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TAG	Description	Trade Name	Model	Series N°	Criticity	Location	Registred Date
AU2	AUTOCLAVE	HOGNER	VAP 5001 PHARMA SANITARIO VL/DP	°030426	CP	PB 2.9	29/10/04
AU3	AUTOCLAVE	HOGNER	VAP 5001 PHARMA SANITARIO VL/DP	°030427	CP	PB 4.20	29/10/04
ML1	LAVADORA LANCER	LANCER	ML1	3W050029	NC	PB 2.6	21/02/05
I0001	CAMARA FRIA 2° - 8° C - INTERMEDIA	E.F.C.	CPM-5-SSE	104071 / 104072	CP	PB 2.18	27-10-04
I0002	CAMARA FRIA - 15° C - SKIN BOTTLES	E.F.C.	CPB-8-SSE	104073 / 104074	CSP	PB 3.8	27-10-04
I0003	CAMARA FRIA 2° - 8° C - STORAGE	E.F.C.	CPM-25-SSE	104068/104069/104070	CP	PB 3.1	27-10-04
I0004	COMPRESORES DE AIRE COMPRIMIDO	ATLAS COPCO	ZT 37 WPP86	A11-702828	CP	PB 1.10	01/06/04
I0005	COMPRESORES DE AIRE COMPRIMIDO	ATLAS COPCO	ZT 37 WPP86	A11-702834	CP	PB 1.10	01/06/04
I0008	CALDERA	GONELLA	CALDERA HUMOTUBULARS2 (10 Kg/cm2)	5093	CSP	PB 1.13	01/06/04
I0009	CALDERA	GONELLA	CALDERA HUMOTUBULARS2 (10 Kg/cm2)	5095	CSP	PB 1.13	01/06/04
M0001	APILADORA ELÉCTRICA	LINDE	L 16 MS	B4X 091 S00056	NC	PB 3.25	01/06/04

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TAG	Description	Trade Name	Model	Series N°	Criticity	Location	Registred Date
M0002	CODIFICADORA LASER	DOMINO	S-SERIE PLUS	E1F 03820	CSP	PB 3.3c	25/03/08

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Systems Master List

TAG	System Type	Supplier ID	Location	Criticity	Registered Date
ACO	SISTEMA DE AIRE COMPRIMIDO	N/A	PB 1.10	CSP	Jun-04
CA	SISTEMA DE AGUA CALIENTE	N/A	PB 1.13	CSP	Jun-04
SVI	SISTEMA DE VAPOR INDUSTRIAL	N/A	PB 1.13	CSP	Jul-04
ACI	AGUA CALIENTE INDUSTRIAL	N/A	PB 1.13	CSP	Jul-04
SDG	SISTEMA DE DISTRIBUCIÓN DE GAS	N/A	CABINA DE GAS	CSP	Jun-04
ACP	AGUA CALIENTE POTABLE	N/A	PB 1.13	CSA	Jun-04
AFP	AGUA FRIA POTABLE	N/A	PB 1.14/5	CSP	Jul-04
PT	PRETRATAMIENTO DE AGUA	N/A	PB 1.11A	CSP	Jul-04
PW	GENERACION, ALMACENAJE Y DISTRIBUCION DE PW	N/A	PB 1.11A	CSP	Jun-04
WFI	PRODUCCION, ALMACENAJE Y DISTRIBUCION DE WFI	N/A	PB 1.11B	CSP	Jun-04
VL	GENERACION DE VAPOR LIMPIO	N/A	PB 1.11B	CSP	Jun-04
BMS	SISTEMA DE CONTROL BMS	N/A	PB 1.7	CSP	Jun-04
EMS	MONITOREO CONTINUO EMS	N/A	PB 1.7	CSP	Ene-05
SEE	SUB ESTACIÓN ELECTRICA	N/A	PB 1.4	CSP	Ene-05
TE	TABLEROS ELECTRICOS	N/A	PB 1.4	CSP	Jul-04
UMA1	UNIDAD MANEJADORA DE AIRE	N/A	1 P1.2	CSP	Jul-04
UMA 2	UNIDAD MANEJADORA DE AIRE	N/A	PB 0.24	CSP	Ene-11
UMA3	UNIDAD MANEJADORA DE AIRE	N/A	1 P1.2	CSP	Jul-04
UMA4	UNIDAD MANEJADORA DE AIRE	N/A	1 P1.2	CSP	Jul-04
UMA5	UNIDAD MANEJADORA DE AIRE	N/A	1 P1.2	CSP	Jul-04

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TAG	System Type	Supplier ID	Location	Criticity	Registered Date
UMA6	UNIDAD MANEJADORA DE AIRE	N/A	1 P1.2	CSP	Jul-04
UMA7	UNIDAD MANEJADORA DE AIRE	N/A	1 P4.2	NC	Jul-04
UMA8	UNIDAD MANEJADORA DE AIRE	N/A	1 P4.2	CSP	Jul-04
UMA 9	UNIDAD MANEJADORA DE AIRE	N/A	PB 0.25	CSP	Ene-11
UMA10	UNIDAD MANEJADORA DE AIRE	N/A	1 P1.2	CSP	Jul-04
UMA11	UNIDAD MANEJADORA DE AIRE	N/A	1 P1.2	CSP	Jul-04
UMA12	UNIDAD MANEJADORA DE AIRE	N/A	TERRAZA COMEDOR	CSP	Jul-04
UMA13	UNIDAD MANEJADORA DE AIRE	N/A	1 P4.2	NC	Jul-04
UMA14	UNIDAD MANEJADORA DE AIRE	N/A	TERRAZA GUARDIA	CSP	Jul-04
UMA15	UNIDAD MANEJADORA DE AIRE	N/A	1 P1.2	CSP	Jul-04
UMA16	UNIDAD MANEJADORA DE AIRE	N/A	1 P4.2	CSP	Jul-04
VE 17	VENTILADOR DE EXTRACCION	N/A	PB 1.3	NC	Jul-04
VE 18	VENTILADOR DE EXTRACCION	N/A	PB 1.5	NC	Jul-04
ES19	SPLIT	N/A	PB 1.4	CSP	Jul-04
VE 20	VENTILADOR DE EXTRACCION	N/A	PB 1.10	NC	Jul-04
VE 21	VENTILADOR DE EXTRACCION	N/A	PB 1.13	NC	Jul-04
VE 22	VENTILADOR DE EXTRACCION	N/A	PB 1.14	NC	Jul-04
UMA 23	UNIDAD MANEJADORA DE AIRE	N/A	PB 1.11	NC	Jul-04
VE 24	VENTILADOR DE EXTRACCION	N/A	1P 1.2	NC	Jul-04
VE 25	VENTILADOR DE EXTRACCION	N/A	1P 1.2	NC	Jul-04
VE 26	VENTILADOR DE EXTRACCION	N/A	1P 1.2	NC	Jul-04

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TAG	System Type	Supplier ID	Location	Criticity	Registered Date
VE 27	VENTILADOR DE EXTRACCION	N/A	1P 1.2	NC	Jul-04
VE 28	VENTILADOR DE EXTRACCION	N/A	PB 0.6	NC	Jul-04
VE 29	VENTILADOR DE EXTRACCION	N/A	1P 1.2	NC	Jul-04
BAC	BOMBAS DE AGUA CALIENTE	N/A	1P 1.2	CSP	Jun-04
BAF	BOMBAS DE AGUA FRIA	N/A	1P 1.2	CSP	Jun-04
EP	EXTRACTORES DE POLVO	N/A	1P 1.2	NC	Jul-04
MEL	MAQUINAS ENFRIADORAS DE LIQUIDO	N/A	1P 1.3	CSP	Jun-04

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8. Main Activities

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8.1. SQO Main Activities

- To lead, define, implement, manage and control all Quality systems of the site.
- To assure that produced and distributed products are in accordance with cGMP, Sanofi Pasteur's guidelines and the current regulatory requirements so that to support the decision of approving or rejecting the production batches.
- To guarantee that the control tests on materials, products and services are executed following validated analytical methods and approved in compliance with the cGMP.
- To define and implement Pilar SVMP, establishing the related strategies of validation and to assure that all process, equipment, production areas, utilities, computerized systems and methods are validated and keep that said validated status.
- To assure the implementation of CQRs, adjusting the systems and procedures applied at Pilar site so as to promote and assure the correct compliance.
- To coordinate the sanitary authorities inspections as well as Headquarters' audits.
- To lead Quality Steering Committee (QSC)

8.1.1. QA Main Activities

- **Operational areas**
  - Batch Deviation Investigation
  - GMP review of proponed changes
  - Batch documents review and approval
  - Control Records review and approval
  - SOPs review and approval
  - Quality Systems Mgmt in specific area
  - Q & V support in specific area
- **Product Quality**
  - Batch Release (AFP and Imported Products)
  - Management of Returned Products and Recall Quality Systems
  - Ensure that re-packaging activities of imported products are performed according to GMP and regulatory requirements
  - Ensure that distribution of AFP and imported products are performed according to GMP and regulatory requirements

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- **Quality Systems**

  - Global Quality Systems Management
  - Management of CQRs implementation and follow up of remediation plans
  - Informatic Documentation System Administration (Q-Pulse)
  - Internal / External Audits organization and follow up
  - GMP Training Program
  - Supplier and Subcontractors Quality Assurance
  - Site Master File
  - Annual Product Review

- **Q&V**

  - Define and implement SVMP
  - Review and approval of validation results
  - Set up monitoring program following initial validation of equipment, process, systems or methods
  - Validation of Computarized Systems
  - Define the requalification strategy for the site
  - Manage deviations coming from qualification and requalification activities data base

- **Management**

  - Batch Release
  - Management of Inspectional Readiness Program
  - Failure Investigation Closure
  - Change Control Closure
  - OOS Closure
  - Review and approval SOPs
  - Maintenance and Calibration Program approval

8.1.2. QC Main Activities

- To execute all physicochemical, biochemical and microbiological tests as appropriate in:

  - Raw materials
  - Imported products and bulk products
  - WSL

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- Environmental monitoring
- Monitoring of Pharmaceutical Water, Clean Steam and Compressed Air.

- Release of raw materials and packaging materials.
- Validation of analytical methods.
- To establish stability protocols, execute them and write the corresponding reports.
- To manage Out of Specification results (OOS) including stability OOS.
- To assure the management of reference standards according to cGMP requirements.
- To assure the qualification status and the performance of the maintenance and calibrations programs of the laboratory equipment.
- To execute trend analysis from the environmental and pharmaceutical water monitoring system data.

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8.3. MTECH Main Activities

- **Process Follow up and Support**
  - Trend and Statistical analysis
  - Parameters and Attributes evaluation and criticality assessment
  - Production and QC support

- **To maintain Process Know How**

- **Validation Activities**
  - Consistency
  - Robustness
  - Membranes and Resins Shelf life
  - Solution Stability / Mixing Studies
  - Support to Cleaning Validation
  - Others

- **Process Standardization and Improvement**
  - Process analysis / Improvement proposals
  - To define trials and Experimental Plans
  - Transfer to production

- **Technology transfer**
  - New process transfer from R&D to Production area

- **Documentation Activities**
  - SOPs /Validation Plans/ Protocols / Reports
  - Failure Investigations and Change Controls
  - Process Documentation (Process Mapping, Parameter and Attributes Risk analysis)

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8.4. Human Resources Main Activities

- **Recruitment**
  - Set up and monitor recruitment standards and processes in order to count on the appropriate Human Resources for the achievement of country objectives.
- **Development**
  - Implement locally HR practices for competences management, training policies, and succession planning so as to contribute to development of productivity, motivation, development and retention of personnel.
- **Compensations and benefits**
  - Implement HR policy for remuneration and motivation, in line with corporate policies, in order to ensure internal equity and external competitiveness.
- **Performance management program**
  - In the frame of corporate guideline and tools, and with a close support to local management.
- **Human Resources Administration**
  - To set up and retain Personnel management database and secure compliance with local regulations.
- **Policies and Procedures**
  - Organization Chart Procedure
  - Job description Procedure
  - Wage anticipates and personnel loan's
  - Pilar Site organization
  - General Training procedure
- **Medical Service**
  - Coordination of medical service activities and preventive and corrective follow up of occupational disease of Pilar Site's employees.

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8.5. Site Services & HSE Main Activities

- **Operational areas**
  - Supervision and control correct functioning of the whole site
  - Maintenance & Calibration Program
  - Assistance and technical support in specific areas
  - Creation, review and approval SOP´s
- **System Operation & Maintenance**
  - Production and preservation of pharmaceutical water
  - Regulation and gas distribution
  - Potable & Industrial water and steam
  - HVAC, Air conditioning and vacuum
  - Electricity, illumination and electrical BMS
  - Fire detection and control
  - Effluents treatment
  - Refrigerated chambers
  - Access control
  - Part of the Global Maintenance Team
- **Management**
  - Maintenance, EIT and HSE annual budget administration
  - Study and management of new investment & engineering projects
  - Part of the Global Engineering Team
  - Services, utilities, building, electrical, electronical and automation maintenance
  - Maintenance and Calibration Programs' management
  - Analysis and implementation of applicable CQRs
- **HSE Management System**
  - Pilar HSE system built in accomplishment with HSE Corporate requirements
  - HSE support in specific areas with internal audits
  - Management of the HSE system
  - PASS program in place since 2005 and at Department level
  - ISO 14001/OHSAS 18001 certification
  - Firemen Internal Brigade
  - 5 S" program management

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- 2 HSE Chairman Award won
- Part of the Global HSE Team

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8.6. Supply Chain Main Activities

- **Warehouse**

  - Organize discharge and reception of general materials and raw materials.
  - Reception of materials and keep Quality Control area informed on arrival of raw materials.
  - Codification of general materials, packaging materials and raw materials.
  - Location of RM, packaging materials and general materials in their specific position, according to their codification status.
  - Picking requests from internal customers.
  - Manage materials, packaging materials and raw materials within warehouse.
  - Issue and follow-up of documentation on dispatch and shipment.
  - Physical Inventory Control.
  - Guarantee permanent flow of RM and general materials of each area, avoiding stock rupture (internal customer) and stock out (external customer)
  - Follow-up of the dispatcher's service level (cold chain – delivery time)
  - Work together with the Planning area on inventory levels, and re-order levels.

- **Planning**

  - Launching of purchase requisition of Raw Materials, packaging materials and general materials.
  - Inventory management.
  - Planning of raw materials, packaging materials and general materials needs
  - Coordination with Production and QC Areas necessity plans of Raw Materials and materials
  - Management of import
  - Management of export
  - Keep planning support system database settings updated
  - ERP Business owner (Navision), follow-up of problems and general functionality improvement.

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- **Re-Packaging**
  - Re-Packaging of imported products for local commercialization.
- **Logistics and Distribution**
  - Distribution management of imported products.
  - Delivery logistics of Hep B Bulk to France.
- **Documentation**
  - Management of other specific cGMP documentation (SOPs, Protocols, Reports, log books, records, etc.) related to Supply Chain main activities.

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9. Hep B Bulk Production Process