

## REPORT self-inspection



<b>Date:</b> <i>25-Nov-2013</i>	<b>AFFAIR:</b>  <i>Deposit</i>	<b>P.:</b> <i>1 32</i>
<b>Number program:</b>  <i>PLAN-RAR-006/03 02/13 No.</i>		<b>REPORT</b>
<b>No. Plan:</b> <i>FOGL-RAR-035/01 No. 03/13</i>		<i>NO: 03/13</i>

## 1. Full name

## Firm

## Date

**Auditor:**

Viviana Dominghini  
Quality guarantee

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**Auditor:**

Denis Sanchez  
Quality guarantee

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**Auditor:**

Silvina Bermejo  
Quality guarantee

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**Audited:**

Sergio Guajardo  
Deposit

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**Audited:**

Pablo Dulio  
Deposit

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**Reviewed by:**

Luis Ruffet  
Maintenance

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**Approved by:**

Enrique Ciccioli  
Technical director

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two. **Objective:**

Describe the results and observations made to deposit self-inspection.

3. **Developing:**

On 30 and 31 October 2013 it was conducted self-inspection tank.

Group Appointed Auditor:

- ❖ Viviana Dominguni
- ❖ Denis Sanchez
- ❖ Silvina Bermejo

Personal Audited:

- ❖ Sergio Guajardo
- ❖ Pablo Dulio

**Organization and Staff**

<i>Department:</i>	<i>Deposit</i>	<i>Management:</i>	operations management Luis Ghio
<i>Staff amount</i>	8	<i>Responsible Floor:</i>	Pablo Dulio
<i>position</i> <i>Responsible Plant</i>	<i>Head of Central Deposit and Heavy</i>		
<i>Report to:</i>	Plant management (Enrique Ciccioli)		
<i>He reported:</i>	5 Operators, 1 Administrative 1 Supervisor		

Staff involved in heavy central warehouse tasks. (4 operators and Central Depository Heavy,

1 auxiliary Depository and Central Pesadas 1 Administrative deposit 1 Supervisor and Central Depository

Heavy, 1 Head of Central Deposit and Heavy)

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**Task description and Registration of Firms**

Market Stall	Occupant Position Description Task Log		Firm	Acronyms allocation
Boss DP and CP	Pablo Dulio	Signed	Signed	PED
Supervisor DP and CP.	Sergio Guajardo	Signed	Signed	SEG
DP and CP operator	Hector Garcia	Signed	Signed	HFG
DP and CP operator	Martin Capurro	Signed	Signed	MAC
DP and CP operator	Victor Balbis	Signed	Signed	VAB
DP and CP operator	Mariano Rivero	Signed	Signed	MER
CP and DP Assistant	July Toledo	Signed	Signed	JLT
administrative Deposit	Cristian Gonzalez	Signed	Signed	CDG

**Development of the audit:**

On 30 October 2013 was launched at the opening meeting. In the same plan presented audit FOGL-RAR-035/01 No. 03/13, and a brief summary of how this would be provided Ileva out the audit.

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He start reviewing documentation sector and the specific requirements are given as available 2372/08. reviewing payroll records and review of comments were made previous self-inspections.

GUIDE FOR INSPECTORS GOOD MANUFACTURING PRACTICE OF DRUGS				
CHAPTER 5				
DEPOSIT				
Terms	YES	NO	NA	Observations
If access of materials / inputs and outputs of products is direct from the outside, is there a procedure for re- I keep the integrity of the same?	X			. . . .
Is there a system that protects inputs / materials and products located inside?	X			. . . .
Floors, walls and ceilings are they in good condition and hygiene?		X		painting was observed in poor condition on the walls and stains. Under quarantine it is in disrepair. Like the left wall of MP approved, and the doorframe of solvents.
Drains and pipes are they in good condition and hygiene?	X			. . . .
The visible electrical installations are in good condition?	X			. . . .
Local environmental conditions do they allow storage meet the requirements established?	X			. . . .
Is the temperature control and registration is required?	X			SOPS-RAR-154/06: "Control and Record Temperature and Humidity Deposit"

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If they are needed, is there equipment to control the temperature?	X			. . .
Are there records?	X			- FOGL-RAR-008/03 - Records issued by continuous letter
Is there a need to control moisture in warehouses?	X			Humidity is controlled in the tank capsules (<-65%) according LIST-RAR0002 / 04.
If they are needed, is there equipment to control humidity?	X			continuous letter
Temperature and humidity Do they match the parameters established for stored materials and products?	X			In the capsule magazine Humidity is controlled by RAR-LIST-0002/04, but does not match requested by the capsule manufacturer.
Is there need for cold room?		X		. . .
Are there temperature logs?			X	. . .
Is there a warning system indicating deviations from the set temperature in the cold?			X	. . .
Scales used in the reception and / or dispatch are they calibrated periodically?	X			calibration of the balance BVM CA13365 with Vto verified. December 13
Are they checked frequently defined?	X			Biannual
The staff is dressed in the uniform defined in the instructions dress for the sector?	X			. . .
Are the uniforms clean and in good condition?	X			. . .
Are there areas physically separated or systems that prevent the mixing of productive and non-productive inputs?	X			SOPS-RAR-009: "Entering materials Plant"

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Are there procedures for all operations in this sector (receipt of goods, movement of packages, load conditions, offices, etc.)	X			. . .
Is there a receiving area?	X			Reception areas and forwarding are not physically separated
Is the income of inputs documented?	X			. . .
Does the record entry of inputs is:	X			. . .
I computerized?	X			. . .
Manual?		X		. . .
Is the system reliable?		X		QAD version was changed. the new version (QAD Net) will be validated in the first half of 2014
Does the control stock of inputs and outputs is:				. . .
I computerized?	X			
Manual?	X			control is performed according SOPS-RAR-232/01: "Inventory Control" and SOPS-RAR290 / 01: "Management control stock at warehouse"
Is the system reliable?		X		It is not validated
Does the location of productive and non-productive inputs is:	X			. . .

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I computerized?	X			. . .
Manual?		X		. . .
Is the system reliable?		X		It is not validated
The receiving area is designed and equipped so as to allow, if necessary, cleaning before storage containers?	X			. . .
A visual inspection done at the reception to check damage during transport?	X			SOPS-RAR-009: "Entering materials Plant"
Each unit is labeled container received your income?		X		enter labeled
The label does it contain the following information ?: Name input	X			. . .
Number assigned to your reception.	X			. . .
Number of bulk / Total packages	X			. . .
If necessary, special storage conditions	X			. . .
The label is attached to the container body and not the top?	X			. . .
Is there sampling area?	X			. . .
In the absence of such an area, does the sampling is done to prevent contamination and cross-contamination?	X			. . .
Is PON taken to ensure the identity of the contents of each container of raw material?	X			. . .
Sampled containers are they identified as such?	X			SOPS-RAR-004/06: "Sampling of raw materials"

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Is the number of containers sampled is consistent with the standard sampling?	X			. . .
Are all packaging materials, without exception, are sampled for quality control according to the rule?	X			SOPS-RAR-119/04: "Sampling plan and acceptance of packaging materials according to ISO 28591" packaging material is sampled in the tank.
Before his release by Quality Control Are all inputs and finished products remain in physical or quarantine system, identified as such?	X			. . .
Is there an area or computer system that demarcates or restrict the use of raw materials, packaging materials, semi-finished and finished products quarantined?	X			There is a segregated and locked quarantine area for material. The QAD system does not allow the use of inputs or bulk materials that are not in status Approved
Rejected materials, are they properly identified and stored separately in restricted areas, so that access to them is prevented by unauthorized personnel?	X			SOPS-RAR-120/03, "Storage Material"
Is there a procedure for destruction of materials?	X			SOPS-RAR-019/04: "Destruction of hazardous waste by incineration"
Approved, properly identified inputs are they?	X			. . .
Reanalysis The date is indicated on the label or computer system?	X			. . .
Is there a process or system to ensure the non-use of raw materials and / or bulks due or overdue date reanalysis?	X			The QAD system does not allow the use of inputs or bulk materials that are not in status Approved
Do all available raw materials are within its validity period?	X			. . .



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Is the available storage is good and rational in order to preserve the identity and integrity of inputs and outputs?	X			. . .
Are the shelves and / or pallets are separated from floors and walls so as to allow cleaning?	X			. . .
Do the movements of inputs and stowed products are made with mechanical equipment?	X			. . .
How propulsion used, it is done so as not to release gases that pollute the environment?			X	. . .
Are packaging containing inputs (drums, kegs, boxes, etc.) are tightly closed?		X		The remaining raw materials is closed only with seals, no external bags are placed as secondary protection.
Is there a safe area or sector and restricted access to store tags or labels?	X			. . .
Everything outdated printed materials is destroyed?	X			. . .
Does the same fate recorded?	X			. . .
Are there sectors within the tank with actual physical separation, security and restricted access psychotropic and narcotic substances?	X			Psychotropics are stored in the deposit lock cages (SOPS-RAR120 / 03: "Storage Material")
Are there any measures in the Stowage of corrosive materials in order to protect the integrity of the other inputs / materials are taken?	X			. . .
Is there a PON in case of spillage of corrosive or toxic and active substances?	X			SOPS-RAR-127/04, "Spill toxic, corrosive and active substances"
Is there a place for storage of flammable and explosive products?	X			. . .
Is there a body in the jurisdiction competent security to enable these deposits?	X			. . .

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If such a body exists, bonded warehouse Is this him?	X			. . .
There is enough (1 per 100 m2) of portable fire extinguishers?	X			. . .
The type of portable fire extinguishers there, are adequate for existing content?	X			. . .
Extinguishers are adequate load (pressure, amount recharging time)?	X			. . .
Are accessible fire extinguishers? They are properly marked and identified by type fire extinguishers?		X		. . .
Is there an automatic fire detection?	X			. . .
There is a routine maintenance and testing for the system?	X			. . .
The system (detectors and control panels) is approved	X			. . .
The system has emergency power supply?	X			. . .
Is there a spill containment system?	X			. . .
The floors are waterproofed	X			. . .
There is a freight and insurance systems download	X			. . .
It exists and is available contingency plan for accidents and spills?	X			- SOPS-RAR-209/02, "Occupational accidents and medical emergencies"  - SOPS-RAR-127/04, "Spill toxic, corrosive and active substances"
What residues are separated by type and characteristics?	X			SOPS-RAR-056/05: handling, sorting and treatment of common waste and is-



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				peciales "
They are identified?	X			. . .
Provide in materials for packaging or special waste containers, unattackable materials chemically suitable physical strength and roll systems.	X			. . .

Facilities

traveled was carried out by the sector, inspecting the facilities, equipment and operative.  
At the time of the audit sector he was ordered. Operational staff used the equivalent  
pursuit of personal protective equipment (PPE) for circulation in the tank.

During the tour observed lack of paint on the walls, stains and drop re-  
Voque.

Wall Deposit entry



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Gateway to Deposit



Wall MP left approved.



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Gateway to Quarantine



Wall MP left approved.





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**Join operative Materials**

operative input materials was audited plant according to the procedure **SOPS-RAR**

**009/06: " Income materials plant "**

the entry of the following raw materials were witnessed: Citric acid grinding, Polyethylene Glycol, Sodium bicarbonate, cases Asotrex row.

The kegs containing primary packages at entry had open tops.



Before entering the plant not the kegs were reviewed with a cloth soaked in alcohol as indicated ca procedure.

**Operatoria output materials**

Exit the operation returns to pillar witnessed several. This transaction is not contemplated It gives a procedure.

**Operatoria material transfer between Central and deposit Pesadas**

the transfer operation is witnessed between Central materials Heavy and Storage for OT110820 Phenazopyridine, batch 72146 according to the procedure SOPS-RAR-202

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It was observed that during this transaction no materials are reviewed with alcohol as required procedure nor the personnel employed PPE referred to in SOPS.

**Control and assembly materials**

the momentary arrangement of materials assembled ready for shipment was observed at tercerista developer:

- Product **Creon Forte OT106355 lot: 49143.**

He was not in the area for that purpose.

Div Vartalon product materials were observed for assembly:

- Code: 10710 Chondroitin Sulfate, 13mp0664 analysis.
- Code: 11050 Glucosamine Sulfate analysis. 13mp0657

They do not have a sector destined for control and assembly materials for shipment to third.

**Control Locations**

different positions of materials were checked, comparing the actual location against the system

<u>Code</u>	<u>Description</u>	<u>No. Analysis</u>	<u>actual location</u>	<u>Location System</u>
21095	Lemon oil	12mp0672	07A03 (MP AP)	It does not match
20325	aspartame	13mp0293	05B04 (MP AP)	It does not match
315118	Beclasma HFA Cases	13me1073	15B02 (CUA)	They do not load positions nes
22240	Propylene glycol	13mp0737	(CUA Floor)	Match
37092	20.2 mm seal	11me0667	04C03 (ME AP)	are not loaded positions

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## Monitoring of the action plan corresponding to self-inspection 2012 INFO-RAR-006/03 N ° 02/12

Point	Result	Grade	Action	Responsable	Target date	State
one	lack of paint and water stains were observed due to possible leaks about the <u>wall adjoining the neighboring building.</u>	two	It will be repaired and painted	Luis Ruffet	Apr 2013	CUMPLIDO December 2012
two	deteriorated paint was observed in the basin floor Inflamables.	two	It will be repaired and painted	Luis Ruffet	Apr 2013	CUMPLIDO December 2012
3	Deposit luminaries Capsules and the Office have the corresponding protection.	two	protection will be placed in the tank luminaries Capsules	Luis Ruffet	Mar 2013	CUMPLIDO April 2013
4	They do not have smoke detectors in the office of the tank or the tank capsules.	two	Smoke detectors are placed in these sectors.	Luis Ruffet	June 2013	IN PROCESS PO 60004 (30-Jan-13)
5	The waste tank does not have an extraction system or air renewal generating accumulation of odors.	two	extraction will be placed in the waste tank following the law.	Luis Ruffet	February 2013	PENDING



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Point	Result	Grade	Action	Responsable	Target date	State
6	The send and receive not physically separated from and is not defined in a process system for the operation in order to avoid cross contamination	one	will be included in the procedures SOPS-RAR-009/06, "Entry Materials" SOPS-RAR-039/06, "delivery terceristas" guidelines for receiving and forwarding so as to avoid cross contamination.	Pablo Dulio	Apr. 2013	PENDING
7	In the area intended for semi-finished and semifinished materials approved raw materials and raw materials was quarantined.	two	part assigned to "Semifinished Approved" to "Semi-finished quarantine 'sector will be allocated and identification sign will be placed.	Pablo Dulio	May. 2013	PENDING
8	In the area fractionation flammables output compressed air without using met.	3	a sign "Out of Service" will be placed.	Pablo Dulio	Feb. 2013	PENDING
9	The deposit has a system of continuous letter and alarms for temperature control. The alarm system and measures to take if the temperature excursion are not covered by the procedure.	two	"Control and recording of temperature and humidity Deposit" including the operation of the alarm system and actions to take in case of temperature excursions: a new version of SOPS-RAR-154/06 is issued.	Pablo Dulio	Apr. 2013	PENDING

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Point	Result	Grade	Action	Responsible	Target date	State
10	The QAD system is not reliable. He is not validated and there have been no challenges to verify inability to use inputs quarantined due, in reanalysis or rejected.	two	QAD system will validate the NET	Carlos Favata	Jan to Aug 2013	PENDING
eleven	The emergency door connecting corridor R & D Inflammables tank has an unfriendly system. The deposit of flammable, in turn, has two doors of the same characteristics, one toward the hallway in front of the camera stabilities and another toward the General Deposit so, in this way, can be accessed from the hallway annulling the General Deposit restricted access to it.	two	A sensor is placed to triggers an alarm when opening the door	Luis Ruffet	Apr. 2013	CUMPLIDO November 6, 2013

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Point	Result	Grade	Action	Responsable	Target date	State
12	<p>The FOGL-RAR-189/01: Bitácora Packaging Materials</p> <p>It does not contain the signature on "Con-</p> <p>He trolled "in the understood period</p> <p>dido between the 23/09/11 to</p> <p>25/10/11 and in the period com-</p> <p>pinned between 10/18/12</p> <p>until 03/12/12.</p> <p>Guidelines for use</p> <p>This FOGL not Encoun-</p> <p>tran detailed in an SOP.</p>	one	an SOP that describes guidelines for using the FOGL mentioned and train staff will be issued.	Pablo Dulio	Apr 2013	PENDING
13	<p>The following SOPS not cuen-</p> <p>as with the training of the</p> <p>current version:</p> <ul style="list-style-type: none"> <li>- SOPS-RAR-009/06</li> <li>- SOPS-RAR-256/01</li> </ul>	one	<p>staff will be trained in</p> <p>current versions of the</p> <p>SOPS mentioned.</p> <p>-SOPS-RAR-009/06: Sergio Guajardo and Cristian González</p> <p>-SOPS-RAR-256/01: July Toledo</p>	Pablo Dulio	Apr 2013	PENDING

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Point	Result	Grade	Action	Responsible	Target date	State
14	The BVM003 balance displays the calibration date 21/05/12 with Certificate No. 12192. It is defeated in November 2012.	one	Balance must be calibrated	Pablo Dulio / Ya-Yemi thousand	December 2012	CUMPLIDO DIC / 2012
fifteen	In the FOGL-RAR-156/01, "Income, changes and declines in deposit locations" blanks without voiding without saving and amendments were observed.	one	He reconsider the staff in GDP	Silvina Bermejo	June 2013	CUMPLIDO SEP / 2013

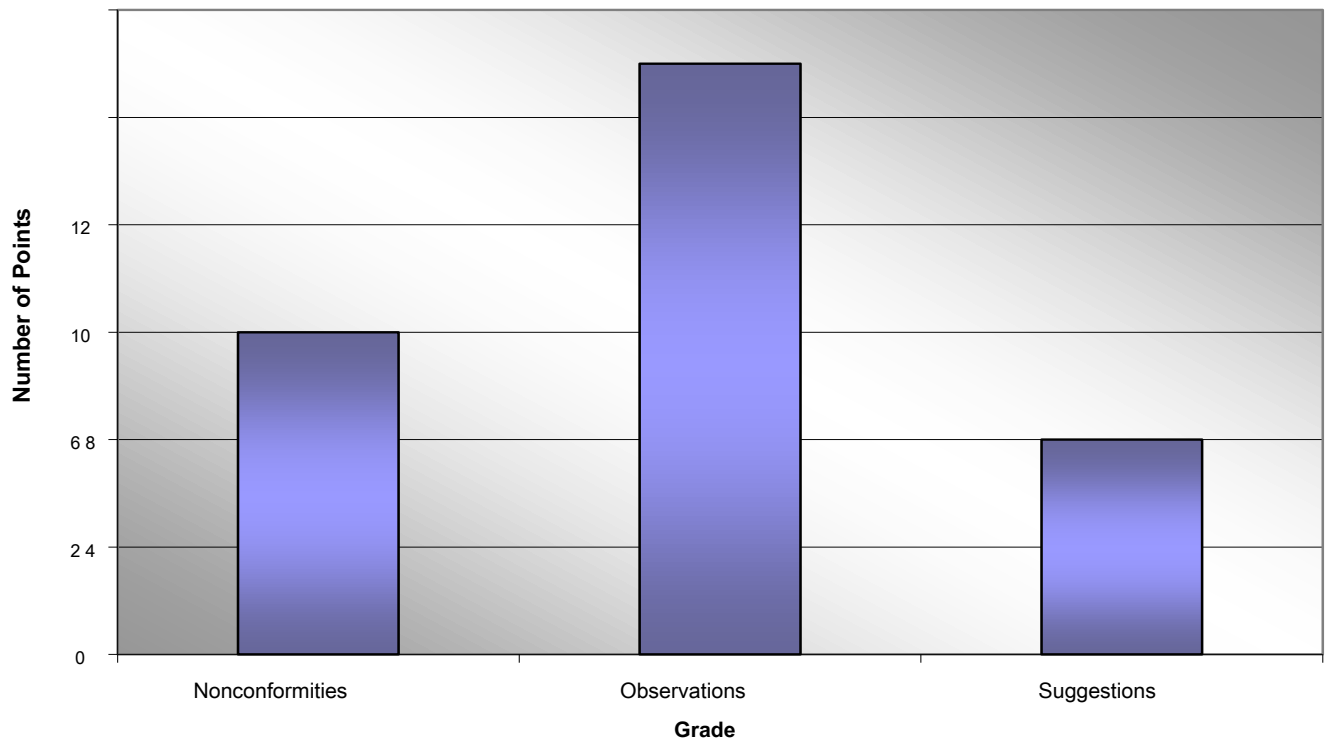
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**Self-inspection conclusions:**

Of a total of 21 points they were recorded:

- ❖ 6: Nonconformity
- ❖ 11: Observations
- ❖ 4: Tips

**References:**

- Grade 1: Nonconformance
- Grade 2: Observation
- Grade 3: Tip

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Point	Result	Grade	Recommendation	Corrective action	precautionary measure associated	Responsible Date	Pro- Gramada
one	lack of paint was observed, un- prendimiento plaster, maintained chas moisture in pare- des deposit.	2	Repair and paint	It will be repaired and painted	Corrective Action Me- DIATA	Luis Ruffet	Apr 2014
two	In the tank Capsules stores packaging material, raw materials and clothing Personal deposit.	two	Relocating materials  The sectors for this purpose.	He unmount the deposited to the capsules, leaving the  This space avail- ble for another use.  measures be taken suitable for the soul STORAGE CARE transient of inputs moisture controlled.  this transaction will be included in the SOP-RAR-120: "Al- macenamiento of mate- rials ".	NA	Pablo Dulio	July 2014

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Point	Result	Grade	Recommendation	Corrective action	precautionary measure associated	Responsible Date	Pro-Gramada
3	<p>The LIST-RAR-0002 specifies humidity conditions</p> <p>Deposit capsules, CUA-</p> <p>They do not match the request by the manufacturer on the packaging the capsules. The manufacturer re-</p> <p><b>He wants a range ( 35-65%) HR and</b></p> <p>LIST indicated in only the limit higher.</p>	two	<p>Include in the range LIST specified by the manufacturing for the storage ment of capsules.</p>	<p>RAR-LIST is removed from 0002 tank Cap-Sulas.</p> <p>the range will be added moisture SOPS-RAR 120: "Storage materials"</p>	NA	Pablo Dulio	July 2014
4	<p>The SOPS-RAR-120/03 mentions storage of materials</p> <p>Premiums and hormone-Oncológicas them both in "quarantine" as in "approved" within a closet.</p>	two	<p>Update the procedure according to the operating current</p>	<p>It will update the SOPS-RAR-120 in which will include the deposit Segregated.</p>	NA	Pablo Dulio	July 2014

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Point	Result	Grade	Recommendation	Corrective action	precautionary measure associated	Responsible Date	Pro-Gramada
5	an internal payroll used Stock control not encoded or is con-warm in a procedure.	3	Include a method and encode the spreadsheet.	the use of the template is removed.	NA	Pablo Dulio	November 2013
6	The remaining raw materials It is closed only with seals, not outer bags are placed (secondary Darias), labels are attached partially, allowing its un-engraftment.	two	Double bag for use remaining materials premiums and	It will be included in the SOPS-RAR-034 fractionation tion of materials, operative for conditioners tioning material surplus.	immediate corrective action	Pablo Dulio	July 2014
7	Printed packaging material, It is segregated, but cages are open, the same with the boxes They are containing them.	1	Keep closed cages das with restricted access	Is recondition the open boxes. The open bars are determined ben working day and activity within this.	NA	Pablo Dulio	November 2013



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Point	Result	Grade	Recommendation	Corrective action	precautionary measure associated	Responsible Date	Pro- Gramada
8	<p>Entrance floor:</p> <p>The containers containing kegs primary at admission to plant had the tops abier-tas exposing the primary container.</p> <p>Before entering the plant not</p> <p>They reviewed the kegs with a cloth soaked in alcohol as indicated</p> <p>SOPS-RAR-009/06</p>	1 re-s	skill staff in SOPS-RAR-009/06	Retrain staff in the SOPS	NA	Sergio Gua- Jardo	July 2014

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Point	Result	Grade	Recommendation	Corrective action	precautionary measure associated	Responsible Date	Pro-Gramada
9	It does not have a DISTILLED industry swim for control and in-samle of raw materials fractionated.	3	Devote sector control and assembly ma-fractioned raw Terias	The dimensions, occupations tion of deposit and character-istics volume our fraccionamien-cough, they make it impossible for It delimits a zone for making checks on frac-tioned. Will the greater emphasis on providing a space chord allow perform this task with comfort	NA	Pablo Dulio	November 2014
10	Exit operative mate-rials production is not contem-Plada in proceedings	two	Include such transaction in the SOPS entry materials.	It amend the SOPS-RAR-009 Income ma-terials to plant trans-forming this in SOPS income and egre-sw.	Corrective action scheduled	Pablo Dulio	July 2014

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Point	Result	Grade	Recommendation	Corrective action	precautionary measure associated	Responsible Date	Pro-Gramada
eleven	It was found that in the operation transfer of materials De- pósito the Centra of Pesadas not materials are reviewed with al- Cohol as required by SOPS- RAR-202/04, neither staff used PPE referred to in SOPS.	1 re-	skill staff in SOPS-RAR-202/04	Retrain staff	NA	Sergio Guajardo	July 2014
12	The location on the system deposit is not updated or not has the information loaded. The SOPS-RAR-249/01 'Locations in deposits "in its" Scope " It includes quarantine tank, currently not designated ubica- tions in the Quarantine.	3	Update the procedure according to the operating current	Updated informa- tion locations.	NA	Pablo Dulio	May 2014

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Point	Result	Grade	Recommendation	Corrective action	precautionary measure associated	Responsible Date Pro-	Gramada
13	They do not have detectors hu- mo in the office of deposit or the tank capsules.	Two	detectors be placed smoke in these sectors.	They will be placed detectors smoke said sec- beef.	NA	Luis Ruffet	December 2014
14	Waste reservoir does not count with an extraction system or Air renewal generating accumulation of malodors.	two	Consult with the depart- ment of Hygiene and securi- ty conditions You must comply extraction and place following the le- gis lation in force.	the circuit will be modified collection and manipulated tion waste ma- Nera to move bags closed and full drums not exceeding 90% of its ability to avoid Spills and generation smells.	NA	Luis Ruffet	July 2014

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Point	Result	Grade	Recommendation	Corrective action	precautionary measure associated	Responsible	Date Pro-Gramada
fifteen	The send and receive not They are separated physically and it is not defined in a procedure ment system for the operative way to avoid cross contamination	one	Included in the process guidelines for performing zar reception and experi- diting so as to avoid pollution crusade.	It will be included in the pro- dures SOPS-RAR 009/06: "Entering mate- rials " and SOPS-RAR 039/06: "Sending a terceris- tas "guidelines for perform reception and forwarding so avoid contamination crusade.	NA	Pablo Dulio	July 2014
16	In the area intended for semi-processed borated and approved raw materials two materials was semie- worked and raw materials in CUA- rentena.	two	Earmark part of the sector for materials semielabora- do quarantined and place poster.	Se- not be stored mielaborados state AP, because the normal Mativa prevents analysis and approved at this stage. Semielabora- sector two only store in CUA state	NA	Pablo Dulio	February 2014

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Point	Result	Grade	Recommendation	Corrective action	precautionary measure associated	Responsible Date	Pro-Gramada
17	In the area of fractionation flammable materials found output compressed air use.	3	Place a label of "Fuera Use "	a sign will be placed "Out of use".	NA	Pablo Dulio	January 2014
18	The deposit has a system Continuous letter and alarm para temperature control. The alarm system and measures to take if Outing temperature are not contemplated two in the procedure.	two	PCOS include the functional tioning system alarms and measures take if excursio- nes temperature.	It is issued a new version of SOPS-RAR 154/06: "Control and registration Temperature and Hume Deposit dad "INCLUDING going operation alarm system and actions to take in For trips temperature.	NA	Pablo Dulio	July 2014

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Point	Result	Grade	Recommendation	Corrective action	precautionary measure associated	Responsible Date	Pro-Gramada
19	The QAD system is not reliable. Do not It is validated and have not been challenges made to verify inability to use inputs quarantine expired in reanalysis or rejected.	2	Confirm the new version of QAD system	the system will be validated QAD .NET	NA	Carlos Favata	Jan- Aug 2014
twenty	The FOGL-RAR-189/01: Logbook Packaging materials not contain signature in "Controlled" in the pe- riod between the 23/09/11 to 25/10/11 and the period 10/18/12 to 03/12/12. The guidelines for the use of This FOGL are not detailed opened in an SOP.	one	Issue an SOP detailing guidelines for FOGL use and training to the staff.	SOP will be issued to Describe the guidelines for the use of FOGL mentioned and Capacitación It TARA staff.	immediate corrective action	Pablo Dulio	July 2014

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Point	Result	Grade	Recommendation	Corrective action	precautionary measure associated	Responsible Date	Pro- Gramada
twenty-one	<p>The following SOPS not count with training version valid:</p> <ul style="list-style-type: none"> <li>- SOPS-RAR-009/06</li> <li>- SOPS-RAR-256/01</li> </ul>	one	Train staff current versions of SOPS mentioned.	<p>staff will be trained in current versions the SOPS mentioned two.</p> <p>-SOPS-RAR-009/06: Sergio Guajardo and Cristian González</p> <p>-SOPS-RAR-256/01: July Toledo</p>	NA	Pablo Dulio	July 2014

This completes the INFO-RAR-006 Report / 03 NO: 03/13