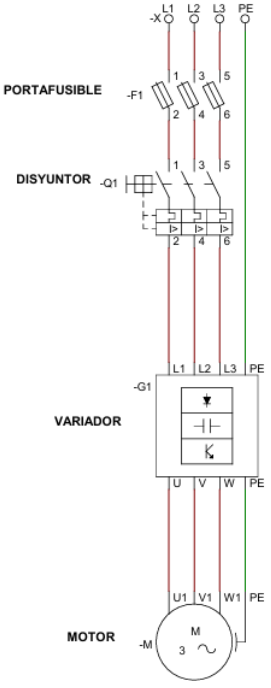


Fig. 9 Force Diagram

C. Design and simulation of an automatic grain dosing, packing and sealing machine.

[51] notes that agricultural production in Latin America, especially in Ecuador, faces challenges due to the lack of adequate machinery. To address this, they have designed and optimized a vertical flow dosing, packing and sealing (VFFS) machine for smallholder farmers. Where, this machine is designed to handle granular products from 2

to 20 mm, such as grains and legumes, with a simplified design and robust components of Ecuadorian origin. In their research, the design methodology is based on the framework of [61] who managed to use CAE software for structural, thermal and storage validations. They obtained their results from the simulations where they indicate that the machine will be able to dose, pack and seal these products complying with the established requirements.

D. Automation of a dosing machine. Case: Industrias Venado SA.

[51] points out that in the contemporary era, numerous dosing machines are equipped with outdated systems; however, operator safety and operational efficiency of these machines have progressively deteriorated over time. Furthermore, he mentions that it has become necessary and mandatory to explore novel alternatives that take advantage of existing technologies in the industry, thus facilitating the assembly of a control system that encompasses multiple machine characteristics and, at the same time, improves machine performance.

E. Design of dosing-sealing machine for powders and grains.

[62] state that in Ecuador, the production of machinery is limited, which forces companies to use artisanal methods or import machinery. For this reason, it is proposed to design equipment that meets the needs of entrepreneurs and is manufactured locally. As an example, he mentions the company ZARUCOFFEE, which automated its coffee packaging and sealing processes. Two devices were designed there: one accurately doses the coffee using containers and a stepper motor, and the other seals and codes the containers with a conveyor belt and hot clamping systems. Likewise, the design was based on the needs of the company and a market analysis. He concludes, noting that the first device dispenses coffee in 12-16 seconds, and the second seals containers at a rate of 8-16 per minute. The devices meet the company's needs, are competitive in price and are produced locally, boosting employment and national development.

F. Machine learning approach for carrier surface design in carrier-based dry powder inhalation.

[63] employed a machine learning methodology to evaluate the influence of operational and design parameters on the efficiency of dry powder inhalation. Such that, data regarding the emitted dose and fine particle ratio were meticulously extracted from the existing sample comprising various drug and carrier combinations. Likewise, they indicate that the carrier surface characteristics were obtained by image analysis of documented scanning electron microscopy (SEM) images. They then formulated comprehensive models that integrate artificial neural networks with genetic algorithms to determine both the emitted dose and the proportion of fine particles. Finally, they proposed design strategies for the carrier surface to improve fine particle fractions.

G. Automatic filling and sealing machine of PET type container for powdered condiments.

[64] point out that this project focuses on the design of a machine for condiment packaging, considering the granulometry, the design of the container and the physical structure of the mechanical systems. The stability of the machine model is analyzed and a control system is implemented to facilitate its use. Likewise, they indicate that the project arises from the observation of the lack of machinery for food packaging in the Colombian industry, which hinders the automation of SMEs. Finally, they mention that the appendices include information on mechanical drawings, flow charts, technical data sheets and the machine operation manual.

H. Reverse engineering and design of the automation of a powder doser, using load cell through atmega microcontroller for the company Jacs.

[65] describes the analysis and redesign of a powder dosing apparatus using reverse engineering and automation. Then examined reverse engineering methodologies to analyze a foreign dosing machine. So, performed a comprehensive analysis of the systems (operational, physical and electronic) and then identified advantages and disadvantages. The reverse engineering data was also used to redesign the dispenser, improving each mechanism. Then developed a mechanical and electronic redesign with the corresponding software. So, built a prototype and performed tests to evaluate its operational effectiveness, including the control system, weight sensor, additional components, program sequence and a comprehensive test of all components. Finally, the redesign was deemed successful after simulation and testing.

CONCLUSIONS

- The machine was designed to allow precise dosing of solid particles with a diameter of less than 300 µm, complying with hygiene and sanitary quality standards.
- The designed machine will be capable of adjusting to different container and product formats, demonstrating flexibility in its use for various types of powders.
- Through partial automation and ergonomic design, the machine will reduce operation time and costs associated with batching, minimizing material waste.
- The design of the machine after having undergone a validation has achieved compliance with national and international regulations (NMP 02 2008 and NTS No 071-MINSA/DIGESA V0.1) and this guarantees safety and quality in the dosing process.
- The machine will be a useful tool for the development of practices and research in engineering courses and will promote interdisciplinary training and the generation of new knowledge for students of the FIE-UNFV.
- Likewise, the data obtained will contribute to the design of future dosing equipment, setting a precedent in technological innovation for the handling of pulverized solids.
- The machine has a potential application in various sectors, such as food and pharmaceutical, improving processes and ensuring the required accuracy in critical

products. The design complies with the standards required for proper maintenance and sanitary control, ensuring the durability and usability of the equipment.

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Jaime Antonio Cancho Guisado (coresponding author)
ORCID: ID: 0000-0002-7476-6979
Federico Villarreal National University, Peru
e-mail: jcancho@unfv.edu.pe

José Moro Pisco
ORCID: ID: 0000-0003-0061-6932
Federico Villarreal National University, Peru
e-mail: jmoro@unfv.edu.pe

José Julio Rodríguez Figueroa
ORCID: ID: 0000-0002-3672-1526
Federico Villarreal National University, Peru
e-mail: jrodriguez@unfv.edu.pe

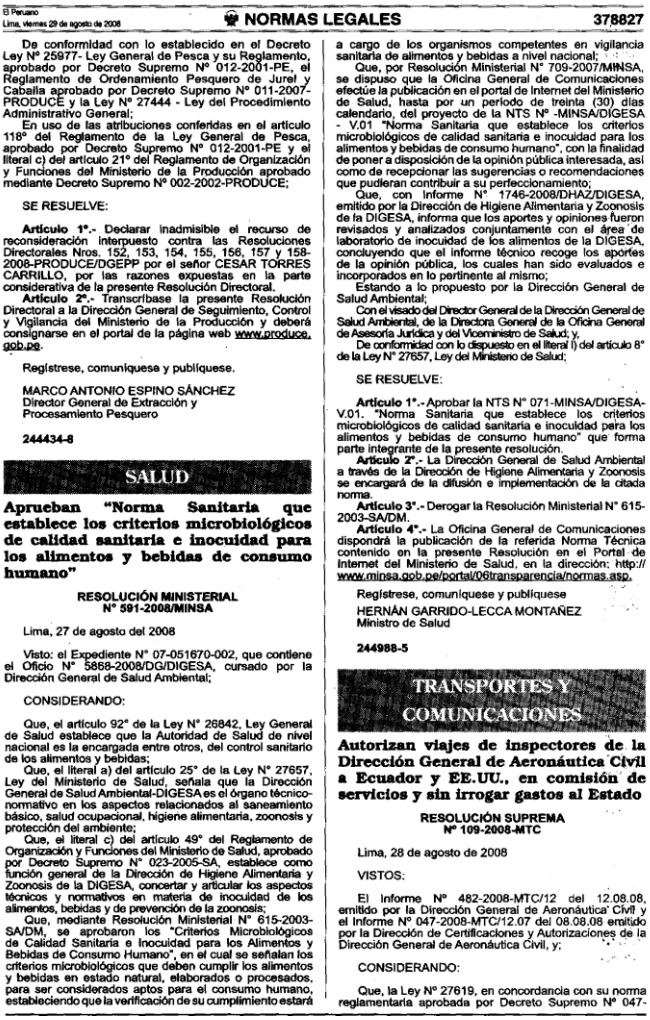
ANNEXES

Annex A: Quality Table

TABLA DE CALIDAD

Observaciones en la muestra, n	Factores para límites de control			Factores para línea central		Factores para límites de control				Factores para línea central		Factores para límites de control				
	A	A_2	A_3	c_4	$1/c_4$	B_1	B_2	B_3	B_4	d_2	$1/d_2$	d_3	D_1	D_2	D_3	D_4
2	2.121	1.880	2.659	0.7979	1.2533	0	3.267	0	2.606	1.128	0.8865	0.853	0	3.686	0	3.267
3	1.732	1.023	1.954	0.8862	1.1284	0	2.568	0	2.276	1.693	0.5907	0.888	0	4.358	0	2.574
4	1.500	0.729	1.628	0.9213	1.0854	0	2.266	0	2.088	2.059	0.4857	0.880	0	4.698	0	2.282
5	1.342	0.577	1.427	0.9400	1.0638	0	2.089	0	1.964	2.326	0.4299	0.864	0	4.918	0	2.114
6	1.225	0.483	1.287	0.9515	1.0510	0.030	1.970	0.029	1.874	2.534	0.3946	0.848	0	5.078	0	2.004
7	1.134	0.419	1.182	0.9594	1.04230	0.118	1.882	0.113	1.806	2.704	0.3698	0.833	0.204	5.204	0.076	1.924
8	1.061	0.373	1.099	0.9650	1.0363	0.185	1.815	0.179	1.751	2.847	0.3512	0.820	0.388	5.306	0.136	1.864
9	1.000	0.337	1.032	0.9693	1.0317	0.239	1.761	0.232	1.707	2.970	0.3367	0.808	0.547	5.393	0.184	1.816
10	0.949	0.308	0.975	0.9727	1.0281	0.284	1.716	0.276	1.669	3.078	0.3249	0.797	0.687	5.469	0.223	1.777
11	0.905	0.285	0.927	0.9754	1.0252	0.321	1.679	0.313	1.637	3.173	0.3152	0.787	0.811	5.535	0.256	1.744
12	0.866	0.266	0.886	0.9776	1.0229	0.354	1.646	0.346	1.610	3.258	0.3069	0.778	0.922	5.594	0.283	1.717
13	0.832	0.249	0.850	0.9794	1.0210	0.382	1.618	0.374	1.585	3.336	0.2998	0.770	1.025	5.647	0.307	1.693
14	0.802	0.235	0.817	0.9810	1.0194	0.406	1.594	0.399	1.563	3.407	0.2935	0.763	1.118	5.696	0.328	1.672
15	0.775	0.223	0.789	0.9823	1.0180	0.428	1.572	0.421	1.544	3.472	0.2880	0.756	1.203	5.741	0.347	1.653
16	0.750	0.212	0.763	0.9835	1.0168	0.448	1.552	0.440	1.526	3.532	0.2831	0.750	1.282	5.782	0.363	1.637
17	0.728	0.203	0.739	0.9845	1.0157	0.466	1.534	0.458	1.511	3.588	0.2787	0.744	1.356	5.820	0.378	1.622
18	0.707	0.194	0.718	0.9854	1.0148	0.482	1.518	0.475	1.496	3.640	0.2747	0.739	1.424	5.856	0.391	1.608
19	0.688	0.187	0.698	0.9862	1.0140	0.497	1.503	0.490	1.483	3.689	0.2711	0.734	1.487	5.891	0.403	1.597
20	0.671	0.180	0.680	0.9869	1.0133	0.510	1.490	0.504	1.470	3.735	0.2677	0.729	1.549	5.921	0.415	1.585
21	0.655	0.173	0.663	0.9876	1.0126	0.523	1.477	0.516	1.459	3.778	0.2647	0.724	1.605	5.951	0.425	1.575
22	0.640	0.167	0.647	0.9882	1.0119	0.534	1.466	0.528	1.448	3.819	0.2618	0.720	1.659	5.979	0.434	1.566
23	0.626	0.162	0.633	0.9887	1.0114	0.545	1.455	0.539	1.438	3.858	0.2592	0.716	1.710	6.006	0.443	1.557
24	0.612	0.157	0.619	0.9892	1.0109	0.555	1.445	0.549	1.429	3.895	0.2567	0.712	1.759	6.031	0.451	1.548
25	0.600	0.153	0.606	0.9896	1.0105	0.565	1.435	0.559	1.420	3.931	0.2544	0.708	1.806	6.056	0.459	1.541

Annex B: NTS 071-MINSA/DIGESA: Establishes the important microbiological criteria for food and beverages



El Peruano
Lima, viernes 29 de agosto de 2008

NORMAS LEGALES 378827

De conformidad con lo establecido en el Decreto Ley Nº 25977- Ley General de Pesca y su Reglamento, aprobado por Decreto Supremo Nº 012-2001-PE, el Reglamento de Ordenamiento Pesquero de Jurel y Caballa aprobado por Decreto Supremo Nº 011-2007-PRODUCE y la Ley Nº 27444 - Ley del Procedimiento Administrativo General;

En uso de las atribuciones conferidas en el artículo 118º del Reglamento de la Ley General de Pesca, aprobado por Decreto Supremo Nº 012-2001-PE y el literal c) del artículo 21º del Reglamento de Organización y Funciones del Ministerio de la Producción aprobado mediante Decreto Supremo Nº 002-2002-PRODUCE;

SE RESUELVE:

Artículo 1º.- Declarar inadmisible el recurso de reconsideración interpuesto contra las Resoluciones Directorales Nros. 152, 153, 154, 155, 156, 157 y 158-2008-PRODUCE/DGEPP por el señor CESAR TORRES CARRILLO, por las razones expuestas en la parte considerativa de la presente Resolución Directoral.

Artículo 2º.- Transcríbase la presente Resolución Directoral a la Dirección General de Seguimiento, Control y Vigilancia del Ministerio de la Producción y deberá consignarse en el portal de la página web www.produce.gob.pe.

Regístrese, comuníquese y publíquese.

MARCO ANTONIO ESPINO SÁNCHEZ
Director General de Extracción y Procesamiento Pesquero

244434-8

SALUD

Aprueban "Norma Sanitaria que establece los criterios microbiológicos de calidad sanitaria e inocuidad para los alimentos y bebidas de consumo humano"

RESOLUCIÓN MINISTERIAL Nº 591-2008/MINSA

Lima, 27 de agosto del 2008

Visto: el Expediente Nº 07-051670-002, que contiene el Oficio Nº 5868-2008/DG/DIGESA, cursado por la Dirección General de Salud Ambiental;

CONSIDERANDO:

Que, el artículo 92º de la Ley Nº 26842, Ley General de Salud establece que la Autoridad de Salud de nivel nacional es la encargada entre otros, del control sanitario de los alimentos y bebidas;

Que, el literal a) del artículo 25º de la Ley Nº 27657, Ley del Ministerio de Salud, señala que la Dirección General de Salud Ambiental-DIGESA es el órgano técnico-normativo en los aspectos relacionados al saneamiento básico, salud ocupacional, higiene alimentaria, zoonosis y protección del ambiente;

Que, el literal c) del artículo 49º del Reglamento de Organización y Funciones del Ministerio de Salud, aprobado por Decreto Supremo Nº 023-2005-SA, establece como función general de la Dirección de Higiene Alimentaria y Zoonosis de la DIGESA, concertar y articular los aspectos técnicos y normativos en materia de inocuidad de los alimentos, bebidas y de prevención de la zoonosis;

Que, mediante Resolución Ministerial Nº 615-2003-SA/DM, se aprobaron los "Criterios Microbiológicos de Calidad Sanitaria e Inocuidad para los Alimentos y Bebidas de Consumo Humano", en el cual se señalan los criterios microbiológicos que deben cumplir los alimentos y bebidas en estado natural, elaborados o procesados, para ser considerados aptos para el consumo humano, estableciendo que la verificación de su cumplimiento estará a cargo de los organismos competentes en vigilancia sanitaria de alimentos y bebidas a nivel nacional;

Que, por Resolución Ministerial Nº 709-2007/MINSA, se dispuso que la Oficina General de Comunicaciones efectúe la publicación en el portal de Internet del Ministerio de Salud, hasta por un período de treinta (30) días calendario, del proyecto de la NTS Nº -MINSA/DIGESA - V.01 "Norma Sanitaria que establece los criterios microbiológicos de calidad sanitaria e inocuidad para los alimentos y bebidas de consumo humano", con la finalidad de poner a disposición de la opinión pública interesada, así como de recepcionar las sugerencias o recomendaciones que pudieran contribuir a su perfeccionamiento;

Que, con Informe Nº 1746-2008/DHAZ/DIGESA, emitido por la Dirección de Higiene Alimentaria y Zoonosis de la DIGESA, informa que los aportes y opiniones fueron revisados y analizados conjuntamente con el área de laboratorio de inocuidad de los alimentos de la DIGESA, concluyendo que el informe técnico recoge los aportes de la opinión pública, los cuales han sido evaluados e incorporados en lo pertinente al mismo;

Estando a lo propuesto por la Dirección General de Salud Ambiental;

Con el visado del Director General de la Dirección General de Salud Ambiental, de la Directora General de la Oficina General de Asesoría Jurídica y del Viceministro de Salud; y,

De conformidad con lo dispuesto en el literal l) del artículo 8º de la Ley Nº 27657, Ley del Ministerio de Salud;

SE RESUELVE:

Artículo 1º.- Aprobar la NTS Nº 071-MINSA/DIGESA-V.01. "Norma Sanitaria que establece los criterios microbiológicos de calidad sanitaria e inocuidad para los alimentos y bebidas de consumo humano" que forma parte integrante de la presente resolución.

Artículo 2º.- La Dirección General de Salud Ambiental a través de la Dirección de Higiene Alimentaria y Zoonosis se encargará de la difusión e implementación de la citada norma.

Artículo 3º.- Derogar la Resolución Ministerial Nº 615-2003-SA/DM.

Artículo 4º.- La Oficina General de Comunicaciones dispondrá la publicación de la referida Norma Técnica contenido en la presente Resolución en el Portal de Internet del Ministerio de Salud, en la dirección: http://www.minsa.gob.pe/portal/06transparencia/normas.asp.

Regístrese, comuníquese y publíquese

HERNÁN GARRIDO-LECCA MONTAÑEZ
Ministro de Salud

244988-5

TRANSPORTES Y COMUNICACIONES

Autorizan viajes de inspectores de la Dirección General de Aeronáutica Civil a Ecuador y EE.UU., en comisión de servicios y sin irrogar gastos al Estado

RESOLUCIÓN SUPREMA Nº 109-2008-MTC

Lima, 28 de agosto de 2008

VISTOS:

El Informe Nº 482-2008-MTC/12 del 12.08.08, emitido por la Dirección General de Aeronáutica Civil y el Informe Nº 047-2008-MTC/12.07 del 08.08.08 emitido por la Dirección de Certificaciones y Autorizaciones de la Dirección General de Aeronáutica Civil, y;

CONSIDERANDO:

Que, la Ley Nº 27619, en concordancia con su norma reglamentaria aprobada por Decreto Supremo Nº 047-

Annex C: ISO 468: Specifies Surface roughness requirements.

International Standard ISO 468

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Surface roughness — Parameters, their values and general rules for specifying requirements

0 Introduction

This International Standard replaces ISO/R 468, *Surface roughness*, as far as the list of recommended parameters, their values and general rules for specifying requirements are concerned.

Terminology relevant to this International Standard is given in ISO 4287/1.

1 Scope and field of application

This International Standard relates to the surface roughness of products manufactured of materials and by methods that would normally yield surface roughness parameters within the following ranges of values :

0,008 µm ≤ R_a ≤ 400 µm

0,025 µm ≤ R_z and R_y ≤ 1 600 µm

0,002 mm ≤ S and S_m ≤ 12,5 mm

It indicates the terms to be used for the parameter, lay and type of surface, and gives general rules for specifying surfaces.

NOTE – The use of surface parameters other than those specified in this International Standard is also permitted, but in such cases they will need to be clearly defined.

This International Standard does not relate to surfaces whose characteristics make it impossible to check surface roughness by the methods normally used.

2 References

ISO 1302, *Technical drawings — Method of indicating surface texture on drawings.*

ISO 4287/1, *Surface roughness — Terminology — Part 1: Surface and its parameters.*[1]

3 Definitions

Terms used in this International Standard are defined in ISO 4287/1 (i.e. surface roughness, sampling length l; mean square mean line; profile departure y; line of profile peaks; line of profile valleys; spacing of local peaks of the profile; spacing of profile irregularities; arithmetical mean deviation of the profile R_a; ten point height of irregularities R_z; maximum height of the profile R_y; mean spacing of profile irregularities S_m; mean spacing of local peaks of the profile S; profile bearing length η_p; profile bearing length ratio t_p; profile section level c).

4 General rules for specifying requirements for surface roughness

4.1 General directives

Requirements for the surface roughness should be specified proceeding from its functional application to guarantee the given quality of products. If not required the surface roughness should not be specified and the roughness of such surfaces should not be inspected.

4.2 Surface defects

Requirements for surface roughness are not applicable to surface defects; therefore, during the inspection of the surface roughness the surface defects (for example, scratches) should not be taken into account.

If necessary, the requirements for surface defects should be specified separately.

4.3 Structure of requirements

Requirements for the surface roughness should be specified by indicating the numerical value (maximum, minimum, nominal or the range of values) of the surface roughness parameter (or several parameters) and the value of sampling length on which the parameter is to be determined.

These numerical values of surface roughness parameters refer to sections normal to the geometrical surface. If the direction of these sections along the surface corresponds to maximum values of height parameters (R_a, R_z, R_y) for the given surface, it should not be specified. In other cases the direction of the section should be specified.

Additional requirements for the surface lay, the type or sequence of types of machining, the roughness of various areas should be specified when necessary, for example, requirements for surface areas limited by large pores of the porous material for sections of surface cuts having essentially different irregularities.

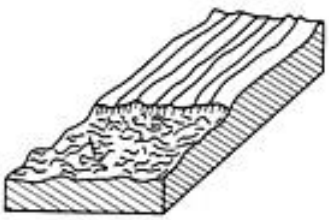


Figure – Surface areas having different types of irregularities

4.4 Expression of nominal values

When using nominal numerical values of surface roughness parameters the admissible deviations of the mean values shall be expressed as a percentage.

Deviations may be symmetrical or asymmetrical.

5 Surface roughness parameters

One or several of the surface roughness parameters listed below should be used for the specification of surface roughness.

R_a : arithmetical mean deviation of the profile;

R_z : height of the profile irregularities in ten points;

R_y : maximum height of the profile;

S_m : mean spacing of profile irregularities;

S : mean spacing of local peaks of the profile;

t_p : profile bearing length ratio.

NOTES

1 Minimum spacing of local peaks (valleys) of the profile which is to be taken into consideration is specified as 1 % of the sampling length l.

2 Minimum height of profile peaks (valleys, local peaks, local valleys), which is to be taken into consideration, is specified as 10 % of R_z.

6 Surface lay

Types of the surface lay are those given in table 2 of ISO 1302.

7 Numerical values of parameters

Numerical values of surface roughness parameters (maximum, minimum, nominal or the range of values) are to be selected from those given in tables 1, 2, 3 and 4.

8 Numerical values of the profile section level, c

Values of the profile section level, c, are to be expressed in linear values in micrometres or as a percentage of R_z to be selected from the following series : 5; 10; 15; 20; 25; 30; 40; 50; 60; 70; 75; 80; 90 %.

9 Numerical values of sampling length l

Values of the sampling length, l, are to be selected from the following series : 0,08; 0,25; 0,8; 2,5; 8; 25 mm.

Surface roughness — Parameters, their values and general rules for specifying requirements