National Organization for Medicines

CERTIFICATE NUMBER : ***105196/ 9-11-2021***

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1, 2]

Part 1

Issued following an inspection in accordance with :
Art. 111(5) of Directive 2001/83/EC as amended
Art. 80(5) of Directive 2001/82/EC as amended
Art. 15 of Directive 2001/20/EC

The competent authority of Greece confirms the following:
The manufacturer :***QACS ΕΠΕ/ QACS LTD***
Site address :***Αντιγόνης 1 / 1, Antigonis str., Μεταμόρφωση Αττική / Metamorfossi Attiki, 14451, Greece***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***0000008934/21/1*** in accordance with Art. 40 of Directive 2001/83/EC , Art. 44 of Directive 2001/82/EC and Art. 13 of Directive 2001/20/EC .

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2021-07-09*** , it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC [3]
- The principles and guidelines of Good Manufacturing Practice laid down in Directive 91/412/EC [3]

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. This certificate is valid only when presented with all pages and both Parts 1 and 2. The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

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[1] *The certificate referred to in paragraph 111(5) of Directive 2001/83/EC and 80(5) of Directive 2001/82/EC, shall also be required for imports coming from third countries into a Member State.*

[2] *Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.*

[3] *These requirements fulfil the GMP recommendations of WHO.*

Part 2

Human Medicinal Products
Veterinary Medicinal Products
Human Investigational Medicinal Products

1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.3 Batch certification
1.2	**Non-sterile products**
	1.2.2 Batch certification
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility *1.6.3 Chemical/Physical*

Clarifying remarks (for public users)

The laboratory also performs the above Quality Control Testing at the facilities of 25-27, Aristotelous street, Metamorfossi Attiki, 14451

2021-12-03

Name and signature of the authorised person of the Competent Authority of Greece

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Confidential
National Organization for Medicines
Tel:***Confidential***
Fax:***Confidential***

MANUFACTURER'S AUTHORISATION [1, 2]

1. Authorisation Number	0000008934/21/1
2. Name of authorisation holder	QACS ΕΠΕ/ QACS LTD
3. Address(es) of manufacturing site(s)	QACS ΕΠΕ/ QACS LTD, Αντιγόνης 1 / 1, Antigonis str., Μεταμόρφωση Αττική / Metamorfossi Attiki, 14451, Greece
4. Legally registered address of authorisation holder	Αντιγόνης 1 / 1, Antigonis str., Μεταμόρφωση Αττική / Metamorfossi Attiki, 14451, Greece
5. Scope of authorisation and dosage forms [2]	ANNEX 1 and/ or ANNEX 2
6. Legal Basis of authorisation	Art. 40 of Directive 2001/83/EC Art. 13 of Directive 2001/20/EC Art. 44 of Directive 2001/82/EC
7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	confidential
8. Signature	
9. Date	2021-12-03
10. Annexes attached	Annex 1 and/or Annex 2 Optional Annexes as required: Annex 3 (Addresses of Contract Manufacturing Site(s)) Annex 4 (Addresses of Contract laboratories) Annex 5 (Name of Qualified Person) Annex 6 (Name of responsible persons) Annex 7 (Date of inspection on which authorisation granted, scope of last inspection) Annex 8 (Manufactured/ imported products authorised) [3]

[1] *The authorisation referred to in paragraph 40(1) of Directive 2001/83/EC and 44(1) of Directive 2001/82/EC, as amended, shall also be required for imports coming from third countries into a Member State.*

[2] *Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.*

[3] *The Competent Authority is responsible for appropriate linking of the authorisation with the manufacturer's application (Art. 42(3) of Directive 2001/83/EC and Art. 46(3) of Directive 2001/82/EC as amended).*

SCOPE OF AUTHORISATION **ANNEX 1**

Name and address of the site : QACS ΕΠΕ/ QACS LTD, Αντιγόνης 1 / 1, Antigonis str., Μεταμόρφωση Αττική / Metamorfossi Attiki, 14451, Greece

Human Medicinal Products Veterinary Medicinal Products

Authorised Operations MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.3 Batch certification
1.2	**Non-sterile products**
	1.2.2 Batch certification
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility *1.6.3 Chemical/Physical*

Any restrictions or clarifying remarks related to the scope of these Manufacturing operations (for Public users)

The laboratory also performs the above Quality Control Testing at the facilities of 25-27, Aristotelous street, Metamorfossi Attiki, 14451

SCOPE OF AUTHORISATION **ANNEX 2**

Name and address of the site : QACS ΕΠΕ/ QACS LTD, Αντιγόνης 1 / 1, Antigonis str., Μεταμόρφωση Αττική / Metamorfossi Attiki, 14451, Greece

Human Investigational Medicinal Products

Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.3 Batch certification
1.2	**Non-sterile products**
	1.2.2 Batch certification
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility 1.6.3 Chemical/Physical

NATIONAL ANNEX
QACS Ltd.
(EOF Decision: 105196/9-11-2021)

MANUFACTURING ACTIVITIES
MEDICINAL PRODUCTS FOR HUMAN AND VETERINARY USE
MICROBIOLOGICAL QUALITY CONTROL TESTING: Tablets, capsules, creams, ointments, oral suspensions, syrups, oral ampoules, solutions Solutions for external use, Solutions for internal use, Ophthalmic solutions, Gels, Nasal solutions, Liquids for Injections, Suppositories, Pharmaceutical shampoos, Powders QUALITY CONTROL TESTING & STABILITY TESTING: Creams for external use, oral suspensions, syrups, suppositories, eye drops (solution), nasal solutions, gels external, external use solutions (lacquers). Tablets, capsules, ointments, pharmaceutical shampoos, Liquid injectable Solutions for external use, Creams, Solutions for internal use, Oral ampoules, Gels, Powders RELEASE OF MEDICINAL PRODUCTS FRO HUMAN AND VETERINARY USE Tablets, Capsules, Creams, Ointments, Oral Suspensions, Syrups, Oral Ampoules, Solutions for internal use, Suppositories, Ophthalmic Solutions, Gels, Solutions for external use, Nasal Solutions, Pharmaceutical Shampoos, Liquids for Injections, Powders
INVESTIGATIONAL MEDICINAL PRODUCTS FOR HUMAN AND VETERINARY USE
MICROBIOLOGICAL QUALITY CONTROL TESTING, QUALITY CONTROL TESTING & STABILITY TESTING: Tablets, Capsules, Creams, Ointments, Oral Suspensions, Syrups, Oral Ampoules, Suppositories, Ophthalmic Solutions, Nasal Solutions, Gels, Solutions for external use, Pharmaceutical Shampoos, Liquids for Injections, Powders Solutions for internal use, Powders
PHARMACEUTICAL STARTING MATERIALS
CHEMICAL QUALITY CONTROL TESTING: Solid and liquid starting materials MICROBIOLOGICAL QUALITY CONTROL TESTING: Solid and liquid starting materials
COSMETIC PRODUCTS
MICROBIOLOGICAL QUALITY CONTROL TESTING: Foambaths, creamsoaps, shampoos, soaps, creams (and sunscreens), masks,

emulsions (and sunscreens), lotions with low concentration of ethanol, toothpastes, body oils, mouthwashes, colognes, lotions containing alcohol, wet tissues, hair foams, shaving foams, deodorants (with or without propellant), products for nail care (mixtures containing aceton), lipsticks, cotton (for pharmaceutical use, demake up, cotton batonettes) CHEMICAL QUALITY CONTROL TESTING: Foambaths, creamsoaps, shampoos, soaps, creams (and sunscreens), masks, emulsions (and sunscreens), lotions with low concentration of ethanol, toothpastes, body oils, mouthwashes, colognes, lotions containing alcohol, wet tissues, hair foams, shaving foams, deodorants (with or without propellant), products for nail care (mixtures containing aceton), lipsticks, cotton (for pharmaceutical use, demake up, cotton batonettes) TESTING OF ALLERGENICS STARTING MATERIALS
MICROBIOLOGICAL QUALITY CONTROL TESTING OF WATER
DISINFECTANTS
CHEMICAL QUALITY CONTROL TESTING: Liquids, Powders, Gels, Antiseptics - Disinfectant wipes MICROBIOLOGICAL QUALITY CONTROL TESTING: Liquid form EFFICACY OF DISINFECTANTS
FOOD SUPPLEMENTS
MICROBIOLOGICAL & CHEMICAL QUALITY CONTROL TESTING: Tablets, Capsules, Syrups
MEDICAL DEVICES
MICROBIOLOGICAL & CHEMICAL QUALITY CONTROL TESTING: Creams, Emulsions (lotions), Gels, Foambaths, Aerosols

The laboratory also performs the above Quality Control Testing at the facilities of 25-27, Aristotelous street, Metamorfossi Attiki, 14451

The Deputy Head of
Inspection Department

Dr D. Dimas