purity chemicals

quality chemicals

STANDARD PRE-AUDIT QUESTIONNAIRE FARMAQEMICAL PRODUCTS

(QQGMP-005)

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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	*QUALITY CHEMICALS: 2000*	*PURITY CHEMICALS: 2009*
▪ **Contact person** ▪ **Position** ▪ **Telephone** ▪ **e-mail**	***Lluís Aragonès*** ***Chief Executive Officer*** ***+34 93 770 97 30*** ***customer-service@qualitychemicals.com***	
1.5. COMPANY DATA		
1.5.1. Web	*www.qualitychemicals.com* *www.purity-chemicals.com*	
1.5.2. Certifications		
▪ Quality	*ISO 9001*	
▪ Environmental	*ISO 14001*	
▪ Risk and safety	*OHSAS 18001*	
▪ Other	*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**

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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*
1.7.5. Should you need a copy of the certificates enlisted, kindly visit our website.	*Comments: Please obtain our certificates and related documentation on 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* ▪ *Dispatch to Customer*
1.7.8. Are sampling and analytical testing performed or stability testing?	*Full testing accord to CoA.*
1.7.9. Management of materials	
A. Is a lot number assigned to the raw materials?	*Yes*
B. Is a lot number assigned to the finished products?	*Yes*
C. Is there a procedure for the releasing of materials?	*Yes*
D. Realising?	*Yes*
E. Are all the materials /batches tested prior to use/shipping?	*Yes*
F. Is there a record of the analysis operations?	*Yes*
G. Are CoA(s) of the shipped batch(es) issued?	*Yes*
H. How many years is the documentation of production & analysis is kept for?	*7 years*
1.7.10. Is there an Environmental, Health and Safety policy?	*Yes*

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2. PERSONNEL

2.1. Are there sufficient personnel qualified and available?	*Yes*
2.2. Are there regular training workshops for staff?	*Yes*
2.3. Does a training plan for employees exist?	*Yes*
2.4. Do your written procedure for training program include training new employees?	*Yes*
2.5. Is training appropriately documented?	*Yes*
2.6. Is there a training program for new employees?	*Yes*
2.7. Is there a training policy for both temporary and permanent employees (on-the job)?	*Yes*
2.8. Is the general training program conducted by QA?	*Yes*
2.9. Do you maintain training records including dates, times, subject matter, course outline, instructor, etc.)?	*Yes*
2.10. Is there a refresher GMP training program in place for existing employees?	*Yes*
2.11. Is there adequate and regular 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. Are self-inspection programs carried out periodically to perform internal inspection?	*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*

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3. BUILDING & FACILITIES

3.1. Is entrance 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 (with doors). As for windows, they are permanently closed (not possible to open) or have protection nets instead. The clean rooms, which are over-pressurized, are equipped with an air conditioning and filtering system.*
3.5. 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 on food defense and APPCC. External personnel and visitors 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.*
3.6. Please describe briefly the procedure in place to prevent cross-contamination during the manufacturing/packaging process: A. Material handling, sampling, dispensing and charging. B. Cleaning of tools and equipment. C. Flow of materials and personnel.	*All the manufacturing 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.*
3.7. 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*
3.8. Do you have clean rooms with dedicated air handling systems to the manufacturing processes?	*Yes*
3.9. Are there separate dust extraction facilities in areas where dust is generated?	*Yes*
3.10. Is there a written cleaning and sanitation program for the facilities?	*Yes*
3.11. Do you have a pest control service?	*Yes*
3.12. Describe your pest control program for the facility including warehouse space (for rodents and for insects), as well as the trap location and review of trends. Kindly include reference number for the procedure.	*Rodents and insect (flying and non-flying) and rodent's traps are l*ocated throughout th *along the facilities, including warehouse area.* *The smart system runs the vigilance 24/7 by domotic-system. Maintenance is performed monthly by an external certified pest company.* *The reference number for the procedure is PPR-02.*

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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. Are there defined storage areas?	*Yes*
4.1.5. Is refiling or repackaging carried out in the storage area?	*No*
4.1.6. How are respective statuses ensured? (quarantined, released, rejected)	*Labelling and MIS system.*
4.1.7. Do you have a system to differentiate to work in progress, quarantined, rejected material with labeling and physical separation? If lyes, specify.	*Yes, according to 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 instructions available for the transport contractor on how-to act in case of accidents?	*Yes*

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5. PACKAGING / LABELING

5.1. PACKAGING

5.1.1. Are the packing materials, including labels, number of materials and etc., reconciled and recorded in the batch record?	*Yes*
5.1.2. Is primary packaging material licensed for good purpose?	*Yes*
5.1.3. The containers are sent: closed, labeled, strapped with specific material?	*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 applicable additional precautions needed to be taken in place (e.g. nitrogen, desiccant, etc.)	*Packaging specifications are shared with customer. Should the customer have different requirement, then they are fulfilled when possible.*
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. Are your pallets treated according to the ISPM15 standard?	*Yes*
5.1.8. Do you stick labelled on the secondary packaging, e.g., drums, big bags, etc.?	*Yes*
5.1.9. Is each container supplied to customer 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	*Yes to all.*
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 comply with the requirements of EU regulation 10/2011?	*Yes*

5.2. LABELING

5.2.1. Are written instructions for labeling available?	*Yes*
5.2.2. Do you have tamper evident seals on all packaging?	*Yes*
5.2.3. Do you use a barcode label for traceability?	*Yes*
5.2.4. Which status codes are labeled internally?	*Quarantine/ Released/ Rejected.*
5.2.5. 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 to all.*
5.2.6. Will the (original). Label of the manufacturer be kept?	*Yes*
5.2.7. Are labeling operations controlled and unused labels destroyed?	*Yes*

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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. Is manufacturing line clearance performed?	*Yes*
6.1.6. Is there a plan 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 established 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, according to QA-011.*
6.1.16. Is the production documented during manufacturing including raw materials' information, 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 are 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 during manufacturing process?	*Yes*
6.2.2. Please describe the quality of water used in production	*Water & Purified water*
6.2.3. What is the water treatment system?	*Dual Reverse Osmosis treatment for high quality water.*
6.2.4. 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.*

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6.2. WATER PRODUCTION	
6.2.5. Is there available a written procedure for sampling ?	*Yes*
6.2.6. Is there available a written procedure for water quality testing?	*Yes*
6.2.7. How is water hygienized?	*Water is disinfected with ozone.*
6.2.8. Specification available? If Yes, please state the chemical and microbiological specifications for the type of water used.	*Yes* *Purified water according to the current E.P.*

7. PROCESS EQUIPMENT

7.1. Does production equipment have a well defined 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, multipurpose plant.*
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. Are there cleaning procedures in place for: A. each manufacturing/packaging area B. each piece of manufacturing/packaging equipment	*Yes*
7.7. Do you have a calibration policy for inspection, weighing and measuring equipment (e.g. thermometer, manometer, stirrer speed)?	*Yes*
7.8. 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 priorly. Additionally, the status is shown in barge color-codified labels, which are placed in a visible point of each equipment.*
7.9. Describe your corrective and preventive maintenance program in place, for all equipment pieces of equipment (laboratory and manufacturing).	*Corrective 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.*
7.10. Do you have a calibration politics/procedures for laboratory equipment, with traceability to national and international standards?	*Yes*
7.11. What is the frequency of the equipment's recalibration?	*According to the type of equipment.*
7.12. Are calibration records kept on file and are they up-to-date.	*Yes*

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8. STARTING MATERIALS

8.1. RAW MATERIALS

8.1.1. Do you have procedure to release raw materials?	*Yes*
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. Labeling G. Dispensing H. Specifications I. Processing J. Packaging	*Yes, according to 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, the origin of the starting material is synthetic.*
8.2.2. Are other materials (e.g. reagents like chromatographic media, buffers etc.) of animal or human origin used in the manufacturing process of the product?	*No, present in product and MFG line.*
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, present in product and MFG line.*
8.2.4. Is the material tested for absence of melamine?	*No, present in product and MFG line.*
8.2.5. Does the material contain crustaceans and products thereof?	*No, present in product and MFG line.*
8.2.6. Does the material contain Antibiotic (where antibiotic is not the active ingredient and present only as residual impurity)?	*No, present in product and MFG line.*
8.2.7. Does the material contain Eggs, or manufactured in eggs?	*No, present in product and MFG line.*
8.2.8. Does the material contain Aspartame?	*No, present in product and MFG line.*
8.2.9. Does the material contain Benzoates including: benzoic acid, sodium benzoate?	*No, present in product and MFG line.*
8.2.10. Does the material contain Ethanol (where ethanol is present in a concentration of 3% V/V or more)?	*No, present in product and MFG line.*
8.2.11. Does the material contain gluten, i.e. wheat, rye, barley, oats, spelt, kamut or their hybridized strains?	*No, present in product and MFG line.*
8.2.12. Does the material contain galactose?	*No, present in product and MFG line.*
8.2.13. Does the material contain pollen?	*No, present in product and MFG line.*
8.2.14. Does the material contain phenylalanine?	*No, present in product and MFG line.*
8.2.15. Does the material contain avian?	*No, present in product and MFG line.*
8.2.16. Does the material contain fish?	*No, present in product and MFG line.*
8.2.17. Does the material contain Odor?	*No, present in product and MFG line.*
8.2.18. Does the material contain Milk (including lactose)?	*No, present in product and MFG line.*
8.2.19. Does the material contain celery?	*No, present in product and MFG line.*
8.2.20. Does the material contain soybeans oil (comment if refined)?	*No, present in product and MFG line.*
8.2.21. Does the material contain peanuts?	*No, present in product and MFG line.*
8.2.22. Does the material contain nuts, i.e. almonds, hazelnuts, walnuts, cashews, pecan nuts, Brazil nuts, pistachio nuts, macadamia nuts and Queensland nuts, any other tree nuts?	*No, present in product and MFG line.*
8.2.23. Does the material contain sesame seeds?	*No, present in product and MFG line.*

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8.2 FREE OF COMPOUNDS	
8.2.24. Does the material contain mustard?	*No, present in product and MFG line.*
8.2.25. Does the material contain 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. Does the material contain lupin?	*No, present in product and MFG line.*
8.2.27. Does the material contain molluscs?	*No, present in product and MFG line.*
8.2.28. Does the material contain natural rubber latex?	*No, present in product and MFG line.*
8.2.29. Does the material contain Iodine?	*No, present in product and MFG line.*
8.2.30. Does the material contain 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. Does the material contain hydrolyzed plan protein?	*No, present in product and MFG line.*
8.2.32. Does the material contain 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. Does the material contain 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. Does the material contain 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. Does the material contain seeds (poppy, sunflower, cottonseed, sesame)?	*No, present in product and MFG line.*
8.2.36. Does the material contain starch and modified starches?	*No, present in product and MFG line.*
8.2.37. Does the material contain propolis?	*No, present in product and MFG line.*
8.2.38. Does the material contain royal jelly?	*No, present in product and MFG line.*
8.2.39. Does the material contain saccharin, including: saccharin calcium; saccharin sodium?	*No, present in product and MFG line.*
8.2.40. Does the material contain sucralose?	*No, present in product and MFG line.*
8.2.41. Does the material contain live infectious agents of birds and livestock?	*No, present in product and MFG line.*
8.2.42. Does the material contain 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. Does the material contain sorbates, including: potassium sorbate; sorbic acid?	*No, present in product and MFG line.*
8.2.44. Does the material contain 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. Does the material contain 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. Does the material contain 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?	*No, present in product and MFG line.*

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8.2 FREE OF COMPOUNDS	
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 the material contain Phthalates?	*No, present in product and MFG line.*
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.*

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9. QUALITY CONTROLS

9.1. MANAGEMENT

9.1.1 Are all laboratory test methods are 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 specifications agreed by customer?"	*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 for product control?	*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, according to 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. Are retained samples kept from all?	*Yes*
9.1.14. How long are retained samples kept for?	*7 Years*
9.1.15. Are reference substances (standards) checked on a regular basis?	*Yes*
9.1.16. Do you assure to maintain the batch integrity (no blending batches)?	*Yes*
9.1.17. 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 consult the product in our website www.qualitychemicals.com. The retest period is defined according to the data obtained from stability studies.*
9.1.18. Do you have a written procedure documenting on how to conduct analytical method validations?	*Yes, according to QA-010.*
9.1.19. Do you have a procedure in place for handling out of specification (OOS) results in the laboratory?	*Yes, according to QC-002.*
9.1.20. Are all test parameters indicated in the certificate of analysis tested on the delivered batch?	*Yes*
9.1.21. 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 periodically?	*Yes*
9.2.3. Any written instructions in place?	*Yes*
9.2.4. Are logbooks available?	*Yes*

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10. IN-PROCESS CONTROL

10.1. PRODUCTION

10.1.1. Describe the controls in place to assure homogeneity of the material.	*All our manufacturing 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 by the computer system.*
10.1.6. Are line start-up inspection performed and documented prior to operations?	*Yes*
10.1.7. With respect to the manufactured material, are the process controls and critical control points carried out?	*Yes*
10.1.8. Have yield limits been set?	*Yes*
10.1.9. Is the yield (material loss) calculated and documented?	*Yes*

10.2. INTERMEDIATES

10.2.1. Are there adequate storage for intermediates?	*Yes*
10.2.2. Are intermediates identified before their use?	*Yes*
10.2.3. Are intermediates tested and released?	*Yes*

10.3. FINAL PRODUCT

10.3.1. Is blending performed to any material that does not conform to specification?	*No*
10.3.2. Are failures in the production process documented?	*Yes*
10.3.3. Are materials reworked?	*No*
10.3.4. Are process waste and unusable residues destroyed?	*Yes, using an external service.*
10.3.5. Is the material processed via irradiation technology?	*No*
10.3.6. Does the product conform to the current EU food regulations?	*Yes*
10.3.7. Does the product conform to the current Swiss medicinal products regulations?	*Yes*
10.3.8. 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*
10.3.9. Do laboratory test results comply 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*

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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. Are changes classified according to ICH Q7?	*Yes*
11.1.7. Is a QA manual available?	*Yes*
11.1.8. Is the quality manual applied within the 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/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 and 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 Quality Assurance Manager?	*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. To whom does Quality Assurance report?	*Technical Manager*
11.3.6. Is every production step documented?	*Yes*
11.3.7. How is the expiration / retest date of the product determined?	*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 Quality Assurance department? If yes, please state the procedure reference.	*Yes, Documents: P-GS-07, QA-009.*

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11.3. QUALITY MANAGEMENT	
11.3.11. For all quality documentation, do you have procedures defining: A. Update / revisions B. Approval C. Controlled Distribution D. Use and Storage	*Yes to all.*
11.3.12. Is there a formal procedure for the assessment of production deviations?	*Yes*
11.3.13. 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
11.3.14. Is there a controlled document that describes how the material is produced?	*Yes*
11.3.15. Is the manufacturer and manufacturing site mentioned on the certificates of analysis?	*Yes*
11.3.16. Where are the manufacturing date and/or expiry date of a batch indicated?	*In the label & CoA.*
11.3.17. Are you able to provide to customer the following information, related to product and 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. ▪ List of all major batch related changes ▪ Executed Batch record	*Yes, Upon request Customer shall receive complete records of Minor deviations.*
11.3.18. Are products affected by BEE / TSE, GMO, dioxins? Can you issue a certificate?	*No, products are not affected. Yes, we can issue a certificate.*
11.4. CHANGE CONTROL	
11.4.1. Does Quality Chemicals / Purity Chemicals perform a change control procedure?	*Yes*
11.4.2. Is a change control procedure established 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. Is there a change control procedure?	*Yes*
11.4.5. In case of a change in the specifications affecting the quality of the product, would Quality Chemicals / Purity Chemicals inform their customers?	*Yes*
11.4.6. 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 specifications available for all raw materials?	*Yes*
11.6. COMPLAINT HANDLING	
11.6.1. Are customer complaints systematically documented?	*Yes*
11.6.2. Does Quality Chemicals / Purity Chemicals have a procedure for management of customer complaints?	*Yes, according to P-GS-07.*
11.6.3. Are investigations conducted in a timely manner to establish if the complaint is justified and to identify root cause?	*Yes*
11.6.4. Are investigations conducted to identify whether the reported defect is limited to a single batch if other batches need to be considered?	*Yes*

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11.6. COMPLAINT HANDLING	
11.6.5. Do you inform the original manufacturer in the event of a complaint?	*Yes*
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 implemented to manage product recall promptly and effectively?	*Yes*
11.7.2. Do you evaluate the effectiveness of your recall arrangements at regular interval?	*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 customer.	*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 to the results obtained, it will be classified as compliant or non-compliant, and therefore requalified, reprocessed or managed as waste. Following procedures of QA-027, P-GS-04.*
11.8.3. Are the goods returned from the customer re-used?	*No*
11.9. NON-CONFORMING MATERIALS	
11.9.1. Does Quality Chemicals / Purity Chemicals have a procedure for managing of non-conformities?	*Yes*
11.9.2. Are written procedures for handling of non-conforming materials implemented?	*Yes*
11.9.3. Is non-conforming material, if necessary, 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 and tour facilities. ▪ Perform a quality audit of production and quality control process.	 *Yes* *Yes*
11.10.4. Does Quality Chemicals / Purity Chemicals have customer quality audits? If yes, how many audits and how often?	*Yes, about 25 audits per year.*

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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. The entire manufacturing process is collated in the master batch record?	*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. Is batch traceability assured?	*Yes*
12.9. Is the manufacturing line clearance documented in the batch record?	Yes

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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, according to 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. Do the contract testing laboratories and external manufacturers implement quality system according to international standards?	*Yes, Yes, compliant with international standards is required, however, certification is not mandatory. 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 time 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 validated? If yes, please write the code of the Validation Master Plan (VMP).	*Yes, according to QA-011.*

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, according to QA-002.*

13.2. IMPURITIES

13.2.1. Does the product comply with the requirements of the ICH Q3B (current edition) Guideline for 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) Guideline for Residual Solvents?	*Yes*
13.2.5. Are metal catalysts or metal reagents used during the manufacturing of the finished material?	*No*
13.2.6. Are stability data studies performed according to ICH conditions, including on-goings stability studies?, 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*

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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 If yes, provide 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, 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, according to SOP QA-032.*
14.8. Is there a 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 use electronic signatures in your systems?	*Yes*
14.14. Do you apply the use of the review through the principle of the four eyes?	*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, according to QA-003 which 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.*

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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, according to 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