

Proposal for the implementation of good manufacturing practices (bpm) in the "Francisco Navas" pasteurized orange juice plant in the city of Guayaquil.

Propuesta de implementación de buenas prácticas de manufactura (BPM) en la planta de zumo de naranja pasteurizado "Francisco Navas" en la ciudad de Guayaquil.

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Abstract

One of the aspects that has been developed on a large scale in recent years is quality management, as organizations have understood their social responsibility in the face of an increasingly informed and demanding society. It is under this approach that the present study tried to know what the situation was in an orange juice processing plant in the city of Guayaquil, observing deficiencies in its production process, making a comparative analysis, and questioning suppliers about the quality of the juice. product that they deliver to the plant, that is, a study was carried out of all those phases that affect the quality of the product, understanding that a product with higher quality implies the satisfaction of the final customer and therefore an improvement in the profitability of the organization. This project suggests a guide to implement good manufacturing practices for the development of the juice processing stages, making effective the improvement of its production processes and optimization of resources, which due to management negligence have not been applied, violating the current regulations that stipulate that all food processing plants must base their processes on good manufacturing practices as a tool for handling and manipulating food products.

key words: restructuring, marketing, production, safety, pastry.

Resumen

Uno de los aspectos que se ha desarrollado a gran escala en los últimos años es la gestión de la calidad, ya que las organizaciones han entendido su responsabilidad social frente a una sociedad cada vez más informada y exigente. Es bajo este enfoque que el presente estudio intentó conocer cuál era la situación en una planta procesadora de zumo de naranja de la ciudad de Guayaquil, observando deficiencias en su proceso de producción, haciendo un análisis comparativo, y cuestionando a proveedores acerca de la calidad del producto que entregan a la planta, es decir se efectuó un estudio de todas aquellas fases que inciden en la calidad del producto, entendiéndose que en un producto con mayor calidad implica la satisfacción del cliente final y por tanto un mejoramiento de la rentabilidad de la organización. Este proyecto sugiere una guía para implementar buenas prácticas de manufactura para el desarrollo de las etapas de elaboración del zumo, efectivizando el mejoramiento de sus procesos de producción y optimización de recursos, que debido a la negligencia de la gerencia no han sido aplicadas, infringiendo la normativa vigente que estipula que toda planta procesadora de alimentos debe basar sus procesos bajo las buenas prácticas de manufactura como herramienta de manejo y manipulación de productos alimenticios.

Palabras clave: Deficiencia, calidad, mejora, procesos, inocuidad alimentaria.

1. Introduction

The objective of this work is to develop a proposal for the implementation of Good Manufacturing Practices in the artisanal processed juice and pasteurized orange juice plant "Francisco Navas" in the city of Guayaquil for the year 2019.

The company employs around 20 people, most of them operators, who are responsible for the production of the different products manufactured by the company. Currently the company presents a somewhat disorderly business growth, something commonly associated with undertakings that emerged as a source of underemployment and therefore lacking administrative and productive processes [1].

The juice and orange juice plant "Francisco Navas" will have achieved an improvement in its production process and therefore will be able to serve the public as an establishment selling juices and juices under regulations that ensure the quality and hygiene of its products.

The study is organized by sections, in a first part the problem that arises in the "Francisco Navas" plant will be evidenced, as well as why it is necessary to address it in a timely manner, establishing objectives for this purpose aimed at solving the problem.

In the second part of the study a theoretical framework is mentioned conceived from the need to present

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bibliographic argumentation that serves as support for the development of the study [2]. In the third part, the methodological framework used to access reliable information is mentioned, which allows presenting the proposal in a final chapter.

In Ecuador, the implementation of a food company is governed by quality parameters established under ISO 9001 standards which are based on the quality management system, which allows companies to manage and improve the quality of their products or services from imports. Other supports that guarantee safe food are the use of good agricultural practices (GAP) and good manufacturing practices (GMP), both used at the beginning of the agri-food chain, the former applicable during planting, harvesting and distribution of the raw material used and the second as a basic tool to ensure the safety of processed foods. Both are the prerequisite for the HACCP system [3].

Good manufacturing practices are governed by the recommendations and guidelines established in the Codex Alimentarius, which includes the compilation of food standards, created to protect consumer health, ensure fair behavior in the international food market and coordinate all international work on food standards, with the aim of protecting consumer health [3]. To guarantee safe food there are preventive systems and support tools that are governed by recommendations from international bodies, which have created standards that must be implemented to ensure the quality of food for human consumption [4].

Preventive systems that ensure food safety in the agri-food chain.

In general, it is necessary for countries worldwide to have food control programs, which ensure their quality and safety, as an appropriate way to guarantee the health and nutrition of the population. Talking about safety refers to the control of the stages of the process through which a food previously went through to be qualified as suitable for consumption [5]. Therefore, it is essential to know the mechanisms used within the agri-food chain:

- Good Agricultural Practices - GAP
- Good Manufacturing Practices - GMP
- Standardized Sanitation Operating Procedures - SSOP
- Hazard Analysis and Critical Control Points – HACCP

In the food industry, safety measures are taken to ensure food safety, in which quality systems interact that are used for the identification, prevention, correction, control and improvement of the production process. This food safety management is designed based on the risk involved in producing them. For this, it is important to consider the threats that compromise the production of a

food, Marconi [6] considers the interaction of three appropriate tools for the optimization of production stages and obtaining a high-quality product for the consumer, which are:

- Traceability, for the identification and monitoring of the product during all stages of the process.
- Safety management systems, which eliminate hazards that cause harm to health such as GAP, GMP, SSOP and HACCP.
- Quality management systems, applying standardized regulations such as ISO, which certify the conditions of a food, to meet market demands.

Codex Alimentarius, an indispensable tool.

The food industry must be subject to regulations that govern the conditions for producing a food at the international level, which indicates what should be the composition of said product and under what parameters it will be manufactured.

For this purpose, the Codex Alimentarius exists, which is the compilation of all standards, Codes of Conduct, Guidelines and Recommendations of the Codex Alimentarius Commission, involving food labeling, the use of additives, pollutants, analytical methods and tests, food hygiene, nutrition and special dietary foods, food importation and inspection and certification systems for food exports, veterinary drug residues and pesticides [7].

Ecuadorian orange juice agribusiness.

Globally, agribusiness is part of the economic development of countries and a preponderant factor in eradicating poverty, in terms of job creation, value addition and feeding people. For the Ecuadorian Ministry of Industry and Productivity [8] "Agribusiness is a production unit that processes materials of animal or plant origin. Processing may include transformation and preservation through physical or chemical alterations, storage, packaging and distribution.

Thanks to the type of soil, microclimates and geography that Ecuador has, a variety of fruits can be grown throughout the year, among the most important are pineapple, papaya, passion fruit, peaches, blackberry, lemon, banana, among others favoring small farmers and large and small companies dedicated to the marketing of juices and nectars made from these fruits.

More than 50 years ago, Ecuador began to venture into juice making, the first company that decided to produce it is Canning Industries of Guayas, currently there are more than 15 national companies that venture into this type of product in different presentations [9].

Processing may include transformation and preservation through physical or chemical alterations, storage,

packaging and distribution." With state policy being to promote the generation of added value and employment in this sector.

Globally, the agribusiness industry directly affects the productivity development of countries, thanks to the modernization of its processes and the industrialization of its primary products. This is how agricultural products, when industrialized, can generate derivatives with added value, as is the case with agricultural products [10].

Generalities of the orange.

It originated in Southeast Asia and central China, the Philippines and the Indo-Malay Archipelago to New Guinea. The first varieties were identified during the reproduction of wild plants. The variety of orange is differentiated according to the use to be given, whether for fresh consumption or for freezing, in Ecuador there are varieties: navel, white and blood oranges. There are species of the genus *Citrus sinensis* (sweet orange), *Citrus aurantium* (sour orange) [11]

History of juices.

The marketing of fruit juices began in the 20th century, with the evolutionary changes in diet and lifestyles as determining factors, a new market was developed that contributes to the modernization of the processes corresponding to cultivation, production, storage and transportation [12].

Commercial juices and nectars are foods that have adapted to consumer needs. It has been like this since its origin before the industrial revolution and urban concentration, since then, processed foods have gained greater prominence because the population began to concentrate in large cities without direct access to certain products [12].

Table 1. Companies dedicated to juice production.

Company	Location	Brand
Toni S.A.	Guayaquil	Tampico
Sumesa	Guayaquil	Frutal
Sumesa	Guayaquil	Sumesa
Reysahwal A.G.R.S.A.	Sangolquí	Rey néctar
Resgasa	Guayaquil	All Natural
Quicornac S.A.	Los Ríos	Sunny
Lácteos San Antonio	Cuenca	Nutri-jugo
Northtop	Guayaquil	Deli
Nestlé - Ecu jugos	Cayambe	Natura
Lecocem - Parmalat	Latacunga	Santai
Lechera Andina S.A.	Pichincha	Supermaxi
Lechera Andina S.A.	Pichincha	Andina
Fadesa - Ecuavegetal	Babahoyo	Facundo
Fadesa - Ecuavegetal	Babahoyo	Facundo
Alpina	Pichincha	Fruto
Ajgroup	Guayaquil	Pulp

Nutritional value.

The orange is a fruit that has very few calories, soluble fiber, low fat content, high amount of ascorbic acid (vitamin C), different vitamins and trace elements, etc. It is characterized by the presence of different types of carotenoids and organic acids. It has antioxidant, anti-inflammatory, anti-cancer properties, helps with obesity and sclerosis problems. [13] The nutritional components of the orange are composed, per 100 g of edible portion, by portions of 225 g and daily consumption recommendations for men and women.

Situation of the agribusiness in Ecuador (orange juice sector).

Globally, agribusiness directly affects the productivity development of countries, thanks to the modernization of its processes and the industrialization of its primary products. This is how agricultural products, when industrialized, can generate derivatives with added value, as is the case with agricultural products.

Agribusiness represents 4.5% within GDP [14], the participation of the food and beverage company in Ecuador's manufacturing industry is 47% [14].

As of 2006, 3,318 companies were agro-industries, within a total of 51,000. 52% were in Guayas [14].

Production is concentrated in juices and concentrates with 55.4% of total value and sales with 49.5% corresponding to juices [14].

Within the participation in total permanent crop production, oranges comprise 0.23% [15].

Bolívar represents 4% of the agricultural area nationwide. Orange is its main crop [15].

Suppliers of raw materials such as oranges, their total supply nationwide is 1% [14].

As for imports, juices occupy 13% and within this category orange juice comprises 8.2% [14].

Orange juice quality.

The alkalizing properties of oranges contribute to the purification of the blood since they dissolve acids and prevent them from settling in the kidneys and producing kidney stones or renal calculi. The properties of pasteurized and reconstituted concentrated orange juice [16].

Botanical description.

The orange is a subtropical species that has no resistance to cold, it needs warm temperatures during the summer for the correct ripening of the fruits. It needs light for the flowering and fruiting processes. [17]

Table 2. Physicochemical parameters of orange juice

Physicochemical Parameters	Jugo Pasteurized juice at 94 - 96°C For 30 sec.	Reconstituted concentrated juice at 11 brix
pH	3,84	3,70
Total Soluble Solids (brix)	11,2	11,00
Acidity (% anhydrous citric acid)	0,86	0,90
Ascorbic Acid (mg/100 ml juice)	60,96	56,58
Direct reducing sugars (g/100 ml juice)	4,38	5,73
Amine Nitrogen (mg/100 ml juice)	30,50	25,33
Total Sugars (g/100 ml juice)	8,92	9,36
Flavonoids (hesperidin) (mg/100 ml juice)	100,94	110
Essential Oils (ml/100 ml juice)	0,0006	0,0062

Orange juice composition.

Citrus fruits contain a series of very important nutrients for nutrition such as sugars, vitamins, amino acids, mineral salts.

Ascorbic acid or vitamin C plays an important role in many reactions involving the incorporation of oxygen from molecular oxygen to the substrate. It is involved in collagen synthesis; it is also important for the synthesis of steroid hormones and lipid metabolism.

Vitamin C does not prevent the appearance of viral colds, but the continued intake of vitamin C can reduce cold symptoms [18].

2. Materials and methods.

The methods and tools that have been used to create this project are:

Good Manufacturing Practices.

GMP is a representation of principles and several National and International Standards on the proper handling of food, which must ensure its safety and security for consumers [19]. It includes:

Set of principles, standards, and technical recommendations, which allows controlling hazards by minimizing risk of occurrence and ensuring that applicable control and prevention measures are adopted for the production, processing, and transportation of food.

They highlight the basic hygiene controls that are carried out at each stage for the prevention of sanitary design and construction applicable during production operations, to minimize food contamination. They include documented procedures for hygiene, handling and operation of facilities.

2.1 Methods and techniques for GMP inspection. Buildings and facilities

The location and access to the plant must be in isolated places from any danger or risk that can contaminate food or products. Free of garbage accumulation with flat surfaces and covered with materials that facilitate maintenance and prevent the generation of dust and stagnant water or the presence of contaminating sources for food.

Structures.

The internal transit routes must have a paved surface to allow the circulation of trucks, internal transports, and containers. The structures must be solid and adequate and the material with which the buildings are built must be of a material that prevents the transmission of undesirable substances. The openings must prevent the entrance of domestic animals, insects, rodents, flies, and environmental contaminants such as smoke, dust and steam.

Raw material.

The quality of the raw materials must not compromise the development of GMP. They must be stored under appropriate conservation conditions that ensure protection against contaminants.

Its deposit must be isolated or away from finished products to prevent cross contamination. Optimal storage conditions such as temperature, humidity, ventilation, and lighting must be considered.

The measures to avoid physical, chemical, and microbiological contamination are specified for each establishment or industry.

Interview with operational collaborators.

The operational staff of the Francisco Navas orange juice plant was interviewed with the aim of determining the application of GMP in the production process of the product investigated, where everything was considered from the reception of the raw material to the clothing and sampling of the juice.

It was indicated that the raw material is subjected to a superficial review, separating the one that is in poor condition, that a thorough inspection is not carried out indicating Brix or organoleptic characteristic that affects the quality of the juice.

They point out that the amount of juice produced daily is 3000 liters, that for this there are no policies regarding the clothing that the plant personnel must use, cleaning is carried out before and after the process, not during, there are no policies for handling the raw material other than the basics such as hand washing and use of clean clothes.

No other products are produced, only orange juice, the production processes are not validated, only the owner takes a quick review to know if the product was finished, but the stages of the process are not supervised to determine whether or not there were failures during the process, there is no training by the company regarding the standardized regulations for the production of food products, they do not know what GMP is.

3. Results.

Foodborne diseases are a public health problem that occur daily in the lives of citizens. Prevention is the most appropriate option and must be implemented from the early stages of the agri-food chain until the product is placed in the hands of the consumer. For this, international bodies concerned about diseases caused by the ingestion of unsafe food products create tools that certify food safety through safety and quality management mechanisms.

One of the essential tools is Good Manufacturing Practices, which are a set of rules necessary for the operation of food processing plants, which indicate the handling and manipulation of raw materials during the production stages. This guide is structured covering five parts, dealing with the proper handling of:

- Facilities.
- Equipment and utensils.
- Materials and supplies.
- Production operations.
- Packaging and labeling.

3.1 Guide for the implementation of good manufacturing practices.

Beneficiaries.

Pasteurized orange juice plant "Francisco Navas" Manager, Administrative Staff and Staff working at the "Francisco Navas" Plant.

"The orange juice processing plant "Francisco Navas" is committed to improving production processes, through the implementation of tools that maintain quality standards, thus ensuring compliance with customer specifications, as well as current regulations. legal, this through constant training of personnel, as well as validation that the pre-established guidelines are being met".

Design and construction.

The plant design provides protection against dust, foreign matter, insects, rodents, birds and other elements of the outside environment and must maintain the sanitary conditions of the product being processed.

The construction is solid and has sufficient space for the installation, operation, and maintenance of equipment, as well as for the circulation of personnel and the transfer of materials or food, to take advantage of all the physical space and avoid risks of cross-contamination.

There are sufficient facilities for personal hygiene.

Distribution of areas.

The division should be given as follows: Entrance, area for reception and storage of raw material, production area, finished product storage area, bathrooms, waste area and must have signage in all areas of the plant.



Fig. 1. Plunger machine for orange juice extraction.

Floors and drains.

Floors, walls, ceilings and drains should be designed in such a way that they can be cleaned and kept clean, should prevent the accumulation of dust and the joints between floor and wall should be concave.

Freezer and refrigeration rooms allow for adequate cleaning, drainage, and sanitary conditions.

Floor drains are protected, and their design allows for easy cleaning.

Management indicators.

Compliance with the resulting actions by the manager, in this way an indicator will be created that allows knowing of the planned actions by the manager, which of them were fulfilled.

Customer satisfaction: implementation of an indicator that allows knowing how many are the number of

complaints that the company receives on a monthly basis, so the objective will be to reduce them in the aforementioned period, that is, monthly.

Percentage of fruit observed in poor condition with respect to the total order, this will be done by randomly removing 10 oranges for every 100 units.

Name the best quality representative each month, giving them lunch monthly and a 10% bonus of their salary.

3.2 Operating processes.

Production.

The production stages for the elaboration of orange juice are described in the following figure:

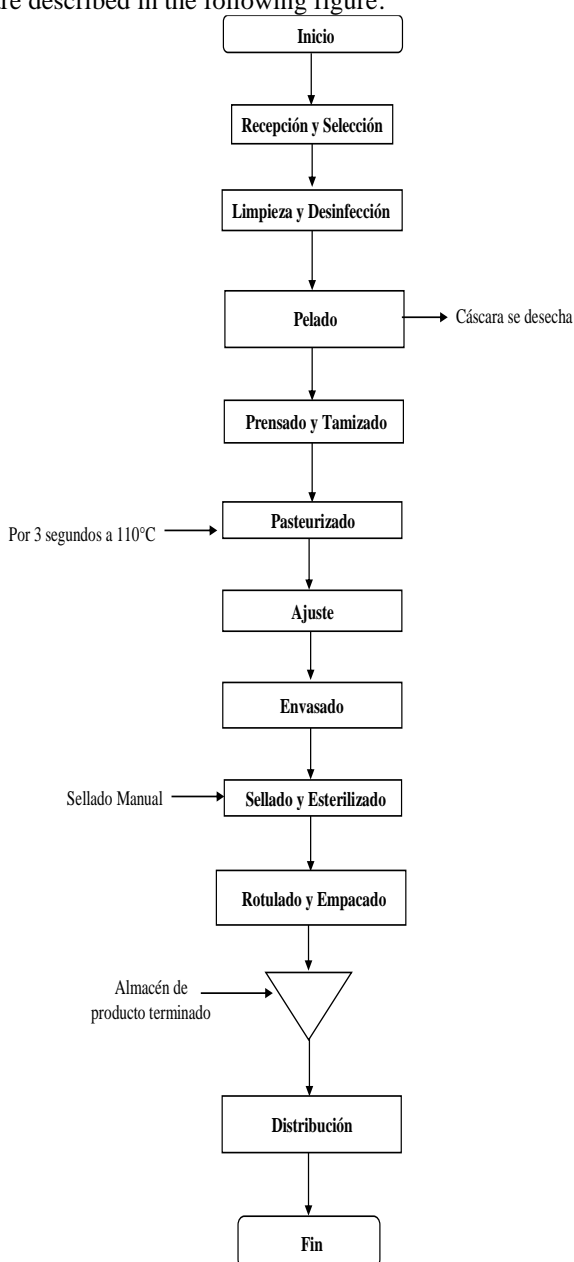


Fig. 2. Orange juice production stages.

Purchase of raw material.

The raw material, which is the orange, must be fresh and its weight ratio of sugar in water depending on its type is 10 to 13 degrees Brix. The cultivation fields that provide this raw material must be close to the plant in order to reduce transportation costs.

Preservatives are substances that are added in small quantities to foods to preserve their appearance, flavor, texture or some other characteristic property of the product.

- Electrical energy
- Good quality drinking water.
- Local fuels.
- Collection of organic waste.

The orange is the main raw material and can be purchased directly from the farmer or in the supply centers themselves.

Among the auxiliary materials, the most common preservatives are: sodium benzoate, sulfite, sodium bisulfite and sulfur dioxide, which are sold by chemical product distributors, which can be located through the directory of the National Chamber of the Canning Food Industry.

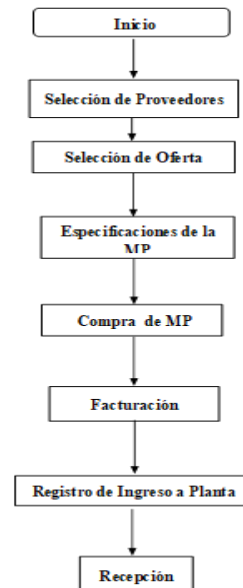


Fig. 3. Purchase of raw material.

Projection of expenses by participation

Scientifically, the study would obtain information about this industry, as well as its productive chain, generating a body of knowledge that would contribute to decision making for both the plant and other industries.

Undoubtedly, making the proposal would imply for the juice and orange juice plant "Francisco Navas" the possibility of improving its income level, thanks to the changes in the production process that are being recommended, in this way the company would be more efficient and would have products of higher quality.

Projection of expenses for training personnel in the process area, maintenance, and equipment installation for 5 years. The following table describes the details of these expenses.

Table 3. Projection of expenses by participation.

Expense Projection					
Years:	1	2	3	4	5
Training of personnel	200	2.100	2.205	2.315	2.431
Maintenance of equipment	120	1.260	1.323	1.389	1.458
Maintenance of facilities	150	1.575	1.653	1.736	1.823
Cleaning of areas and utensils	180	1.890	1.984	2.083	2.187
Total	1300	6.825	7.165	7.523	7.900

Electrical installations and water networks

Through the development of a Good Manufacturing Practices guide, it is suggested that knowledge be established on the handling of raw materials and inputs, cleaning and disinfection of work areas, establishment design, proper management of production operations, proper hygiene of personnel involved directly and indirectly in the production stages, packaging and labeling of orange juice. This is expected to minimize contamination hazards in the manufacturing stages.

The plant must have toilets, showers and changing rooms in sufficient quantity, separate for men and women, keeping the sanitary facilities clean and without direct access to the production areas.

Soap dispensers, hand-drying implements, and closed waste receptacles must be installed in the restrooms and disinfectant dispensers must be installed at the entrances to the production areas.

At present, there are different types of electrical installations whose common purpose is to conduct and distribute the electrical current from its point of origin or producer elements (electrical service) to its point of exit or consumer elements (electrical appliances, light points, among others).

Among the different types of electrical installations, we have by their use, their voltage and their location, next, we will detail the types of electrical installations according to their use and according to their voltage.



Fig. 4. Electrical installations.

Good Manufacturing Practices BPM Programs.

By having a GMP program, compliance records must be kept daily, which allow the correct functioning of the program. The most frequently kept records are:

- Sanitary quality monitoring or Cleaning and disinfection or Labeling
- Post-operational of the day.
- Staff health status.
- Production control.
- Staff training and health records.
- Records of visits to facilities.
- Records of Corrective and Preventive Actions.
- Record of product information throughout the production line.

3.3 GMP Regulations.

Resolution ARCSA 057- 2015.

Technical health standard on good hygiene practices for food processing establishments categorized as artisanal and organizations of the social and solidarity economy system NTE - INEN 3039 2015. Catering services for good manufacturing practices.

That is, this regulation defines operating guidelines for establishments dedicated to food processing, in order to guarantee the hygiene of their products. resolution arcsa-de-067-2015 ggg.

Technical health standard for processed foods, distribution establishments, marketing, transportation and collective feeding establishments, that is, as of 2015 by resolution arcsa-de-067-2015-ggg, processed foods require Sanitary Notification instead of Sanitary Registration, for their distribution and marketing in Ecuador.

Therefore, processed foods that have a current sanitary registration will maintain said code, once the validity has

expired and if they have the certificate of good manufacturing practices.

Through the development of a Good Manufacturing Practices guide, it is suggested to establish knowledge about the handling of raw materials and inputs, cleaning and disinfection of work areas, establishment design, proper handling of production operations, proper hygiene of personnel directly and indirectly involved in the stages of production, packaging and labeling of orange juice. For which it is expected to minimize contamination hazards in the manufacturing stages.

3.4 Production process.

It is done with drinking water manually, the impurities on the surface of the fruit are removed, but the disinfection of the fruit is not ensured.

The use of chemical solutions is suggested to lower the microbial load, using chemical compounds such as iodine which comes in various concentrations of iodine at 2.5% - 3% - 3.5%. Which is diluted in water to which it is an excellent viricidal, fungicidal and bactericidal (gran + or gran-), even in the presence of hard water. It is formulated in different concentrations.

Juice extraction.

It is done manually, with semi-industrial squeezer and with human intervention.

It is suggested: The use of an online system. It consists of inserting the fruit into a cannula and pressing it between two plungers.

Pasteurization.

It is done in an artisanal way with stainless steel pots and a thermometer to measure 110°C for 3 minutes. It is suggested: the use of an industrial pasteurizer.

Filtration of orange juice.

Sieving of the juice to remove peel residues is done with large stainless-steel strainers.

The use of an industrial sieve is suggested to make filtration more effective and with less intervention from the human hand.

Manual bottling.

The use of a 6-nozzle manual bottling machine is suggested, which would improve time.

Storage.

It is carried out in horizontal freezers controlling the temperature. A semi-industrial vertical freezer cooler is suggested.

4. Conclusions

This project determined that the orange juice plant "Francisco Navas" does not comply with the parameters and specifications in force established by the different regulatory entities in the country that ensure the proper

performance of the activities applied to food processing plants.

A checklist was carried out to verify the current situation of the processes and facilities and based on the results it was concluded that there was partial compliance with the Arca Regulations in the area of production and raw materials, among which are:

The plant does not have an adequate distribution of the production areas.

The lack of instruction of operational and administrative personnel regarding the implementation of Good Manufacturing Practices that determine the behavior and obligations of the staff.

The plant's operating personnel do not have regulations for the proper handling and manipulation of equipment, utensils, raw materials and inputs in order to optimize resources.

It does not have an employee training program and therefore does not favor continuous improvement in its processes.

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