

Doc nº:	QQGMP-004
Replaces to:	QQGMP-003
Title:	STANDARD PRE-AUDIT QUESTIONNAIRE FARMAQEMICAL PRODUCTS

1. COMPANY NAME	QUALITY CHEMICALS S.L.
2. ADDRESS	<i>C/ Fornal 35, 08292 Esparreguera (Barcelona, Spain)</i>
3. YEAR OF FOUNDATION	1997
4. MANUFACTURING SITE	QUALITY CHEMICALS S.L. / PURITY CHEMICALS S.L.
5. MANUFACTURING SITE ADDRESS	QUALITY CHEMICALS S.L. <i>C/ Fornal 35 08292 Esparreguera (Barcelona, Spain)</i> PURITY CHEMICALS S.L. <i>Av. Tren Expreso, 82-84 34200 Venta de Baños (Palencia, Spain)</i>
a. Date of construction of production facility	QUALITY CHEMICALS: 2000 / PURITY CHEMICALS: 2009
b. Contact person	Lluís Aragonès
c. Position	General Manager
d. Telephone	+34 979 76 10 97
e. e-mail	qemical@qualitychemicals.com
6. COMPANY DATA	
f. web	www.qualitychemicals.com www.purity-chemicals.com
g. Certifications (please attach a copy of the certificates):	
i. Quality	ISO 9001:2015
ii. Environmental	ISO 14001:2015
iii. Risk and safety	OSHAS 18001
iv. Other	GMP certificate (AEMPS) ISO 22000
v. In process of implementing:	-
7. HUMAN RESOURCES	
h. Number of employees	78 (Quality Chemicals: 54. Purity Chemicals: 24)
i. Production	42 (Quality Chemicals: 26. Purity Chemicals: 16)
1. Production plant	35
2. Warehouse	7
ii. Engineering and maintenance	6
iii. Quality Unit	15
1. Quality control	12
2. Quality management	3
iv. HSE	1
v. R&D	2
vi. Sales	5
vii. Human resources	1
viii. Rest of departments	7
i. Is Quality Unit independent from production?	Yes
j. Who Quality Assurance reports to?	Technical Manager
k. Does a training plan for employees exist?	Yes
l. Are there records of training for employees?	Yes
m. How many hours are spent on training per employee / year?	30 h

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8. 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. Is the releasing of materials recorded?	Yes
e. Are all the materials/batches tested prior to use/shipping?	Yes.
f. Is there a record of the operations of analysis?	Yes
g. Are CoA of the shipped batches issued?	Yes
h. How many years is documentation of production and analysis kept?	7 years
9. PRODUCTION	
a. Productive capacity (kg/year)	Aprox. 1,500 Tn/year
b. Are production methods written and approved?	Yes
c. Are production methods validated? If yes, please write the code of the Validation Master Plan (VMP)	Yes
d. Is the production documented in manufacturing sheets with information of raw materials, batches, operations, workers and supervision?	Yes
e. Is there a preventive maintenance plan for equipments?	Yes
f. Is there a calibration plan for equipment/measuring instruments in production plant?	Yes
g. Does production equipment have an unambiguous reference that relates to the production documentation?	Yes
h. Are deviations in production registered and/or investigated?	Yes
i. Are critical parameters in the production process defined?	Yes
j. Are there measures to prevent cross-contamination in production plant?	Yes
k. Is there a plan for cleaning the production plant equipment?	Yes
l. Are cleaning operations registered?	Yes
m. Are products manufactured in dedicated or multipurpose equipments?	Multipurpose equipments
n. In case of multipurpose plant, are products manufactured in the same equipment/facilities which manufacture pesticides, herbicides, penicilinic derivatives, hormones, cephalosporines, sensitizing and anti-cancer products?	No
o. Please describe the quality of water used in production	Deionized Water
p. Please describe the quality of the air in the last production step	ISO 8 Class D

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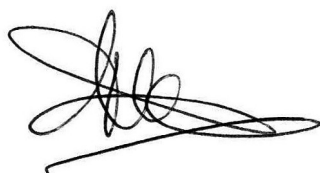
10. QUALITY		
a.	Does the company have a Quality Manual?	Yes
b.	Who performs the sampling of finished products?	Qualified operators
c.	Is there a formally approved quality specification for the product? If yes, does a change control procedure exist?	Yes
d.	Are all the batches analyzed and formally approved or refused?	Yes
e.	¿Does Quality Chemicals / Purity Chemicals retain a sample of every batch? How long?	Yes. 7 years
f.	Is there a calibration procedure for analytical equipment?	Yes
g.	Does Quality Chemicals / Purity Chemicals carry out stability studies?	Yes
h.	What's the expiry date / retest date of the product?	Determined by stability test according to ICH Q1A (R2) for APIs
i.	Are products affected by BEE/TSE, GMO, dioxins? Can you issue a certificate?	No. We can issue a certificate.
j.	Does Quality Chemicals / Purity Chemicals perform a qualification of suppliers?	Yes
k.	Does Quality Chemicals / Purity Chemicals have a procedure for management of non conformities?	Yes
l.	Does Quality Chemicals / Purity Chemicals have a change control procedure?	Yes
m.	Does Quality Chemicals / Purity Chemicals carry out product quality review?	Yes
n.	Does Quality Chemicals / Purity Chemicals have a procedure for management of customer complaints?	Yes
o.	Does Quality Chemicals / Purity Chemicals carry out internal audits?	Yes
p.	Is there a CAPA program in place?	Yes
q.	Would Quality Chemicals / Purity Chemicals allow to:	
	i. Visit our facilities	Yes
	ii. Perform a quality audit of production and quality control processes	Yes
r.	In case of a change in the process o specifications affecting the quality of the product, would Quality Chemicals / Purity Chemicals inform their customers?	Yes
s.	Do Quality Chemicals / Purity Chemicals have customer quality audits? How many and how often?	Yes. About 20-25 audits per year

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11. ENVIRONMENT AND SAFETY		
a.	Is there a system in place in order to prevent job risks?	Yes
b.	Are accidents at work recorded and investigated? Is there a CAPA system for accidents at work?	Yes
c.	Does the staff in Quality Chemicals / Purity Chemicals have appropriate security measures to the operations carried out?	Yes
d.	Does Quality Chemicals / Purity Chemicals perform environmental analysis concerning risk and safety at work?	Yes
e.	Does Quality Chemicals / Purity Chemicals have an internal emergency plan?	Yes
f.	Does Quality Chemicals / Purity Chemicals have a fire fighting system?	Yes
g.	Is there an environmental management system?	Yes
h.	Does Quality Chemicals / Purity Chemicals aim to reduce its potential environmental impact?	Yes
i.	Is Quality Chemicals / Purity Chemicals aware of REACH regulation?	Yes

QUESTIONNAIRE COMPLETED BY:

Name: **David Carreras**
Position: **Quality Assurance**
Date and signature:

**02/01/2019**