Doc nº:	**QQGMP-005**
Replaces to:	QQGMP-004
Title:	***STANDARD PRE-AUDIT QUESTIONNAIRE FARMAQEMICAL PRODUCTS***

1. GENERAL INFORMATION

1.1. COMPANY NAME	***QUALITY CHEMICALS S.L.***	
1.2. ADDRESS	*C/ Formal 35, 08292 Esparreguera (Barcelona,Spain)*	
1.3. YEAR OF FOUNDATION	*1997*	
1.4. MANUFACTURING SITE		
1.4.1. MANUFACTURING SITE ADDRESS (including the GPS coordinates)	***QUALITY CHEMICALS S.L.*** ***C/ Formal 35, 08292 Esparreguera (Barcelona,Spain)*** *N 41º 32' 48"* *E 1º 51' 29"*	***PURITY CHEMICALS S.L.*** ***Av. Tren Expreso, 82-84 34200 Venta de Baños (Palencia, Spain)*** *N 41º 55' 55"* *W 4º 29' 12"*
1.4.2. MAIN DATES ▪ Date of construction of production facility ▪ Contact person ▪ Position ▪ Telephone ▪ e-mail	*QUALITY CHEMICALS* *2000* *Lluís Aragonès* *Chief Executive Officer* *+34 979 76 10 97* *custumer-service@qualitychemicals.com*	*PURITY CHEMICALS* *2009*
1.5. COMPANY DATA		
1.5.1. Web	*www.qualitychemicals.com* *www.purity-chemicals.com*	
1.5.2. Certifications ▪ Quality ▪ Environmental ▪ Risk and safety ▪ Other	*ISO 9001* *ISO 14001* *OHSAS 18001* *GMP CERTIFICATE, ISO 22000, KOSHER, HALAL*	

1.6. HUMAN RESOURCES

1.6.1.	Total number of employees	88	
1.6.2.	Total number of employees per plant	*Purity Chemicals*	*Quality Chemicals*
		28	***60***
1.6.3.	Production	*26*	*17*
1.6.4.	Quality Assurance	*4**	*4*
1.6.5.	Quality Control	*2*	*9*
1.6.6.	Analytical Development	*1**	*1*
1.6.7.	Warehouse	*2*	*7*
1.6.8.	Engineering	*1*	*1*
1.6.9.	Maintenance	*2*	*2*
1.6.10.	Regulatory Affairs	*4**	*4*
1.6.11.	Marketing and Sales	*6**	*6*
1.6.12.	RRHH	*2**	*1*
1.6.13.	General administration	*1*	*1*
1.6.14.	R&D	*3**	*3*

*** personnel belonging to Quality Chemicals**

Doc nº:	**QQGMP-005**
Replaces to:	QQGMP-004
Title:	***STANDARD PRE-AUDIT QUESTIONNAIRE FARMAQEMICAL PRODUCTS***

1. GENERAL INFORMATION

1.7. MAIN ASPECTS

1.7.1. Are all steps of the manufacture (including purification, packaging, warehousing, assembly)/ testing of the product performed at this site?	*Yes*
1.7.2. Has a Health Authority inspected this site in the last 5 years? If Yes, Please specify authority, year and outcome.	*Authority: Spanish Health Agency, Year: 2017, Outcome: Satisfactory*
1.7.3. Have you been awarded any nationally or internationally recognized quality standards (e.g., GMP Certificates, FDA registration, ISO9001, ISO14001, ANSI/ASQCQ91, EU Directive 94/62, OHSAS, 18001, GMPs, EMAS, IPEC, IPEA, AIB, GMA-SAFE, BRC, other).	*If Yes, specify: ISO 9001, ISO 14001, ISO 22000, OHSAS 18001, GMP, KOSHER, HALAL*
1.7.4. Have you received an import ban, warning letter, GMP suspension or similar in the last 10 years? If yes, please inform authority, event (GMP suspension, partial interdiction of activities, import ban, etc.), year of event and current status. Please provide evidences of the current status (warning letter lifted, Health Authority communication authorizing reestablishment of activities, etc.).	*No, never*
1.7.5. You need a copy of current certificates, we provide on web	*Comments: Please, obtain our certificates and related documentation in our website www.qualitychemicals.com*
1.7.6. What materials are marketed	▪ *Chemical / Solvent* ▪ *Excipient / Raw material* ▪ *API intermediate* ▪ *Active Pharmaceutical ingredient (API)*
1.7.7. Site Activities	▪ *Packaging* ▪ *Transportation* ▪ *R&D* ▪ *Warehousing* ▪ *Relabelling* ▪ *Repackaging* ▪ *Chemical Synthesis* ▪ *Stability Testing* ▪ *Sampling and Analytical Testing* ▪ *Realise to Customer*
1.7.8. Sampling and Analytical Testing or Stability testing	*Full testing accord to CoA*
1.7.9. Management of materials A. Is a lot number assigned to the raw materials? B. Is a lot number assigned to the finished products? C. Is there a procedure for the releasing of materials? D. Is the realising of materials recorded? E. Are all the materials /batches tested prior to use/shipping? F. Is there a record of the operations of analysis? G. Are CoA of the shipped batches issued? H. How many years is documentation of production and analysis kept?	*Yes* *Yes* *Yes* *Yes* *Yes* *Yes* *Yes* *7 years*
1.7.10. Is there an environmental, Health and Safety policy?	*Yes*

Doc nº:	**QQGMP-005**
Replaces to:	QQGMP-004
Title:	***STANDARD PRE-AUDIT QUESTIONNAIRE FARMAQEMICAL PRODUCTS***

2. PERSONNEL

2.1. Is there sufficient personnel qualified and available?	*Yes*
2.2. Are there regular training workshops for staff?	*Yes*
2.3. Is there a training program for a new employees?	*Yes*
2.4. Do you have a written procedure for a training program including new employees?	*Yes*
2.5. Is training appropriately documented?	*Yes*
2.6. Does a training plan for employees exist?	*Yes*
2.7. Is there a general training program, conducted by QA?	*Yes*
2.8. Is there a training policy for both temporary and permanent employees (on-the job training)?	*Yes*
2.9. Do you maintain training records including dates, times, subject matter, course outline, instructor, etc.)?	*Yes*
2.10. Is refresher GMP training program in place for established employees?	*Yes*
2.11. Is there adequate and continued personal hygiene training for personnel who handle materials?	*Yes*
2.12. Do you have hygiene programs relating to health and clothing?	*Yes*
2.13. Are smoking, eating, drinking, chewing and the storage of food, drinks and personal medication prohibited in the manufacturing, storage and laboratories area?	*Yes*
2.14. How many hours are spent on training per employee / year?	*Approximately 30h*
2.15. Is periodic internal inspection performed according to a self-inspection program?	*Yes*
A. In production	*Yes*
B. In quality control	*Yes*
C. In warehouses	*Yes*
D. In the QA department	*Yes*
E. Is this documented	*Yes*

3. BUILDING & FACILITIES

3.1. Is access to the building / facility restricted to authorized personnel only?	*Yes*
3.2. Is access to the building / facility secured outside normal business hours?	*Yes*
3.3. Is production building closed or open to the outdoor environment?	*Closed*
3.4. How is the building designed to minimize the risk of potential contamination from outdoor?	*All buildings and rooms are closed (doors). In case of windows, they are permanently closed (no possibility of opening) or have protection nets instead. The clean rooms, which are overpressurized, count with an air conditioning and filtering system*
3.5. Do you manufacture, process, package, store or distribute any substances of high activity and/or toxicity products in the same buildings where others Products are handled?	*No*
3.6. Do you have clean rooms with dedicated air handling systems to the manufacturing processes of these products?	*Yes*
3.7. Are there separate dust extraction facilities in areas where dust is generated?	*Yes*
3.8. Describe the security measures in the building / facility including the warehouse e.g. how is access restricted?	*Restricted areas are labelled. The employees of the operational areas are trained in product and food defense. External*

	personnel and visits are registered at their arrival, identified and supervised by the employees in charge of the corresponding area. The warehouses are locked, only authorized members of the company personnel are allowed to enter.
3.9. Please describe briefly the procedure in place to prevent cross-contamination during the manufacturing/packaging process: A. Material handling, sampling, dispensing and charging B. Use of containment booths? C. Cleaning of tools and equipment D. Flow of materials and Personnel	*All the manufacture steps (except reactor phase) are performed in clean rooms (ISO 8 Class D). The personnel use protective hygienic garments. The product is always protected from the outdoor environment.* - *All of them are described in written procedure*
3.10. Is written cleaning and sanitation program in place including all pest control activities?	*Yes*
3.11. Please describe your pest control program for the facility including warehouse space (for rodents and for insects), including the trap location and review of trends. Include reference number for the procedure.	*Insect (flying and non-flying) and gnawer traps are distributed along the facilities, including warehouse area.* *The smart system run that vigilance 24/7 by domotic-system. Maintenance is performed monthly by an external certified pest company. PPR-02*

4. WAREHOUSING / DISTRIBUTION & TRANSPORTATION

4.1. WAREHOUSE

4.1.1. Is access to the warehouse restricted to authorized personnel only?	*Yes*
4.1.2. Is access to the warehouse secured outside normal business hours?	*Yes*
4.1.3. Is warehouse building closed or open to the outdoor environment?	*Closed*
4.1.4. Defined storage areas	*Yes*
4.1.5. Is refiling or repackaging work carried out in the storage area?	*No*
4.1.6. Ensuring respective status: quarantine – released-rejected	*Labelling and EDP system*
4.1.7. Do you have a system to differentiate work in progress / quarantined / rejected material and labelling, physical separation?	*Yes, P-SP-06*
4.1.8. Is pest control carried out on warehouse?	*Yes*

4.2. DISTRIBUTION & TRANSPORTATION

4.2.1. For dangerous goods: Are instruction available for the transport contractor on how to behave in case of accidents?	*Yes*
4.2.2. Is there a process in place that would ensure that defects identified after distribution to Customer Technical Operations are notified to the relevant Customer Technical Operations Site?	*Yes*

Doc nº:	**QQGMP-005**
Replaces to:	QQGMP-004
Title:	***STANDARD PRE-AUDIT QUESTIONNAIRE FARMAQEMICAL PRODUCTS***

5. PACKAGING / LABELING

5.1. PACKAGING

5.1.1. Are the packaging materials including labels, reconciled and the number of materials used and destroyed recorded on the batch record?	*Yes*
5.1.2. Is primary packaging material licensed for good purpose?	*Yes*
5.1.3. Are containers/ closures / labels / packaging material specified?	*Yes*
5.1.4. Please describe the primary and secondary packaging + transport containers used for the product to be supplied to Customer. (e.g., double liner within fiber drums, metal drum, etc.) Also specify special precautions in place (e.g. nitrogen, desiccant, etc.) if applicable.	*According customer's requirements. Specifications have already been provide to customer.*
5.1.5. Are your transport pallets treated with chemicals or other substances?	*No*
5.1.6. Are your pallets heat treated?	*Yes*
5.1.7. Pallets treated to standard ISPM15	*Yes*
5.1.8. Do you stick: labels on the secondary packaging, e.g., drums, big bags, etc.?	*Yes*
5.1.9. Is each container supplied to Customer labelled with the following: A. material name B. batch number C. name of the company D. manufacturing site address E. name of the product including pharmaceutical grade F. net weight G. retest / expiry date H. storage and transport conditions	*All, Yes*
5.1.10. Does the plastic materials used for primary packaging meets the requirements of Guidance for Industry on Container Closure Systems for Packaging?	*Yes*
5.1.11. Does the plastic materials used for primary packaging meets the requirements of EU regulation 10/2011?	*Yes*

5.2. LABELING

5.2.1. Written instructions for labelling available?	*Yes*
5.1.12. Do you have tamper evident seals on all packaging?	*Yes*
5.2.2. Do you use a barcode label for traceability?	*Yes*
5.2.3. Which status codes are labelled internally?	*Quarantine/ Released/Rejected*
5.2.4. Is the following information available on the containers? A. Material and type B. Manufacturer C. Lot/batch number D. Manufacturing date E. Shelf life F. UN Number (in case of dangerous goods) and corresponding labelling and marking G. If necessary, safety information related to hazardous properties	*Yes, All*
5.2.5. Will the(original) labelling of the manufacturer be preserved?	*Yes*
5.2.6. Are labelling operations controlled and unused labels destroyed?	*Yes*

Doc nº:	**QQGMP-005**
Replaces to:	QQGMP-004
Title:	***STANDARD PRE-AUDIT QUESTIONNAIRE FARMAQEMICAL PRODUCTS***

6. PRODUCTION

6.1. MANUFACTURING PROCESS

6.1.1. Productive capacity (Tn/Year)	*Aprox: 1,500 Tn/Year*
6.1.2. Is access to production areas restricted?	*Yes*
6.1.3. Are products manufactured in dedicated or multipurpose equipments?	*Multipurpose equipments*
6.1.4. In case of multipurpose plant, are products manufactured in the same equipment/ facilities which manufacture pesticides, herbicides, penicillin derivate, hormones, cephalosporin, sensitizing and anti-cancer products?	*No*
6.1.5. Manufacturing Line Clearance Performed	*Yes*
6.1.6. Is there a plant for cleaning the production plan equipment?	*Yes*
6.1.7. Are cleaning operations registered?	*Yes*
6.1.8. Are written cleaning procedures available?	*Yes*
6.1.9. Is the cleaning frequency establish in written form?	*Yes*
6.1.10. Are production facilities routinely maintained, and is this documented?	*Yes*
6.1.11. Is a hygiene/sanitation program available, covering rooms, staff and equipment?	*Yes*
6.1.12. Are there measures to prevent cross-contamination in production plant?	*Yes*
6.1.13. Is there a clear separation of batches throughout the entire manufacturing process?	*Yes*
6.1.14. Are production methods written and approved?	*Yes*
6.1.15. Are production methods validated or Validation Master Plan (VMP)?	*Yes*
6.1.16. Is the production documented in manufacturing, sheets with information of raw materials, batches, operations, workers and supervision?	*Yes*
6.1.17. Are critical parameters in the production process defined?	*Yes*

6.1. MANUFACTURING PROCESS

6.1.18. Are deviations in production registered and/or investigated?	*Yes*
6.1.19. Please describe briefly the procedure in place to prevent cross-contamination and product mix up during the manufacturing/packaging process:	*Equipment and facilities are cleared and cleaned when a change of product is done. Products are kept in closed recipients and are clearly labelled and identified during its manufacture. All activities except the reactor stage is performed in white rooms, and the personnel wear protective and disposable clothes.*
6.1.20. Please describe the quality of the air in the last production step. Does the finagling of the material, take place in defined cleanliness Classes, ISO class according 14644, and GMP class?	*Yes ISO 8 – Class D rooms.*

6.2. WATER PRODUCTION

6.2.1. Do you use water in production or manufactured product?	*Yes*
6.2.2. Please describe the quality of water used in production	*Deionized Water & Purified water*
6.2.3. Water treatment system?	*Twin de-ionized system water by osmosis*
6.2.4. Water quality monitoring program establish?	*Yes*

6.2.5. Do you have a water monitoring/testing program established and does it include a procedure to investigate results out of specification (chemical / microbiological)?	*Yes, Documents: PPR-05, QA-013*
6.2.6. Written procedure for sampling available?	*Yes*
6.2.7. Written procedure for water quality testing available?	*Yes*
6.2.8. Water hygienization	*Disinfection of water with ozone*
6.2.9. Specification available?	*Yes*
6.2.10. If Yes, please state the chemical and microbiological specifications for the type of water used.	*Deionized water according E.P.* *Purified water according E.P.*

7. PROCESS EQUIPMENT

7.1. Does production equipment have a unambiguous reference that relates to the production documentation?	*Yes*
7.2. Is there a preventive maintenance plan for equipment?	*Yes*
7.3. Is there a calibration procedure for analytical equipment?	*Yes*
7.4. Do you have dedicated equipment to the manufacturing processes?	*No*
7.5. Do main pieces of equipment used in the production bear identification labels, (e.g. stating lot number, material name etc.)?	*Yes, Each facility and equipment is identified with specific technical code.*
7.6. Is there a calibration procedure for analytical equipment?	*Yes*
7.7. Are there cleaning procedures in place for: A. each manufacturing/packaging area B. each piece of manufacturing/packaging equipment?	*Yes*
7.8. Do you have a calibration policy for inspection, weighing and measuring equipment (e.g. thermometer, manometer, stirrer speed)?	*Yes*
7.9. How do you mark the status of your manufacturing/packaging equipment and environment (e.g. „cleaned", „calibrated", „in use")?	*By means of electronic logbooks, where it is registered the status, as well as the product that it contained formerly to the current one. Additionally, the status is shown in big color-codified labels, which are placed in a visible point of each equipment.*
7.10. Describe your corrective maintenance and preventative maintenance program in place for all pieces of equipment (laboratory and manufacturing).	*Correct and preventive maintenance is performed by means of the validated informatics system of the company. An annual plan of preventive maintenance related to each equipment is performed.*
7.11. Do you have a calibration policy/ procedures for laboratory equipment, considering traceability to national or international standards?	*Yes*
7.12. What is the frequency of recalibration of equipment?	*According type of equipment*
7.13. Are calibration records kept on file, and are they up-to-date.	*Yes*

Doc nº:	**QQGMP-005**
Replaces to:	QQGMP-004
Title:	***STANDARD PRE-AUDIT QUESTIONNAIRE FARMAQEMICAL PRODUCTS***

8. STARTING MATERIALS

8.1. RAW MATERIALS

8.1.1. Describe your Raw Material and API release procedure (include procedure reference code)	*QA-030*
8.1.2. Which of listed procedures are in place for the raw materials used in the manufacturing process and the packaging used for the final product supplied to customer? A. Receipt B. Quarantine C. Sampling D. Storage E. Testing (if applicable) F. Labelling G. Dispensing H. Specifications I. Processing J. Packaging	*Yes, QA-030*

8.2 FREE OF COMPOUNDS

8.2.1. Are the starting materials of the product partly or fully of animal or human origin? (e.g. tissue, tissue extract or fluid such as milk, serum, blood).	*No, Synthetic origin of the starting materials.*
8.2.2. Are other materials (also reagents like chromatographic media, buffers etc.) of animal or human origin used in the manufacturing process of the product?	*No*
8.2.3. Does the current specification include a non-specific test for total nitrogen to check the identity, strength or purity of the material?	*No*
8.2.4. Is the material tested for absence of melamine?	*No*
8.2.5. Crustaceans and products thereof	*No, present in product and MFG line*
8.2.6. Antibiotic (where antibiotic is not the active ingredient and present only as residual impurity)	*No, present in product and MFG line*
8.2.7. Eggs and products thereof, or manufactured in eggs	*No, present in product and MFG line*

8.2 FREE OF COMPOUNDS

8.2.8. Aspartame	*No, present in product and MFG line*
8.2.9. Benzoates including: benzoic acid, sodium benzoate.	*No, present in product and MFG line*
8.2.10. Ethanol (where ethanol is present in a concentration of 3% V/V or more.)	*No, present in product and MFG line*
8.2.11. Cereals containing gluten, i.e. wheat, rye, barley, oats, spelt, kamut or their hybridized strains, and products thereof	*No, present in product and MFG line*
8.2.12. Galactose	*No, present in product and MFG line*
8.2.13. Pollen	*No, present in product and MFG line*
8.2.14. Phenylalanine	*No, present in product and MFG line*
8.2.15. Avian	*No, present in product and MFG line*
8.2.16. Fish and products thereof	*No, present in product and MFG line*
8.2.17. Odor	*No, present in product and MFG line*
8.2.18. Milk and products thereof (including lactose)	*No, present in product and MFG line*
8.2.19. Celery and products thereof	*No, present in product and MFG line*
8.2.20. Soybeans oil (comment if refined), Soybeans not including oil and products thereof	*No, present in product and MFG line*
8.2.21. Peanuts and products thereof	*No, present in product and MFG line*

8.2.22. Nuts, i.e. almonds, hazelnuts, walnuts, cashews, pecan nuts, Brazil nuts, pistachio nuts, macadamia nuts and Queensland nuts, any other tree nuts and products thereof.	*No, present in product and MFG line*
8.2.23. Sesame seeds and products thereof	*No, present in product and MFG line*
8.2.24. Mustard and products thereof	*No, present in product and MFG line*
8.2.25. Sulphur dioxide and sulphites at concentrations of more than 10mg/kg or 10mg/liter expressed as SO2 (some formulations including gelatine must be mentioned as including residues of sulphur dioxide).	*No, present in product and MFG line*
8.2.26. Lupin and products thereof	*No, present in product and MFG line*
8.2.27. Molluscs and products thereof	*No, present in product and MFG line*
8.2.28. Natural Rubber Latex	*No, present in product and MFG line*
8.2.29. Iodine	*No, present in product and MFG line*
8.2.30. Cinnamon, Cocoa, Vanilla, Chicken, Yeast, Legumes (other than peanut), Pulses, Coriander, Umbellifereae, Flavor (any artificial/natural), Glutamate (% if naturally occurring), Monosodium glutamate, Carrot, Fruits.	*No, present in product and MFG line*
8.2.31. Hydrolyzed plan protein	*No, present in product and MFG line*
8.2.32. Corn Maize, Dyes (including but not limited to Yellow (tartrazine)), Metals / trace metals, Sugar, Alcohol, Preservatives, Mercury.	*No, present in product and MFG line*
8.2.33. Gluten or ingredient derived from gluten-containing grain. (where gluten is present in a concentration of 20 parts per million or more.)	*No, present in product and MFG line*
8.2.34. Hydroxybenzoic acid esters, including: ethyl hydroxybenzoate; methyl hydroxybenzoate; propyl hydroxybenzoate; sodium ethyl hydroxybenzoate; sodium methyl hydroxybenzoate; sodium propyl hydroxybenzoate	*No, present in product and MFG line*
8.2.35. Seeds (poppy, sunflower, cottonseed, sesame)	*No, present in product and MFG line*
8.2.36. Starch and modified starches	*No, present in product and MFG line*
8.2.37. Propolis	*No, present in product and MFG line*
8.2.38. Royal jelly	*No, present in product and MFG line*
8.2.39. Saccharin, including: saccharin calcium; saccharin sodium	*No, present in product and MFG line*
8.2.40. Sucralose	*No, present in product and MFG line*
8.2 FREE OF COMPOUNDS	
8.2.41. Does the material contain live infectious agents of birds and livestock?	*No, present in product and MFG line*
8.2.42. Potassium salts, including: potassium bicarbonate; potassium chloride (Where the total potassium content of the maximum recommended daily dose is greater than 39 mg (1mmol) elemental potassium per dose).	*No, present in product and MFG line*
8.2.43. Sorbates, including: potassium sorbate; sorbic acid	*No, present in product and MFG line*
8.2.44. Sugar alcohols, including: erythritol; isomalt; lactitol; maltitol; mannitol; polydextrose; sorbitol; xylitol. Where total sugar alcohol content in formulation exceeds 2g per max. recommended daily dose.	*No, present in product and MFG line*
8.2.45. Sugars, monosaccharides and Disaccharides (including honey as a mixture of sugars) (Where the presence of sugars may have a significant glycaemic effect and the total sugar content (including lactose which requires a separate	*No, present in product and MFG line*
8.2.46. Sulfites, including: potassium metabisulfite; sodium bisulfite; sodium metabisulfite; sodium sulfite; sulfur dioxide. Sulphites are stored in an isolated location of the warehouse and properly identified, according the HACCPP plan. declaration) exceeds 100 mg per maximum recommended daily dose).	*No, present in product and MFG line*
8.2.47. Does the product contain genetically modified material?	*No, present in product and MFG line*

8.2.48. Has the product been sourced from non-genetically modified raw materials by means of segregation measures (i.e. only non-GM materials in the entire supply chain)?	*No, present in product and MFG line*
8.2.49. Has the product been sourced from non-genetically modified raw materials by means of identity-preserving (IP) conditions (i.e. GM and non-GM materials processed in the same equipment, with validated cleaning processes between GM and non-GM batches)?	*No, present in product and MFG line*
8.2.50. Did you complete an assessment of Structure-Activity Relationship (SAR) using computational (Q)SAR (Qualitative Structure-Activity Relationship) methodologies for bacterial mutagenicity?	*No, present in product and MFG line*
8.2.51. Is there a fermentation or a plant extraction step used as part of the API synthesis?	*No, present in product and MFG line*
8.2.52. Is nitrite (NO_2^-), nitrate (NO_3^-) or azide (N_3^-) present anywhere in the synthesis, process, including starting material manufacture?	*No, present in product and MFG line*
8.2.53. Are aliphatic nitro compounds present anywhere in the synthesis, including starting material manufacture?	*No, present in product and MFG line*
8.2.54. Are aliphatic Azo- or Azoxy compounds present anywhere in the synthesis, including starting material manufacture?	*No, present in product and MFG line*
8.2.55. Does your product comply with Phthalates (Adulteration of raw material with plasticizers conformity)?	*Yes*
8.2.56. Does your product contain plastic components?	*No, present in product and MFG line*
8.2.57. Confirm if the product being used as feed to animals during manufacturing or used in finished product being ingested by humans	*No, present in product and MFG line*
8.2.58. Is manufactured and/or stored in an area that has been exposed a nuclear accident or any other case of radiological emergency	*No, present in product and MFG line*

Doc nº:	**QQGMP-005**
Replaces to:	QQGMP-004
Title:	***STANDARD PRE-AUDIT QUESTIONNAIRE FARMAQEMICAL PRODUCTS***

9. QUALITY CONTROLS

9.1. MANAGEMENT

9.1.1 Are all laboratory test methods including methods validated?	*Yes*
9.1.2. Will you validate additional analytical methods when requested by customer?	*Yes*
9.1.3. Are you using skip testing?	*No*
9.1.4. Do you test every batch according to full customer agreed specification?	*Yes*
9.1.5. Do you sample incoming materials, and product according to an approved sampling plan?	*Yes*
9.1.6. Which department/team approve the sampling plan?	*Quality Control department*
9.1.7. Is QC staff responsible for sampling?	*Yes*
9.1.8. Is there a written sampling procedure?	*Yes*
9.1.9. What procedure/rule is used to determine the number of samples to be taken for a defined amount of containers?	*Yes, QC-006*
9.1.10. Are raw data archived?	*Yes*
9.1.11. Is every parameter of the specification tested on every batch?	*Yes*
9.1.12. Are all analytical instructions and standard procedures available in written form?	*Yes*
9.1.13. Do you test every batch according to full customer agreed specification?	*Yes*
9.1.14. Are retained samples kept all batches?	*Yes*
9.1.15. How long are retained samples preserved?	*7 Years*
9.1.16. Are reference substances (standards) checked on a regular basis?	*Yes*
9.1.17. Do you assure to maintain the batch integrity (no blending batches)?	*Yes*
9.1.18. Are there formal written procedures and methods for all analyses performed for all products / raw materials? Please provide the retest period of the material supplied to customer. Do you have data to support the re-test / expiry period?	*Re-test period of material: Yes* *Please consult the product specifications in our website www.qualitychemicals.com. The retest period is defined according to the data obtained from stability studies.*
9.1.19. Do you have a written procedure documenting how to conduct analytical method validations?	*Yes, QA-010*
9.1.20. Do you have a procedure in place for handling out of specification (OOS) results in the laboratory?	*Yes, QC-002*
9.1.21. Are all test parameters indicated in the certificate of analysis tested on the delivered batch?	*Yes*
9.1.22. Is traceability of the material back to the original manufacturer assured?	*Yes*

9.2. INSTRUMENTATION

9.2.1. Are the instrument calibrated/qualified?	*Yes*
9.2.2. Are the instruments checked on a regular basis?	*Yes*
9.2.3. Any written instruction in place?	*Yes*
9.2.4. Are logbooks available?	*Yes*

Doc nº:	**QQGMP-005**
Replaces to:	QQGMP-004
Title:	***STANDARD PRE-AUDIT QUESTIONNAIRE FARMAQEMICAL PRODUCTS***

10. IN-PROCESS CONTROL

10.1. PRODUCTION

10.1.1. Describe the controls in place to assure homogeneity of the material.	*All our processes are performed by batch so homogeneity is assured.*
10.1.2. Is your production process continuous or batch?	*Batch*
10.1.3. Do you perform mixing of materials "heels" / "tails" of different batches in order to achieve target batch size?	*No*
10.1.4. Does the batch numbering represent one homogeneous production run?	*Yes*
10.1.5. Do you have a written procedure for lot numbering? Please describe your batch numbering system	*Batch number is correlatively given automatically from the computer system.*
10.1.6. Line start-up inspection performed and documented prior to operations?	*Yes*
10.1.7. Have yield limits been set?	*Yes*
10.1.8. Is the yield (material loss) calculated and documented?	*Yes*

10.2. INTERMEDIATES

10.2.1. Adequate storage of intermediates?	*Yes*
10.2.2. Identification before use?	*Yes*
10.2.3. Are intermediates tested and released?	*Yes*

10.3. FINAL PRODUCT

10.3.1. Concerning the previously manufactured material?	*Yes*
10.3.2. Any blending of material that does not conform to specification?	*No*
10.3.3. Are failures in the production process documented?	*Yes*
10.3.4. Are materials reworked?	*No*
10.3.5. Are process waste and unusable residues destroyed?	*Yes, using an external service*
10.3.6. Is the material processed via irradiation technology?	*No*
10.3.7. Does the product conform to the current EU food regulations?	*Yes*
10.3.8. Does the product conform to the current Swiss medicinal products regulations?	*Yes*
10.3.9. Does the product comply with the TSE Note for Guidance EMEA/410/01: Minimizing the risk of transmitting animal spongiform encephalopathy via human and veterinary medicinal products, current revision, available via Internet?	*Yes*
10.3.10. Laboratory test results comply with the requirements of Council Regulation (Euratom) 2016/52 of 15 January 2016. Analytical data associated with these tests has been maintained on file and is available if requested.	*Yes*

Doc nº:	**QQGMP-005**
Replaces to:	QQGMP-004
Title:	***STANDARD PRE-AUDIT QUESTIONNAIRE FARMAQEMICAL PRODUCTS***

11. QUALITY MANAGEMENT

11.1. GENERAL ASPECTS

11.1.1. Do you have a quality policy?	*Yes*
11.1.2. Is your company certified?	*Yes*
11.1.3. Does the company have a Quality Manual?	*Yes*
11.1.4. Is a quality management system in place?	*Yes*
11.1.5. Do the operations conform to GMP regulations?	*Yes*
11.1.6. Changes are classified according to ICH Q7?	*Yes*
11.1.7. Is a QA manual available?	*Yes*
11.1.8. Is the quality Manual Applied globally within organization?	*Yes*
11.1.9. Does Quality Chemicals / Purity Chemicals perform a qualification supplier?	*Yes*
11.1.10. Does Quality Chemicals / Purity Chemical periodically measure quality indicators and assess potential trends?	*Yes*

11.2. BATCHES / MATERIALS

11.2.1. Are all the batches analysed and formally approved or refused?	*Yes*
11.2.2. Does Quality Chemicals / purity Chemicals retain a sample of every batch? How long?	*Yes. 7 years*
11.2.3. Are suppliers of raw materials integrated in the QA system?	*Yes*
11.2.4. Do you mark incoming materials with their status (quarantine/approved/rejected)?	*Yes*
11.2.5. Are incoming materials checked prior to their use, or is it assured by certificates of analysis?	*Yes*
11.2.6. Is the approval or rejection of incoming material documented.	*Yes*
11.2.7. Do you investigate the reason for rejection?	*Yes*
11.2.8. Is the decision of releasing / rejecting the product independent from production?	*Yes*

11.3. QUALITY MANAGEMENT

11.3.1. Are certificates of analysis issued by Quality Assurance Department?	*Yes*
11.3.2. Are the certificates signed by head of Quality Assurance?	*Yes*
11.3.3. Which department is responsible for product release?	*Quality Assurance department*
11.3.4. Is product release done by a person who is independent of manufacturing?	*Yes. The products are released by QA.*
11.3.5. Who Quality Assurance reports to?	*Technical Manager*
11.3.6. Is every production step documented?	*Yes*
11.3.7. What´s the expire date / retest date of the product?	*Determined by stability test according to ICH Q1A(R2) for APIs*
11.3.8. Does Quality Chemicals / Purity Chemicals carry out stability studies?	*Yes*
11.3.9. Does Quality Chemicals / Purity Chemicals carry out product quality review?	*Yes*
11.3.10. Are deviations approved by QA?	*Yes, P-GS-07, QA-009*

11.3. QUALITY MANAGEMENT

11.3.12. For all quality documentation, do you have procedures defining: A. update / revisions? B. Approval? C. Controlled Distribution D. Use and Storage?	*All, Yes*
11.3.13. Is there a formal procedure for the assessment of production deviations?	*Yes*

11.3.14. Are quality assurance systems such as GMP, ISO 9000 or HACCP (Hazard Analysis and Critical Control Point) in place for monitoring the production process, traceability and batch consistency?	Yes
11.3.15. Is there a controlled document that describes how the material is produced?	*Yes*
11.3.16. Is the manufacturer and manufacturing site mentioned on the certificates of analysis?	*Yes*
11.3.17. Where are the manufacturing date and/or expiry date of a batch indicated?	*In the Label & CoA*
11.3.18. Are you able to provide to customer the following information, related to product and related API, to allow technical release? ▪ Certificate of Compliance (CoC) with cGMP ▪ Certificate of analysis (CoA) ▪ List of all batch related deviations with complete records of critical and major deviations. Upon request Customer shall receive complete records of Minor deviations ▪ List of all major batch related changes ▪ Executed Batch record	*Yes*
11.3.19. Are products affected by BEE / TSE, GMO, dioxins? Can you issue a certificate?	*No. We can issue a certificate*
11.4. CHANGE CONTROL	
11.4.1. Does Quality Chemicals / Purity Chemicals a change control procedure?	*Yes*
11.4.2. Is a change control procedure establish to ensure that changes are evaluated and approved?	*Yes*
11.4.3. Is there a formally approved quality specification for the product? If yes, does a change control procedure exist?	*Yes*
11.4.4. In case of a change in the process of specifications affecting the quality of the product, would Quality Chemicals / Purity Chemicals inform their customers?	*Yes*
11.4.5. Do you routinely inform your customer of changes of: production process, production site and material specification?	*Yes*
11.5. RAW MATERIALS	
11.5.1. Is the quantity of all raw materials used documented?	*Yes*
11.5.2. Are all containers of raw materials identified before usage?	*Yes*
11.5.3. Are raw materials of animal origin processed anywhere?	*No*
11.5.4. Are specifications available for all raw materials?	*Yes*
11.6. COMPLAINT HANDLING	
11.6.1. Are customer complaints systematically documented?	*Yes*
11.6.2. Are investigations conducted in a timely manner to establish if the complaint is justified and to identify root cause?	*Yes*
11.6.3. Are investigations conducted to identify whether the reported defect is limited to a single batch material, or if other batches need to be considered?	*Yes*
11.6.4. Do you inform the original manufacturer in the event of a complaint?	*Yes*
11.6. COMPLAINT HANDLING	
11.6.5. Does Quality Chemicals / Purity Chemicals have a procedure for management of customer complaints?	*Yes, P-GS-07*
11.6.6. Are investigation conducted in a timely manner to identify the root cause of a complaint and to evaluate if the complaint can be confirmed?	*Yes*
11.7. RECALLS	
11.7.1. Are written procedures implanted to manage excipients recall promptly and effectively?	*Yes*

11.7.2. Do you evaluate the effectiveness of your recall arrangements at regular intervals?	*Yes*
11.7.3. Do you inform the original manufacturer in the event of a recall?	*Yes*
11.8. RETURNED GOODS	
11.8.1. Are written procedures implemented to manage holding, labelling, testing and any processing of returned products?	*Yes*
11.8.2. Describe briefly the procedure about handling of goods returned from the market.	*The product is received in the warehouse, identified as non-conform and stored in a segregated zone. Quality Control laboratory checks the compliance of the product. According results obtained, it will be classified as compliant or non-compliant, and therefore requalified, reprocessed or managed as waste. QA-027, P-GS-04*
11.8.3. Are the goods returned from the market re-used?	*No*
11.9. NON-CONFORMING MATERIALS	
11.9.1. Does Quality Chemicals / Purity Chemicals have a procedure for management of non-conformities?	*Yes*
11.9.2. Are writing procedures for handling of non-conforming materials implemented?	*Yes*
11.9.3. Is non-conforming material, if required mixed with conforming material to bring it into specification?	*No*
11.10. AUDITs	
11.10.1. Are internal audits carried out at a regular interval?	*Yes*
11.10.2. Is there a CAPA program in place?	*Yes*
11.10.3. Would Quality Chemicals / Purity Chemicals allow to: ▪ Visit tour facilities ▪ Perform a quality audit of production and quality control process	 *Yes* *Yes*
11.10.4. Do Quality Chemicals / Purity Chemicals have customer quality audits? How many and How often?	*Yes. About 25 audits per year*

Doc nº:	**QQGMP-005**
Replaces to:	QQGMP-004
Title:	***STANDARD PRE-AUDIT QUESTIONNAIRE FARMAQEMICAL PRODUCTS***

12. BATCH RECORD

12.1. Do you have product specific batch records for all manufacturing/packaging/ laboratory testing steps of a batch?	*Yes*
12.2. Do you issue a batch record (manufacturing documentation) for each batch/lot manufactured?	*Yes*
12.3. All production, batch production?	*Yes*
12.4. Which department is responsible for approval and maintenance of the master batch record templates?	*Quality Assurance Department*
12.5. What are the criteria for batch release decision?	*The products obtained must meet their specifications and the related documentation must be correct in terms of the results obtained and data integrity.*
12.6. How long do you keep the analytical and the production records for the supplied or contract manufactured product? Do you perform a batch record review of the production record and QC Raw Data? If Yes, is this part of your release decision? Which department is performing the review of executed batch record?	*7 years* *Yes* *Yes* *Quality Assurance department*
12.7. Is homogeneity of the batches documented(validated)?	*Yes*
12.8. Batch traceability assured?	*Yes*
12.9. Manufacturing Line Clearance Documented In Batch Record	Yes

13. QUALIFICATION

13.1. VALIDATION

13.1.1. Is there a procedure in place to ensure all manufacturing, testing and warehouse activities are performed using calibrated and qualified equipment (IQ/OQ/PQ)?	*Yes, QA-010*
13.1.2. How would you incorporate new customer material/products into you existing cleaning validation concept?	*According procedure QA-012*
13.1.3. Did the contract testing laboratories and external manufacturers implement quality system according to international standards?	*Yes, Compliance with international standards is required, however, certification is not indispensable.*
13.1.4. Is there a written procedure for equipment cleaning and cleaning validation? Please describe your cleaning validation concept and your acceptance limits for carry-over.	*Yes, the equipment to be cleaned is identified and classified, as well as the sampling and analytical methods and cleaning agents to use. Worst cases are defined, and the results obtained are compared against the established limits and times of acceptance which have been defined. A cleaning method will be considered validated when three consecutive cleaning operations are completed obtaining values below the criteria of acceptance established.*
13.1.5. Do you perform on-site audits of the suppliers as part of your approval / qualification package?	*Yes*
13.1.6. Are production methods valeted? If yes, please write the code of the Validation Master Plan (VMP)	*Yes*

13.1. VALIDATION

13.1.7. Is there a procedure for approval and qualification of subcontractors (manufacturing steps, QC tests, etc.), suppliers (Raw Materials, API, excipients, packaging materials, etc.) and service providers (warehouse, shipment, and transportation, etc.)?	*Yes, QA-002*
13.2. IMPURITIES	
13.2.1. Does the product comply with the requirements of the ICH Q3B (current edition) Guideline Impurities in New Drug Products?	*Yes*
13.2.2. Do you have identified potential impurities of raw material and/or from the process/storage?	*Yes*
13.2.3. Is it possible to provide chromatographic profiles of impurities?	*Yes*
13.2.4. Does the product comply with the requirements of the ICH Q3C (current edition) Residual Solvents guideline?	*Yes*
13.2.5. Are metal catalysts or metal reagents used during the manufacturing of the finished material?	*No*
13.2.6. Stability Data from studies under ICH conditions, incl. on-going stability studies	*Yes*
13.3. MICROBIOLOGICAL TEST	
13.3.1. Does the material comply with Ph. Eur. 2.6.12 "Microbiological examination of non-sterile products: microbial enumeration tests"?	*Yes*
13.3.2. Does the material comply with Ph. Eur. 2.6.14 "Bacterial Endotoxins"?	*Yes*
13.3.3. Would you provide the validation report(s) and test procedure(s) for the necessary test parameters?	*Yes*

14. DATA INTEGRITY

14.1. Is there frequency based Training (specific aspects of data integrity requirements as part of each responsible role)?	*Yes*
14.2. Have you any Quality Culture Programs in place linking the roles, responsibilities and actions of employees to patient safety, quality, compliance and the reputation of the company?	*Yes*
14.3. Do you have a defined Data Integrity Program? Give a short overview of the program, including governance.	*Yes, Each department must evaluate its own data integrity risk according the described parameters in the procedure, and establish CAPA, actions accordingly.*
14.4. Is there a Continuous Improvement program (identified targeted investment for new/improved technology based on a pre-assessed inventory of equipment/applications for data integrity risk)	*Yes*
14.5. Are your systems provided with access authorization?	*Yes*
14.6. Do you have Technical and/or Procedural Controls in Place (use of system technical capabilities and/or procedural based controls) to cover 21 CFR Part 11 and MHRA access control and audit trail requirements for manufacturing and laboratory equipment?	*Yes*
14.7. Do you have procedures in place to ensure Data Integrity is incorporated into Process Design? For example for Equipment and System Qualification including computer system validation, are there Data Integrity challenge test performed, are access restrictions applied, is the backup / archival / retrieval / disaster recovery and audit trail functionality tested?	*Yes, SOP QA-032*
14.8. Is there secondary review of paper and/or electronic records, including all relevant audit trail characteristics (electronic or manually captured) as part of the batch release process, and are the personnel performing the review independent?	*Yes*

14.9. Are the requirements of FDA´s CFR Part 11 implemented in your facility?	*Yes*
14.10. Are the procedures for associates to adhere to Data Integrity principles included in SOP's?	*Yes*
14.11. Is access consistently logged (audit trail)?	*Yes*
14.12. Is the security of the archived data tested?	*Yes*
14.13. Do you electronic signatures in your systems?	*Yes*
14.14. Is checked via four-eye-principle?	*Yes*
14.15. Is there an Escalation process in place for any identified data integrity and quality issues found with a defined timeframe and notification to management, relevant health authorities and customers?	*Yes, QA-003, includes all the quality risks related to the GMP system. Data integrity compliance is checked as part of the review of the applicable documentation of each department, during its normal activities.*

15. ENVIROMENT & SAFETY

15.1. Is there an environmental management system?	*Yes*
15.2. Do you have a written procedure in place for Health, Safety and Environmental Policy?	*Yes, Document code: POL_06*
15.3. Is Quality Chemicals / Purity Chemicals aware of REACH regulation?	*Yes*
15.4. Does Quality Chemicals / Purity Chemicals perform environmental analysis concerning risk and safety at work?	*Yes*
15.5. Does Quality Chemicals / Purity Chemicals have an internal emergency plan?	*Yes*
15.6. Does Quality Chemicals / Purity Chemicals have a fire fighting system?	*Yes*
15.7. Does Quality Chemicals / Purity Chemicals aim to reduce its potential environmental impact?	*Yes*
15.8. Does the staff in Quality Chemicals / Purity Chemicals have appropriate security measures to the operations carried out?	*Yes*
15.9. Is there a system in place in order to prevent job risk?	*Yes*
15.10. Are accidents at work recorded and investigated? Is there a CAPA system for accidents at work?	*Yes*

Approved by: Jordi Ferrando

Position: QA Manager

Date: 04/08/2020