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Validity and Reliability of a Good Manufacturing Practices Checklist for the Agro-Biological Industry

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ABSTRACT

This research presents the design of a checklist or questionnaire for the application of GMP-SSOP during the production of liquid agro-biologicals. Content validation was determined by the judgment of experts belonging to three subsidiaries of a well-known company in the sector, whereas internal consistency was determined with the Kuder-Richardson KR_{20} reliability formula. The instrument was established in 210 dichotomous response items distributed in ten dimensions: General, commercial classification, personnel, facilities and equipment, critical support systems, storage area, production area, quality control, documentation, and cleaning and sanitation. It was possible to obtain the applicability consensus of the seven experts and an average KR_{20} value equal to 0.80. Additionally, all the dimensions presented scores higher than 0.75, which confirmed the validity and reliability of the instrument.

Keywords: checklist; GMP; agro-biological; KR_{20}.

INTRODUCTION

Questionnaires are fundamental data collection instruments that provide information (Vargas & Hernández, 2010). They can be unidimensional or multidimensional, of dichotomous response (true/false, yes/no), made of simple items, formulated based on literature review, based on the consultation with experts in the field (Martín, 2004), or be of single application in the study (Campo Arias & Oviedo, 2008).

When writing questions or items, it is important to consider the criteria of clarity, coherence, relevance, and sufficiency (Escobar & Cuervo, 2008; Boluarte & Tamari, 2017). According to Martín (2004), there are certain recommendations, such as using short and easy-to-understand questions, avoiding words that induce opinions or belief, writing questions in a positive way, avoiding the use of "why", avoiding questions that induce a desired answer, and avoiding statements that force to make calculations or memory efforts.

To ensure the success of the results, the questionnaire must be well designed, according to the criteria of validity and reliability (Lacave, Molina, Fernández, & Redondo, 2015). Therefore, it is crucial to measure the questionnaire to check its usefulness (Esposito, Muñoz, Herrera, & Periáñez, 2015) as instrument validation is a process of constant evaluation and modification (Campo-Arias & Oviedo, 2008).

Validity refers to the "*grado en que un instrumento de medida mide aquello que realmente pretende medir o sirve para el propósito para el que ha sido construido* [degree to which a

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measuring instrument measures what it actually intends to measure or serves the purpose for which it was built]" (Martín, 2004, p. 28). In this sense, as mentioned by Urrutia, Barrios, Gutiérrez and Mayorga (2014) in Boluarte and Tamari (2017), content validity represents the first level of validity, and it is used to verify whether the questionnaire and the items written are indicators of what is intended to be measured. Thus, during the judgment of experts, the questionnaire is subjected to evaluation by people with academic or work experience in the subject, who can provide information, evidence and judgments (Galicia, Balderrama & Edel, 2017; Robles & Rojas, 2015).

On the other hand, reliability is the degree to which an instrument provides truthful and consistent results under similar measurement conditions with precision and without error. Thus, internal consistency is the level at which the different questions of a scale are related to each other, that is, the degree of agreement between them, which will determine that these can be accumulated and give an overall score (Martín, 2004). There are different methods for measuring internal consistency; the most commonly used are Cronbach's alpha coefficient and the Kuder-Richardson KR_{20} formula (Ekolu & Quainoo, 2019), which are considered acceptable when their values are between 0.70 and 0.90 (Sánchez & Gómez, 1998) and applicable in instruments that measure attributes or characteristics (Campo-Arias & Oviedo, 2008).

Some examples of questionnaires used to study different situations are: student difficulties during learning (Lacave et al., 2015), health training (Esposito et al, 2015), mental health (Fernández, Molerio, Herrera, & Grau, 2017), Index of Dental Anxiety and Fear in the population of pregnant women questionnaire (Ríos, Palma, Herrera, Farías, Morales, Martínez, Lanyon, & Rojas, 2018), postpartum self-care for women (Vargas & Hernández, 2010), teaching quality (Porras & Gil, 2014) and Good Manufacturing Practices (GMP) (Fadda, Aymerich, Hugas, & Garriga, 2005).

Good Manufacturing Practices, also known as Good Processing Practices or Good Fabrication Practices (Diaz, 2009), are defined as the set of rules that determine the activities carried out during the manufacture of a product that ensure compliance with quality standards according to the use it will have and with the requirements established to commercialize it (D. S. N.° 014, 2011). Their implementation requires a person in charge and a set of operating procedures that must be complied with to reduce contamination risks and ensure the quality of the finished product (Tamayo, 2011).

GMPs are complemented by Sanitation Standard Operating Procedures (SSOPs) (Diaz, 2009) and include cleaning and disinfection activities that must be routinely performed before, during and after each production process (Quiñones, 2016). GMPs consist mainly of a procedure manual and its records that include aspects such as raw materials, facilities, equipment, training, and personnel hygiene (Pérez, 2014). Other basic aspects in the application of biological GMPs are documentation, materials, production control and quality control (Quintana & Apezteguía, 2010). In addition, the manuals must have defined objectives that include relevant programs and procedures, which allow the efficiency of operations and control the presence of microorganisms (Quiñones, 2016).

Diaz (2009) details the following aspects of GMPs:

- Facilities: The location, distribution, construction materials, equipment and services of the processing plant should be considered.
- Control of Operations: Control systems must be applied to raw materials, equipment, and inputs, while complying with established time and temperature parameters.
- Maintenance and Sanitation: Effective activities, procedures and methods for cleaning and disinfection, pest control and waste management must be included.
- Personnel Hygiene: Training and control measures must be implemented for the cleanliness and behavior of personnel, the condition of the sanitary facilities, and the equipment for visitors.
- Transportation: The condition of the means of transport, containers and warehouses for both raw materials and finished products must be checked.
- Training: There must be a training program that includes personnel functions and handling, cleaning and disinfection procedures.
- Documentation: Documentation must be properly prepared, accessible, and easy to understand. It makes possible the demonstration, systematization and reproduction of activities.

The objective of GMPs is to obtain products in optimal sanitary conditions and to reduce failures during production, thus improving quality and guaranteeing a reliable product. The advantages of using this

tool are competitiveness in the market, preservation of the reputation of the company, increase of profits, and compliance with current regulations (Puerto & García, 2015). This quality tool is applied in several types of industry, such as food, cosmetics, and pharmaceuticals (Oliva del Cid, 2011). Various researchers affirm that its implementation achieves good microbiological quality and a positive economic effect on companies (Jerke, 2009), allows for the optimization of resources and compliance with national and international standards (Rodríguez, 2018) and facilitates the certification, validation, and training of personnel (Parra, 2015).

For the implementation of Good Manufacturing Practices, the use of an instrument or checklist that allows to know the initial status of the level of compliance with GMP-SSOPs is required, as well as the creation of an improvement plan and the achievement of a higher percentage of compliance (Tamayo, 2011). This instrument facilitates internal and external audits; makes it possible, according to the value obtained, to consider whether GMPs are complied with (value equal to or higher than 70%) or not; and finally, makes it possible tocorrelate GMPs with the microbiological quality of a product (Bastías, Cuadra, Muñoz, & Quevedo, 2013). In Peru, DIGEMID (2017) regulates and provides manuals and checklists to the different industry sectors such as, for example, goods storage, distribution and transportation practices for pharmaceutical products and inspection reports for cosmetics manufacturing facilities.

The design of this instrument targeted the agro-biologicals, bioinoculants or microbial inoculants industry (Aguado, Rascón, & Luna, 2012), which are made up of soil microorganisms that are associated with plants or their environment, constitute an alternative to reduce the use of chemical products in agriculture, and represent an organic strategy towards the integrated management of pests and diseases (Alvarez, Tucta, Quispe, & Meza, 2018). As indicated by the Norma Técnica Colombiana NTC 5842 (2011), they are innocuous products for humans, plants, and animals, which makes them of interest to many exporters (Zapata, 2001).

The products are applied to any crop of agronomic interest and can be formulated industrially (Sanjuán & Moreno, 2010); based on beneficial bacteria such as plant growth promoters-PGPR, rhizobacteria (Terry, Leyva, & Díaz, 2005); nitrogen fixers, such as *Azotobacter chroccocum* and *Azospirillum* sp.; phosphate solubilizers, such as *Pseudomonas* spp; and biological control microorganisms, such as *Bacillus subtilis* (Manitio, 2014). These are applied together with beneficial fungi, such as those that are able to produce phytohormones, like *Penicillum* sp. and *Aspergillus* sp. (Santos, Parra, Herrera, Valenzuela, & Estrada, 2018); arbuscular mycorrhizal fungi (Terry et al., 2005); pest controllers, such as *Trichoderma* sp. (García, Riera, Zambrano, & Gutiérrez, 2006); and entomopathogens, such as *Metarhizium*, *Beauveria*, and *Verticillium* (Monzón, 2001).

Therefore, this study proposes to expand the application of a checklist in the industry of biological products for agriculture in order to generate a positive impact on the quality of the process and contribute to the delivery of optimal products that meet the needs of customers and their crops. In short, the main objective is to design a valid and reliable instrument to evaluate the implementation level of Good Manufacturing Practices (GMP-POEs) on an expanding sector, such as the production of agrobiologicals or bio-inputs.

METHODOLOGY

A checklist or questionnaire was designed based on the Acta de inspección para establecimientos de fabricación de cosméticos (Inspection Act for cosmetics manufacturing establishments) DICER-FOR-014, established by DIGEMID (2017). Likewise, the instrument was organized into a series of questions or items grouped in dimensions according to Quintana and Apezteguía (2010), who studied GMP in biological products.

As in the study conducted by Galicia et al. (2017) and the one by Salazar, Freyle, Tamara and Álvarez (2016), the content validity of the instrument designed in this study was determined through experts judgement, selecting a panel made up of seven experts with knowledge and experience in this area of the industry. The experts belong to three subsidiaries (Mexico, Colombia and Peru) of a well-known company dedicated to the formulation and commercialization of agro-biologicals.

In order to refine the criteria of sufficiency, relevance, wording and response options (Fernández et al., 2017), the experts evaluated the instrument; for this, they were asked to rate with “1” the items that met the criteria, and with “0” those that did not. In addition, the Kuder Richardson KR_{20} formula was applied to quantify the validity of the instrument (Ríos, Leonardo, Ballena, Peralta, Franzo, Díaz, & León, 2013).

Since the instrument is based on a dichotomous response pattern, the internal consistency value was determined with the Kuder Richardson KR_{20}

reliability using the following equation (Campo-Arias & Oviedo, 2008):

$$KR_{20} = \frac{n}{n-1}\left[\frac{Vt - \sum pq}{Vt}\right]$$

Where:

η = number of items contained in the instrument.

Vt = total variance of the test.

$\sum pq$= sum of the individual variance of the items.

The values obtained were evaluated according to the criteria established by Kline (2013) in Díaz, Tirado and Simancas (2017), where >0.90 is considered excellent; <0.85 0.75>, acceptable; and <0.60, good.

RESULTS

In order to design the instrument, the references found were compared and communication was maintained with the experts, which allowed for modifications and reformulations of the questions. After the last evaluation, the seven experts reached a consensus and considered that no further modifications were necessary. In addition, it was determined that the scoring of the questions would be done with values of "YES" or "NO"; where "YES" indicates that the item was correctly fulfilled during the GMP implementation, and "NO" indicates that the item is still not fulfilled.

The GMP checklist for the agro-biological industry consists of 10 dimensions. The first two are related to the company information (general information and commercial classification), and the following eight dimensions comprise the 210 rating items. The dimensions and their respective number of items are described in Table 1.

The first dimension presents the fiscal information of the company and the people responsible for the production process, while the second shows the commercial classification of the company. Neither of these has questions since they do not provide any information for GMP monitoring. The third dimension is subdivided into aspects of training, occupational health, and hygiene and provision of work clothes. The fourth dimension consists of the situation or state of the internal and external areas, sanitary services, dressing rooms, maintenance, and social areas. The fifth dimension includes air and water supply and wastewater treatment systems. The sixth dimension is subdivided into raw materials (which include the microbial active ingredient and inert components), packaging, and finished product. The seventh dimension includes items related to the areas of microbial culture collection, bio-ferments, and formulation, with their respective maintenance, cleaning and control considerations. The eighth dimension includes items related to quality control throughout the manufacturing process, in addition to complaints and claims procedures. The ninth dimension presents information on GMP documentation management, in addition to label and packaging, raw material and finished product management. Finally, the tenth dimension includes items related to sanitation standard operating procedures (SSOPs). The complete document can be viewed at the following free-access link: https://drive.google.com/file/d/1LsVqRLDOznPXMG1NciHUiy5yHL7YXK77/view?usp=sharing

Table 1. *Structure of the Instrument for Good Manufacturing Practices.*

	Dimensions	Number of Items/Questions
1	General	None
2	Commercial classification	None
3	Personnel	21
4	Facilities and equipment	22
5	Critical support systems	12
6	Storage area	34
7	Production area	54
8	Quality control	31
9	Documentation	14
10	Cleaning and sanitization	22
Total		**210**

Source: Prepared by the author.

Table 2 shows the validation based on the evaluation of seven judges or experts. All their observations and suggestions were considered to finally obtain the applicability consensus. The overall validity of the whole instrument was calculated and a KR_{20} value of 0.80 was obtained. The partial validation values are 0.87, 0.72, 0.78, 0.88, 0.85, 0.75, 0.76, and 0.80 in each of the dimensions personnel, facilities and equipment, critical support systems, storage area, production area, quality control, documentation, and cleaning and sanitation, respectively. It was observed that the overall rating and most of the dimensions exceeded the value KR_{20} = 0.75, so they are in the acceptance range.

Internal consistency was calculated using the Kuder-Richardson formula (KR_{20}) and gave an average value of 0.81 for all the dimensions of the instrument, while the partial values of consistency in each of the dimensions are shown in Table 3. All the dimensions presented scores greater than 0.75 and were therefore considered acceptable.

The highest coefficient was obtained in the dimension "Documentation" (KR_{20} = 0.88), while the lowest value, but still representative and acceptable, was obtained in the dimension "cleanliness and sanitation" (KR_{20} = 0.75).

DISCUSSION

In order to define the structure of the checklist, it was necessary to conduct a detailed information search, select the format best suited to the process under study and then contrast it with the suggestions of the experts. This sequence of activities

Table 2. *Content Validity of the Instrument.*

Validating Judge	Position	Applicability
E. Cázares (IG Mexico)	Coordinator process and continuous improvement	Applicable
V. Aldaz (IG México)	Microbiology Supervisor	Applicable
F. Hernández (IG Mexico)	Coordinator of microbial products	Applicable
E. Baquero (IG Colombia)	Coordinator of biological products	Applicable
D. Ortiz (IG Colombia)	Quality and Research Manager	Applicable
G. Rodríguez (IG Colombia)	Biological production manager	Applicable
M. García (IG Peru)	Jefe de investigación	Applicable

Source: Prepared by the author.

Tabla 3. *Consistencia interna obtenida en cada dimensión del instrumento.*

	Dimension	KR_{20}
1	General	N/A
2	Commercial classification	N/A
3	Personnel	0.76
4	Facilities and equipment	0.77
5	Critical Support Systems	0.79
6	Storage area	0.86
7	Production area	0.79
8	Quality control	0.86
9	Documentation	0.88
10	Cleaning and Sanitation	0.75

Note: The dimensions "General" and "Commercial classification" are not evaluated with the KR_{20} formula because they are related to the written description of the company.

Source: Prepared by the author.

made it possible to determine the dimensions and total number of questions, which is suggested by Robles and Rojas (2015) to carry out the validation of the design and define the objectivity of the instrument.

Initially, the checklist consisted of 15 dimensions and 250 questions; however, it was reduced and adjusted to the activities in which it was desired to monitor GMPs until it was established in 210 questions distributed in 10 dimensions. As recommended by Ríos et al. (2018), the instrument was shown to the experts for final approval.

The checklist had an average of 26 items or questions in each dimension, of which, the dimension "Production area" had the highest quantity (54) and the dimension "Critical support systems" had the lowest (12). This agrees with Martin (2004) as although there is no ideal number of items to evaluate a process, the minimum would be 6 items, the average, 10 and the maximum, 90 items.

Once the structure had been established, the questionnaire was submitted to the experts for evaluation and, although the optimal number of judges is not established, some research has included the participation of seven (Fernández et al., 2017), ten (Boluarte & Tamari, 2017) or twelve experts (Ríos et al., 2013). In this research, not only seven knowledgeable people contributed, but also their perspectives from three subsidiaries of the same company, which enriched the validity of the instrument.

Content validity was guaranteed by applying the Kuder-Richardson KR_{20} formula, which resulted in a value of 0.80, very similar to that presented by Vargas and Hernández (2010), who obtained a general content validity index equal to 0.88 with the analysis of ten experts.

Like Salazar et al. (2016), the evaluation of the internal consistency of the checklist with dichotomous scale was performed with the application of the Kuder-Richardson formula. The average value of the instrument in general was equal to 0.81, which is acceptable for Kline (2013, as cited in Díaz et al., 2017) and agrees with the suggestions of Nunnally and Bernstein (1995) cited in Vargas and Hernández (2010), who consider that values between 0.59 and 0.68 are acceptable during initial validation studies. On the other hand, Roberts, Priest and Traynor (2006) suggest that the reliability is adequate if the coefficient reaches values between 0.80 and 0.90.

The minimum value obtained in one of the dimensions (0.75) and the highest (0.88) were not only considered within the acceptable range, but were also considered adequate, due to the fact that internal consistency values below 0.70 indicate a poor relationship between items (Campo-Arias & Oviedo, 2008) and excessive values or above 0.90 indicate redundancy or duplication (Esposito et al., 2015).

Finally, as explained by Lacave et al. (2015), the validity and reliability analysis of an instrument is an iterative process among the interested parties, which should be in constant evaluation during the establishment of the design.

CONCLUSIONS AND RECOMMENDATIONS

The proposal of this study is based on the importance of having a valid and reliable instrument or checklist that can be applied during the implementation and monitoring of Good Manufacturing Practices in the different companies involved in the production of agro-biological products.

Thanks to the contribution of seven experts, the GMP checklist designed presented an acceptable content validity, which reaffirmed its intended purpose due to the coherence and ease of understanding of its 210 items distributed in 10 dimensions.

The values obtained in the internal consistency of each dimension of the checklist confirmed the reliability of this instrument and the accuracy of its application.

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