Design and Evaluation of a Device for Reconstitution of Lyophilized Medications in the Hospital Setting

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***Abstract*—The procedure for reconstituting powdered (lyophilized) medications in hospital settings involves shaking the medication with a diluent, which poses risks of ergonomic injuries to healthcare personnel and incomplete dosing of patients. This study addresses the development of a low-cost mixing device designed for the reconstitution of powdered medications in hospital settings, with the aim of evaluating the reliability of the process compared to manual methods, ensuring the occupational safety of nursing staff, and achieving more consistent solutions. To achieve this objective, the requirements of the healthcare personnel at Hospital III Goyeneche were compiled. The device was then designed using a crank-and-crank mechanism and 3D modeling software; this mechanism allows the powder vials to be shaken more effectively than with the manual method. The prototype was experimentally evaluated using vials of ceftriaxone and PIPTABAC. The results show that the device improves the consistency of the dilution, reduces the need for manual intervention by healthcare personnel, and increases the reliability of the process for the evaluated medications, at a cost that is affordable for hospital settings with limited resources, demonstrating that it is possible to improve the procedure using a low-cost solution compared to high-cost automated systems.**

***Keywords*—design, vials, dilution, hospital settings, reconstitution, 3D modeling, lyophilized**

I. Introduction

Currently, in hospitals, the procedure for preparing freeze-dried medications consists of two phases. First, in the reconstitution phase, the sterile diluent is added to the freeze-dried medications and mixed by manual agitation until a homogeneous solution is obtained. Then, in the second dilution phase, the previous solution is taken and dissolved in a larger volume so that it can be administered to patients intravenously or intramuscularly [1]. It is in the reconstitution phase that healthcare personnel routinely shake the medications manually, which can take a long time, causing ergonomic injuries to staff [2]. In addition, increases from 1.8% to 5.4% were identified in cases of incorrectly prepared medications due to work overload [3]. Similarly, in a study conducted by Campino *et al.* [4], it was found that 5 out of 6 reconstitution procedures were not completed correctly. In a systematic study on medication preparation errors conducted by Hedlund *et al.* [5], up to 49% of solutions were found to be incorrectly diluted. This highlights the need to strengthen medication preparation procedures [6], focusing on the reconstitution phase to obtain homogeneous solutions, safeguarding the ergonomic safety of healthcare personnel, and improving patient treatments.

In response to this situation in hospitals and health centers, measures have been implemented ranging from collaborative work between pharmacists and nurses [7, 8] to the incorporation of advanced technologies and robotic systems for drug preparation [9, 10]. He *et al.* [11] and Jin *et al.* [12] have designed dispensing robots that include medication preparation in their systems, reducing preparation errors. Dispensing robots have also been implemented in pharmaceutical settings [13, 14] to improve safety and operational efficiency in hospitals [15]. In addition, studies on the incorporation and evaluation of robots in the preparation of drugs for chemotherapy treatments [16, 17] demonstrate greater precision and accuracy in dose preparation compared to manual procedures [18]. Similarly, KIRO Oncology [19] and PHARMADUCT [20] robots are used for the preparation of cytotoxic drugs used in chemotherapy. Likewise, the APOTECAchemo robot is used for the preparation of drugs in intravenous procedures [21]. These studies show that the application of robotics optimizes drug preparation procedures, including reconstitution as part of their procedures. However, these robotic systems do not specifically assist in the drug compounding process.

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Furthermore, the high costs of purchase, operation, and maintenance make their implementation unaffordable for low-resource hospitals [22–24].

On the other hand, in recent years, 3D printing technology has been incorporated into hospital settings, enabling advances in the development of customized and affordable medical devices. Orthoses and prostheses adapted to patients' anatomy have been manufactured [25], and clinical 3D printing services have been implemented [26], facilitating the production of clinical tools for surgical procedures, anatomical models, and implants [27]. Nowak *et al.* [28] developed a portable 3D-printed device called "Inkwell" capable of performing thin blood smears for processing laboratory samples. This research reflects how 3D printing is being implemented in more areas of the healthcare sector and demonstrates its ability to generate devices adapted to the work of healthcare personnel at a low cost. However, the application of this technology to the development of devices for reconstituting freeze-dried medications has received little attention.

In this article, we present a new, low-cost device for reconstituting powdered medications in hospital settings, adapted to the tasks of healthcare personnel and economically accessible. This study aims to evaluate whether the proposed device improves the consistency of dilutions and the reliability of the reconstitution process compared to manual methods, using ceftriaxone and PIPTABAC as case studies. Its design was based on the needs and work routine of healthcare personnel, reducing the risk of ergonomic injuries and optimizing medication preparation. It was evaluated through agitation tests with ceftriaxone and PIPTABAC, determining its effectiveness and duration. It was compared with the manual procedure, highlighting our device for its high effectiveness in quickly reconstituting of the evaluated medications, demonstrating its potential to improve process efficiency.

II. Design Requirements

This section presents the design requirements for the development of a machine for reconstituting freeze-dried medications, with a specific focus on medications selected for their frequent use at Hospital III Goyeneche, such as ceftriaxone and PIPTABAC. These requirements are based on the needs and requirements of healthcare personnel.

Nursing staff are responsible for preparing medications according to the patient's condition. In the case of lyophilized medications, they come in the form shown in Fig. 1, with dimensions that comply with ISO 8362-1. For this study, sizes 15R and 20R were used, corresponding to the selected medications Ceftriaxone and PIPTABAC, respectively. The manual medication preparation procedure is divided into two phases, as shown in Fig. 2. In the first phase, called "reconstitution," the compatible diluent is added to the medication vial using a syringe. then the staff shakes the vial in different directions until a homogeneous mixture is visible. In the second phase, called "dilution," the homogeneous mixture is extracted from the vial and diluted in a larger volume to deliver the appropriate dose of medication to the patient.

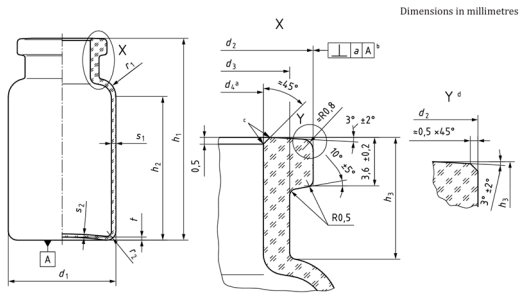

Fig. 1. Dimensions of freeze-dried medicine containers according to IS O 8362-1 [29].

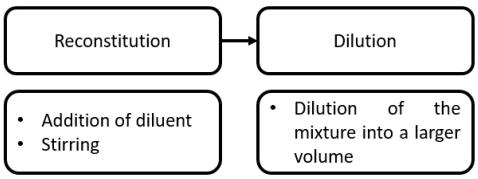

Fig. 2. Procedure for preparing freeze-dried medicines.

It is during the reconstitution phase that healthcare personnel manually shake the medications, exposing themselves to ergonomic injuries. In addition, work overload leads to errors in shaking the medications, resulting in non-homogeneous mixtures, which leads to waste of medication and administration of incomplete treatments to patients, complicating their speedy recovery.

Next, to identify the needs and requirements of healthcare personnel, we conducted interviews and surveys with nurses at Hospital III Goyeneche to obtain information about their experience with preparing freeze-dried medications. Table I shows the design requirements established. Eight requirements were defined: biosafety, maintainability, portability, ergonomics, operation, dissolution efficiency, fastening system, and low cost.

TABLE I. List of Design Requirements

Requirements	Description
Biosecurity	Designed with an easy-to-disinfect surface and a secure fastening system that prevents spills and medication contamination.
Maintainability	Easy maintenance and cleaning for healthcare personnel.
Portability	Compact size and weight less than 2.5 kg.
Ergonomics	Easy to use and convenient to transport in nursing carts.
Drive	High-speed DC motor drive system that ensures uniform dissolution.
Dissolution efficiency	Homogeneous dissolution without visible lumps, measured in %.
Fastening system	Adjustable fastening system for type 15R, and 20R containers.
Low cost	Low manufacturing cost (<100 USD).

III. Mechanical Design

Based on the design requirements in Table I, this section presents the SolidWorks design of the machine for reconstituting freeze-dried medicines. First, based on the

standardized dimensions in ISO 8362-1 in Table II, the 10R, 15R, and 20R medicine containers are designed as shown in Fig. 3, considering that the 15R and 20R sizes correspond to the drugs selected for this study (Ceftriaxone and PIPTABAC). Identical dimensions are identified in the head diameter of the three containers (D2 = 20 mm), the vial neck diameter (D3) ranges from 16.5 to 17.5 mm, similar dimensions for the height (H3) ranging from 9 to 10 mm. These dimensions determine the geometry of the clamp that holds the vials during shaking. On the other hand, the length (H1) determines the size of the rail and the free space for shaking.

TABLE II. STANDARDIZED DIMENSIONS (MM) OF 10R, 15R AND 20R VIALS ACCORDING TO ISO 8362-1 [29]

Designation of vial size	Maximum capacity ml	a	D1	D2	D3	D4	H1	H2	H3	R1	R2	S1	S2	T
10R	13.5	1.2	24.0	20.0	16.5	12.6	45.0	30.0	9.0	4.0	2.0	1.0	0.7	0.7
15R	19.0	1.2	24.0	20.0	16.5	12.6	60.0	45.0	9.0	4.0	2.0	1.0	0.7	0.7
20R	26.0	1.5	30.0	20.0	17.5	12.6	55.0	35.0	10.0	5.5	2.5	1.2	0.7	1.0

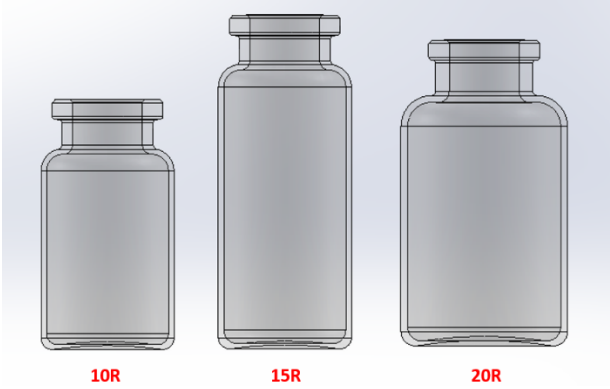

Fig. 3. 3D design of containers designated as sizes 10R, 15R, and 20R.

Next, the reconstitution device is designed, divided into three systems as shown in Fig. 4: the clamping system (push button, plunger, and clamp), the transmission system (connecting rod, crank, motor), and the structural system (rail, frame, and protective casings). First, in the design of the clamping system, the clamp is modeled based on the shape of standardized vials. It has two fingers with an enveloping geometry for better pressure distribution during clamping. Between the clamp and the vials, a flexible sheet is designed to cushion during closure, which prevents damage to the containers. The clamp is opened by manually pressing the mechanical push button, designed with two 45º inclined side rails that, when in contact with the clamps, transmit the movement and open the clamp. To close the clamp, the push button returns to its position with a compression spring. The structure that houses the button and the clamp is the plunger, which is designed with a 3 mm cavity between the vial cap and the structure to prevent contamination of the medication. The plunger moves linearly along the rail over a distance of 30 mm to shake the medication. Then, in the design of the transmission system, the connecting rod is designed, which transmits the movement to the piston coupled at one of its ends. The connecting rod is 100 mm long. The crank, with a radius of 15 mm, is attached to the other end and transforms the rotational movement into linear movement. A D-shaped cavity is designed in the center to attach the gear motor shaft. Finally, in the design of the structural system, the rail is designed to act as a linear guide for the precise movement of the piston. At one end, an opening is designed to insert the piston during assembly, and at the other end, a 3-point coupling is designed to install the motor frame. The frame is designed to couple the gear motor to the system, ensuring correct alignment and minimizing vibrations during the operation of the transmission system. The design of the protective casings houses the various components of the machine, protecting them from damage or external contaminants. Ventilation slots were designed into the structure to prevent the motor from overheating, and chamfered edges were also designed for greater user safety.

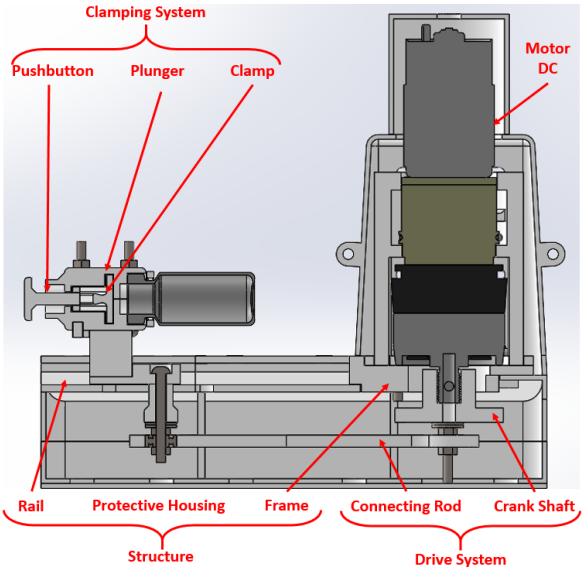

Fig. 4. Component design in SolidWorks software.

The proposed design offers the following advantages over the manual method. First, the clamping system allows the vials to be securely held in place, as it was designed to conform to their geometry, thereby preventing irregular movements and non-homogeneous dissolutions. Furthermore, the crank-and-connecting-rod mechanism generates a repetitive and controlled oscillatory motion; its ability to sustain this motion over an extended period allows for consistent solutions compared to the manual method. Additionally, this device minimizes healthcare workers' exposure to repetitive shaking activities, reducing the risk of ergonomic injuries. Finally, the use of 3D printing allows the prototype to be manufactured at a low cost, making it more accessible in regions with limited resources.

IV. Simulation by Finite Element Analysis

This section presents the Finite Element Analysis (FEA) simulation of the components belonging to the drug reconstitution machine, to determine the mechanical characteristics of its components and ensure that the machine can be manufactured and operated safely. Finite element analysis is used to check the design of structures or mechanisms to correct faults or optimize designs prior to manufacturing [30]. That is why we use this analysis on the components of the drug reconstitution machine, identifying critical stresses and deformations as shown in Fig. 5, in order to obtain an optimal design. We used SolidWorks software with its Simulation tool and applied PETG material. We performed 1 to 3 iterations on the components until we obtained an optimal design.

For the FEA modeling, the torque of the machine's gearmotor was taken into account to determine the loads on the mechanism. The maximum torque of the motor is 30 kg·cm (2.94 Nm). The relationship between the torque and the force transmitted to the connecting rod piston is defined by Eq. (1), where "T" is the driving torque, "F" is the force on the piston, "b" is the length of the crank, "a" is the length of the connecting rod, and "θ" is the crank angle.

$$T = -F \times b \times \sin\theta - \frac{F \times b^2 \times \sin\theta \times \cos\theta}{\sqrt{a^2 - b^2 \times (\sin\theta)^2}} \quad (1)$$

Next, a crank angle of 90° was selected, corresponding to the maximum lever arm; this value was substituted into Eq. (1), and the equation was simplified as shown in Eq. (2). Substituting the torque of 2.94 Nm and the crank length of 0.015 m yields a force of 196 N.

$$F = T/b \quad (2)$$

This force is applied along the piston rod axis, in the axial direction along its travel path, and under compression. It is also transmitted through the connecting rod to the other components of the mechanism in the same direction. In addition, boundary conditions and simulation parameters were established to reproduce the actual behavior in the FEA model. Although the force varies with angular position, this value allows the FEA simulation to be generated, based on the engine's technical specifications and the behavior of the connecting rod-crank mechanism.

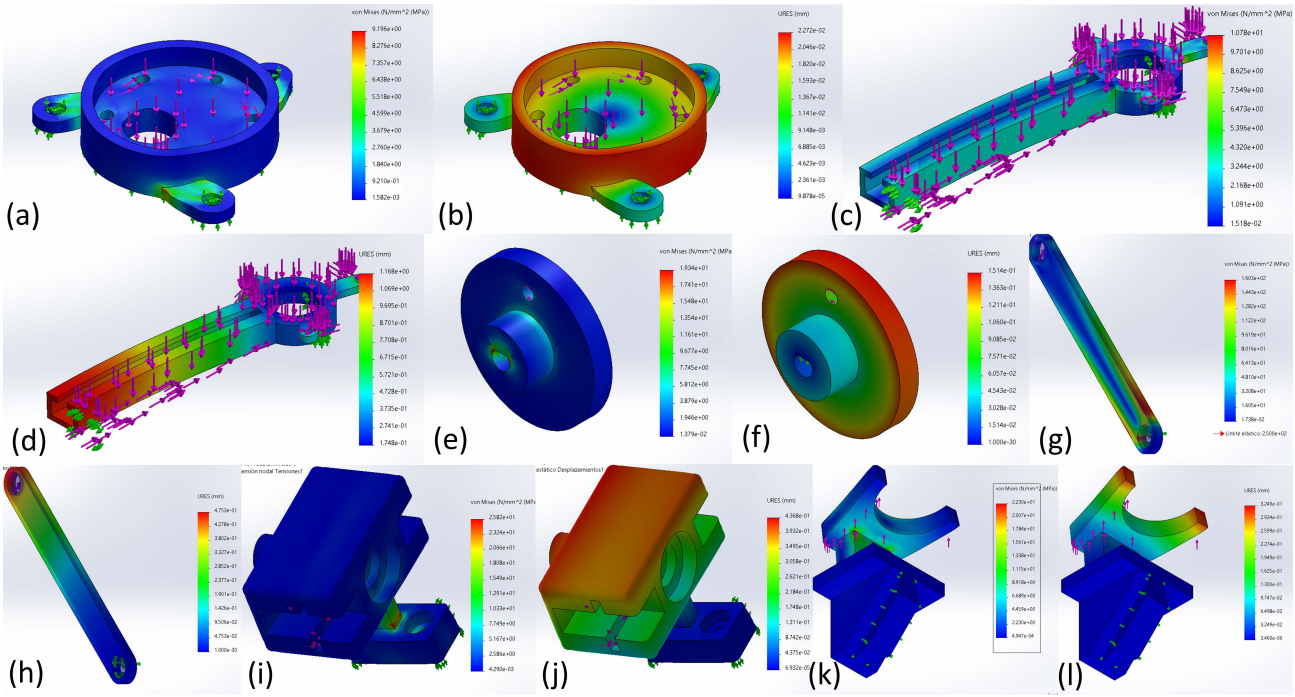

Fig. 5. Finite element analysis (FEA) applied to components of a drug reconstitution machine: (a) stress on frame; (b) deformation on frame; (c) stress on rail; (d) deformation on rail; (e) stress on crank; (f) deformation on crank; (g) stress on connecting rod; (h) deformation on connecting rod; (i) stress on plunger; (j) deformation on plunger; (k) stress on clamp; (l) deformation on clamp.

For the frame, the maximum stress of 9.196 MPa is generated at the coupling lugs joint, as shown in Fig. 5(a), and the maximum deformation is 0.02272 mm in the circumferential direction, as shown in Fig. 5(b). For the rail, the maximum stress is 10.78 MPa at the connection of the lugs, as shown in Fig. 5(c), and the maximum deformation is 1.168 mm at one end of the rail, as shown in Fig. 5(d). For the crank, the maximum stress is 19.34 MPa at the crank joint where the connecting rod is attached, as shown in Fig. 5(e), and the maximum deformation is 0.1514 mm along the outer circumference of the crank, as shown in Fig. 5(f). For the connecting rod, the material was changed to ASTM A36 steel. The maximum stress is 160.03 MPa at the ends of the connecting rod, as shown in Fig. 5(g). The maximum deformation is 0.4753 mm at the end of the connecting rod, as shown in Fig. 5(h). For the plunger, the maximum stress is 25.82 MPa at the joint between the sliding part that goes

to the rail and the plunger structure, as shown in Fig. 5(i). The maximum deformation is 0.4368 mm at the top of the plunger, as shown in Fig. 5(j). For the clamp of the clamping system, the maximum stress is 22.3 MPa located between the joint of the finger and the structure of the clamp, as shown in Fig. 5(k). The maximum deformation is 0.3249 mm in the clamp, as shown in Fig. 5(l).

This analysis shows that the design is safe in terms of strength and rigidity. Regarding strength, the safety factors are greater than 2.0, where the critical components are the connecting rod with a safety factor of 2.495 and the piston structure with a safety factor of 2.219. Regarding rigidity, the deformations in most components are less than 1 mm, where the critical component is the rail, with a deformation of up to 1.168 mm. Given this, prior to manufacturing, 3 mm thick columns spaced 77 mm apart were designed into the protective casing. These columns come into contact with the lower part of the rail, minimizing critical deformation.

V. Dynamic Mechanism Simulation

This section presents the dynamic simulation of the crank-connecting rod transmission system as shown in Fig. 6, using the SolidWorks motion tool to determine the stroke, speed, and acceleration of the plunger during the agitation of the lyophilized medicine.

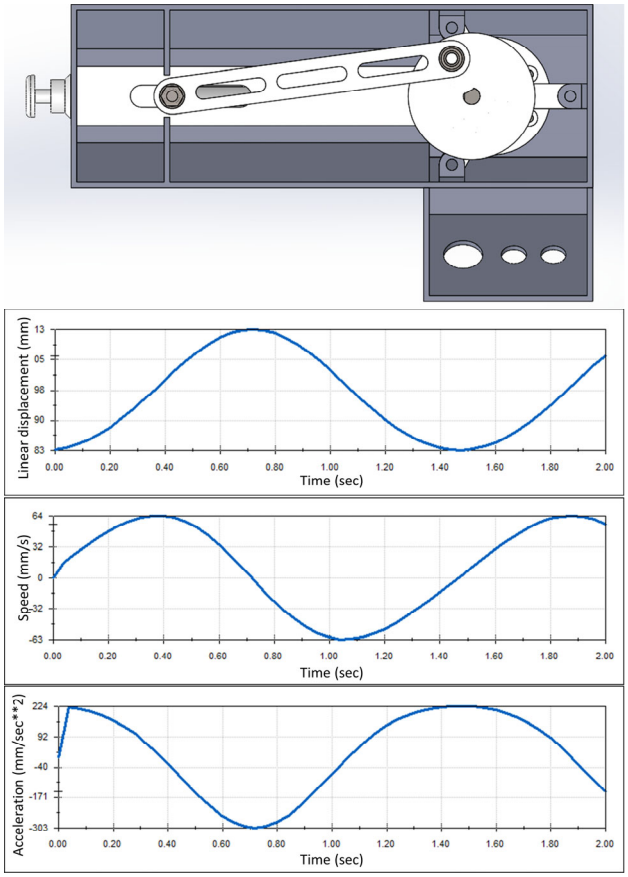

Fig. 6. Simulation of the dynamics of a drug reconstitution machine mechanism.

The simulation begins with the movement of the gear motor at a nominal speed of 40 RPM, which is transmitted to the plunger through the crank-connecting rod mechanism, generating the linear oscillating movement for the agitation of the medication. In the simulation, a travel distance of 30 mm, a maximum speed of 64 mm/s, and a maximum acceleration of 303 mm/s^2 were determined.

VI. Construction and Implementation

This section presents the construction and implementation of the machine as shown in Fig. 7. The machine was manufactured using 3D printing technology, with 1.75 mm diameter PETG filament. The printing speed was 60 mm/s, the extrusion temperature was 240 °C, and the bed temperature was 75 °C. The perimeter of the components has three contours, with a layer height of 0.2 mm. The fill pattern is hexagonal, and the extruder nozzle is 0.4 mm. Components such as 304 stainless steel shafts and 624 rigid ball bearings were also integrated. The manufacturing cost is 83 USD, and the weight and dimensions of the machine are 1263 g and 23.3 × 12.4 × 20 cm, respectively. The power source is a 12 V DC gear motor with a planetary gearbox. To start the machine, first press the mechanical button on the clamping system, then insert the head of the medication into the cavity of the plunger and release the button, trapping the head of the container. Next, activate the gear motor and, through the crank-connecting rod transmission system, transmit the movement to the plunger and agitate the medications.

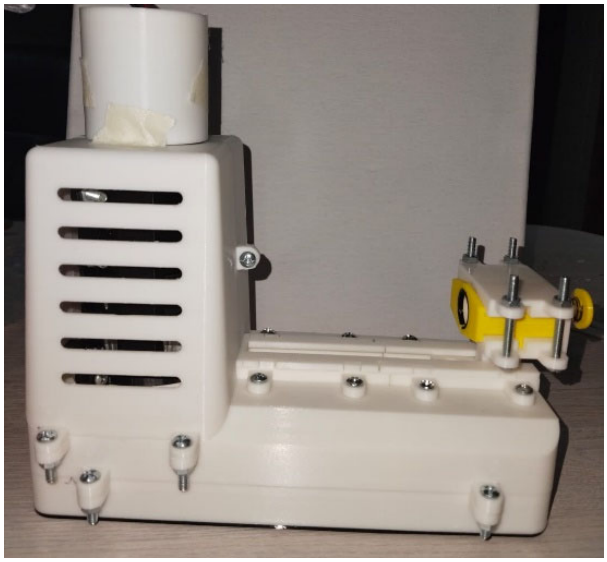

Fig. 7. Assembly of a drug reconstitution machine.

VII. Experimental Validation

In this section, we present the experimental validation of the machine for reconstituting freeze-dried drugs with agitation tests. These tests allow us to verify whether the proposed low-cost device can improve the consistency of the solutions and the reliability of the process compared to the manual method. Six trials were conducted with the proposed device: three with ceftriaxone in 15R vials and three with PIPTABAC in 20R vials. Similarly, six trials were conducted using the manual method. These trials

assessed aspects including biosafety, maintainability, portability, ergonomics, operation, dissolution efficiency, clamping system, and low cost.

The experimental procedure for shaking the medications using the proposed machine is detailed below:

(1) First; open the container of either ceftriaxone or PIPTABAC, as well as the sodium chloride ampoules.
(2) Second; use a syringe to extract the sodium chloride from the ampoules and inject it into the medication container.
(3) Third; press the mechanical button on the clamping system and install the container.
(4) Fourth; the machine is activated and the medication agitation test begins for 30 s, then the movement is stopped and the state of the mixture in the container is inspected, then the machine is activated for 1 min, then the movement is stopped and the state of the mixture is inspected, the machine is activated again for 3 min, then stop the movement and inspect the state of the mixture. Start the machine again for up to 6 min, then stop the movement and inspect the state of the mixture. If 6 min are exceeded, start the machine again for the time required to obtain a homogeneous mixture.
(5) Finally; the medications that form a homogeneous solution are set aside and test the next one.

The evaluation methodology was based on the visual assessment techniques for lyophilized medications used by healthcare staff at Hospital III Goyeneche. To this end, a scoring rubric was developed using a semi-quantitative visual scale, based on the observation of visible clumps and the solution's level of homogeneity. The scale was established as follows:

- 0–25%; presence of large visible lumps and a non-homogeneous mixture
- 25–50%; slightly non-homogeneous solution, with moderate presence of visible particles
- 50–75%; partially homogeneous solution, with few visible particles
- 75–90%; mostly homogeneous solution, with minimal visible particles
- >90%; homogeneous solution, with no visible lumps

The tests were evaluated by two observers with experience in handling lyophilized medications. The percentage values assigned are approximate visual estimates and not precise measurements; in cases of discrepancy in the assigned dissolution percentage, a value agreed upon through collective discussion between both observers was adopted, thereby improving the consistency and reproducibility of the results. Furthermore, the tests were conducted under controlled conditions, with constant lighting and a fixed observation distance of 30 cm. Although verification methods using turbidity measurement instruments or particle counters exist, these are not feasible during the medication preparation process prior to administration to patients due to time constraints and hospital workflow; this is why healthcare personnel visually inspect whether the solution is homogeneous. Therefore, the scale proposed in this study standardizes this visual assessment method used by healthcare personnel in clinical settings into a structured, semi-quantitative method.

Based on the results of the experimental tests in this section, Table III shows that the machine manages to dilute all the drugs, achieving visual homogeneity levels exceeding 90% according to the proposed scale. The ceftriaxone drugs dissolved in a maximum of 30 s, However, PIPTABAC medications took longer, up to 17 min and 10 s. In some cases, occasional bubbles and lumps were observed after about 16 min for PIPTABAC medications, but they did dilute by the maximum time. Furthermore, the dissolution times with this device show low variability between replicates. In addition, after six consecutive tests, overheating of the electric motor was noted. Fig. 8 shows the dilution procedure for a PIPTABAC sample, starting with the medication in a lyophilized state, as shown in Fig. 8(a). After 3 min of agitation with dilutions between 75% and 85%, as shown in Fig. 8(b), followed by 6 min of agitation with a dilution close to 90%, a high degree of homogeneity was finally achieved according to the proposed visual scale after 16 min.

TABLE III. SEMI-QUANTITATIVE RESULTS OF SHAKING TESTS BASED ON THE VISUAL DILUTION SCALE

No. Ítem	Medication	Total dissolution time	Semi-quantitative dissolution profile (visual assessment)	Comments
1	Ceftriaxone	30 s	>90% at 30 s	Rapid homogeneous dissolution; no lumps present
2	Ceftriaxone	28 s	>90% at 28 s	Consistent result; completely dissolved
3	Ceftriaxone	30 s	>90% at 30 s	Dissolution with high homogeneity and no lumps
4	PIPTABAC	17 min	35% (30 s), 55% (1 min), 80% (3 min), 90% (6 min)	Slow dissolution; persistent lumps up to 16 min
5	PIPTABAC	16 min 45 s	30% (30 s), 50% (1 min), 75% (3 min), 90% (6 min)	Same dissolution pattern; small bubbles hinder agitation
6	PIPTABAC	17 min 10 s	40% (30 s), 60% (1 min), 85% (3 min), 90% (6 min)	Slow dissolution, engine overheating

Fig. 8. Dilution of PIPTABAC medication: (a) without diluent; (b) 3 min of shaking; (c) 6 min of shaking; (d) more than 16 min of shaking.

These results demonstrate the potential of this machine to provide consistent dilutions and reliable procedures in less time compared to the manual method. To support this claim, a basic comparison was conducted between manual shaking and the proposed device using the same medications (PIPTABAC and Ceftriaxone), diluents, and vials. The evaluation criteria used were dissolution time and the level of visual homogeneity. In the case of manual shaking, this was performed by a group of three nursing technicians, who carried out the manual procedure for both PIPTABAC and Ceftriaxone, resulting in three trials per medication, as shown in Table IV. Furthermore, greater variability was observed due to the influence of human involvement, stemming from factors such as muscle fatigue and pauses during the procedure. The results of the comparison between manual shaking and the proposed device are shown in Table V, which demonstrate shorter dissolution times, low variability and higher levels of homogeneity with the proposed machine. Furthermore, the device demonstrates its ability to reduce the need for healthcare personnel intervention and minimize the risk of ergonomic injuries caused by manually shaking medications.

TABLE IV. SEMI-QUANTITATIVE RESULTS OF THE MANUAL SHAKING TESTS

No. Item	Medication	Total dissolution time	Semi-quantitative dissolution profile (visual assessment)	Comments
1	Ceftriaxone	4 min 22 s	>90%	Smooth, lump-free dissolution
2	Ceftriaxone	8 min 15 s	>90%	Consistent texture with no lumps
3	Ceftriaxone	6 min 30 s	>90%	High consistency in the mixture, with mild muscle fatigue
4	PIPTABAC	60 min	90%	Slow dissolution; small clumps remain after 60 min
5	PIPTABAC	45 min	85%	Dissolution with small clumps present; test suspended due to staff exhaustion
6	PIPTABAC	49 min 35 s	85%	A slow cool-down, with several breaks due to significant muscle fatigue

TABLE V. COMPARISON BETWEEN MANUAL SHAKING AND THE PROPOSED DEVICE

Medication	Shaking Method	Dissolution time	Level of visual uniformity
Ceftriaxone	Manual	4–9 min	>90%
	Proposed Device	28–30 s	>90%
PIPTABAC	Manual	45–60 min	75–90%
	Proposed Device	16–17 min	>90%

Finally, the results were analyzed based on the characteristics of biosafety, maintainability, portability, ergonomics, operation, dissolution efficiency, fastening system, and low cost:

(1) Biosafety: the prototype offers a high level of safety during the shaking of medications for healthcare personnel, since the operation is performed without the need for personnel to interact directly with the medication. This device firmly holds the vials during agitation, and its structure prevents contamination of the medication with its 4 mm cavity in the plunger structure. Finally, there were no cases of medication detachment from the clamping system, and the casing design is smooth and easy to disinfect.

(2) Maintainability: the device has a simple screw-on assembly/disassembly system for easy maintenance, as well as spaces and slots for inserting tools during maintenance. The machine can be divided into up to eight components, which simplifies the design and facilitates maintenance. This machine is manufactured with locally available materials and 3D printing technology, which allows for immediate technical assistance and availability of spare parts.

(3) Portability: the prototype weighs less than 2,500 g (1,263 g) and measures 23.3×12.4×20 cm, demonstrating its lightness and small size, which allows it to be handled and transported in a nurse's cart, demonstrating its portability.

(4) Ergonomics: the machine's design is geometric and comfortable to hold with the hands, without causing injury to staff, indicating that it is easy to use and handle during operation.

(5) Operation: the machine is easy to operate with a single on/off button to activate the gear motor, which generates a nominal speed of 40 RPM to shake the medications and achieve homogeneous mixtures.

(6) Dissolution efficiency: The machine demonstrates high medication dissolution efficiency, achieving homogeneity levels exceeding 90% for hard-to-dissolve drugs such as PIPTABAC in a rapid time of 17 min 10 s, surpassing the results of manual procedures that often fail to complete the mixtures.

(7) Holding system: the holding system demonstrates safety when holding medications during the high speeds required to shake them. This system also demonstrates its adaptability to reconstitute a wide range of medications with 15R, and 20R shapes.
(8) Low cost: Finally, the prototype stands out for its low cost (83 USD), compared to machines that include agitation in their processes, such as KIRO Oncology or APOTECAchemo, making it accessible to healthcare personnel or low-income healthcare centers.

VIII. Conclusion

This research article presents an innovative, low-cost machine for reconstituting freeze-dried medications that improves the consistency of dilutions and the reliability of the process compared to the manual method. It also reduces the need for manual intervention by healthcare personnel and promotes ergonomic safety in resource-limited hospital settings, making it an affordable alternative to high-cost robotic systems. The design methodology was based on the needs and requirements of healthcare personnel at the III Goyeneche Hospital in Arequipa and on ISO 8362-1 standards, resulting in a design with the required characteristics and performance. Finite element analysis simulations were then performed using SolidWorks software, which allowed structural failures to be anticipated and the design to be corrected through iterations until an optimal design with safety factors greater than 2.0 was achieved. Motion simulations were also performed, which helped to detect possible collisions, as well as speeds and paths during the agitation of the medication. Next, the device was manufactured using 3D printing technology, and mechanisms such as the motor, shafts, and bearings, which are locally available components, were added. The manufacturing cost was 83 USD, which is affordable for healthcare personnel as well as healthcare centers with limited resources. The weight of 1263 g and dimensions of 23.3 × 12.4 × 20 cm confirm the portability of the device. Finally, in the tests, type 15R and 20R containers were used for the drugs Ceftriaxone and PIPTABAC, respectively, consistently producing homogeneous solutions in a short amount of time, with a maximum of 17 min and 10 s for PIPTABAC. These results demonstrate the proposed device's ability to improve the reliability of the dilution process, as well as to reduce preparation times compared to the manual method.

Future research will consider the following aspects to improve the drug reconstitution machine:

- FEA analysis has been shown to improve and help predict mechanical failures prior to manufacturing, however we consider exploring the use of this tool to design topologically optimized structures.
- The prototype developed in this article was evaluated with 15R and 20R type medications; future research plans to evaluate a broader range of test cases, including medications with varying compositions and vials of different sizes.
- The material used to build the machine is PETG, which is not only affordable but also offers good mechanical characteristics, ensuring the functionality of the device. However, in the future, we will evaluate a greater number of materials.

These points will be investigated in future research to optimize the design of freeze-dried drug reconstitution machines.

Conflict of Interest

The authors declare no conflict of interest.

Author Contributions

Franco Pareja Molina and Carlos Rodríguez Dávila developed the main prototype designs, analyzed the validation test results, and wrote the manuscript; Erick Valdeiglesias Flores built the prototype; Daniela Ponte assisted with data collection at Hospital III Goyeneche; Yuri L. Silva reviewed and corrected the manuscript for submission. All authors approved the final version of the manuscript.

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