MANUFACTURER'S AUTHORISATION [1] [2]

1. Authorisation Number	0000006501/15/1
2. Name of authorisation holder	ΦΑΡΜΑΤΕΝ ΑΒΕΕ / PHARMATHEN SA
3. Address(es) of manufacturing site(s)	ΦΑΡΜΑΤΕΝ ΑΒΕΕ / PHARMATHEN SA, Δερβενακίων 6 / Dervenakion 6, Παλλήνη Αττικής / Pallini Attiki, 15351, Greece
4. Legally registered address of authorisation holder	Δερβενακίων 6 / Dervenakion 6, Παλλήνη Αττικής / Pallini Attiki, 15351, 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
7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	
8. Signature	
9. Date	2015-05-11
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 : ΦΑΡΜΑΤΕΝ ΑΒΕΕ / PHARMATHEN SA, Δερβενακίων 6 / Dervenakion 6, Παλλήνη Αττικής / Pallini Attiki, 15351, Greece

Human Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

Part 1 - MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.1 Large volume liquids 1.1.1.4 Small volume liquids
	1.1.2 Terminally Sterilised (processing operations for the following dosage forms) 1.1.2.1 Large volume liquids 1.1.2.3 Small volume liquids
	1.1.3 Batch certification
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.1 Capsules, hard shell 1.2.1.5 Liquids for external use 1.2.1.13 Tablets
	1.2.2 Batch certification
1.3	**Biological medicinal products (list of product types)**
	1.3.2 Batch Certification (list of product types) 1.3.2.6 Human or animal extracted products
1.5	**Packaging**
	1.5.1 Primary Packing 1.5.1.1 Capsules, hard shell 1.5.1.2 Capsules, soft shell 1.5.1.5 Liquids for external use 1.5.1.13 Tablets
	1.5.2 Secondary packing

1.6	**Quality control testing**
	1.6.1 Microbiological: sterility *1.6.2 Microbiological: non-sterility* *1.6.3 Chemical/Physical*

Any restrictions or clarifying remarks related to the scope of these Manufacturing operations

Storage of semifinished and finished products, packaging materials, starting materials, cosmetic products and medical devices, in the warehouse in Afoi Ksintara road, Pikermi Attiki, Greece
Storage of pharmaceutical starting materials, semifinished, finished medicinal products and packaging materials, in the warehouse in NATO Avenue, Site Aspropyrgos, Aspropyrgos, Attiki, Greece.

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

Storage of semifinished and finished products, packaging materials, starting materials, cosmetic products and medical devices, in the warehouse in Afoi Ksintara road, Pikermi Attiki, Greece
Storage of pharmaceutical starting materials, semifinished, finished medicinal products and packaging materials, in the warehouse in NATO Avenue, Site Aspropyrgos, Aspropyrgos, Attiki, Greece.

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported medicinal products**
	2.1.1 Microbiological: sterility *2.1.2 Microbiological: non-sterility* *2.1.3 Chemical/Physical*
2.2	**Batch certification of imported medicinal products**
	2.2.1 Sterile products 2.2.1.1 Aseptically prepared 2.2.1.2 Terminally sterilised
	2.2.2 Non-sterile products
2.3	**Other importation activities**
	2.3.1 Site of physical importation

SCOPE OF AUTHORISATION **ANNEX 2**

Name and address of the site : ΦΑΡΜΑΤΕΝ ΑΒΕΕ / PHARMATHEN SA, Δερβενακίων 6 / Dervenakion 6, Παλλήνη Αττικής / Pallini Attiki, 15351, Greece

Human Investigational Medicinal Products

Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

Part 1 - MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.1 Large volume liquids 1.1.1.4 Small volume liquids
	1.1.2 Terminally Sterilised (processing operations for the following dosage forms) 1.1.2.1 Large volume liquids 1.1.2.3 Small volume liquids
	1.1.3 Batch certification
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.1 Capsules, hard shell 1.2.1.5 Liquids for external use 1.2.1.13 Tablets
	1.2.2 Batch certification
1.5	**Packaging**
	1.5.1 Primary Packing 1.5.1.1 Capsules, hard shell 1.5.1.2 Capsules, soft shell 1.5.1.5 Liquids for external use 1.5.1.13 Tablets
	1.5.2 Secondary packing
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility 1.6.2 Microbiological: non-sterility

	1.6.3 Chemical/Physical

Any restrictions or clarifying remarks related to the scope of these Manufacturing operations

Storage of semifinished and finished products, packaging materials, starting materials, cosmetic products and medical devices, in the warehouse in Afoi Ksintara road, Pikermi Atiiki, Greece
Storage of pharmaceutical starting materials, semifinished, finished medicinal products and packaging materials, in the warehouse in NATO Avenue, Site Aspropyrgos, Aspropyrgos, Attiki, Greece.

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

Storage of semifinished and finished products, packaging materials, starting materials, cosmetic products and medical devices, in the warehouse in Afoi Ksintara road, Pikermi Atiiki, Greece
Storage of pharmaceutical starting materials, semifinished, finished medicinal products and packaging materials, in the warehouse in NATO Avenue, Site Aspropyrgos, Aspropyrgos, Attiki, Greece.

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported medicinal products**
	2.1.1 Microbiological: sterility 2.1.2 Microbiological: non-sterility 2.1.3 Chemical/Physical
2.2	**Batch certification of imported medicinal products**
	2.2.1 Sterile products 2.2.1.1 Aseptically prepared 2.2.1.2 Terminally sterilised
	2.2.2 Non-sterile products
2.3	**Other importation activities**
	2.3.1 Site of physical importation

NATIONAL ANNEX PHARMATHEN S.A.

MANUFACTURING ACTIVITIES
HUMAN MEDICINAL PRODUCTS
STERILE PRODUCTS **Aseptically prepared** **Large volume liquids** **Small volume liquids (in vials)** **Terminally sterilized** **Large volume liquids** **Small volume liquids (in vials & in ampoules)**
NON-STERILE PRODUCTS **Capsules, hard shell: and antibiotics, sustained release** **Liquids for external use: and lotions, pharmaceutical shampoos** **Tablets: and coated, sugar coated, sustained release, dispersable, chewable**
Packaging only : **Sterile products: eye drops (placement in carton)** **Biological products: solution for injection in prefilled syringe.** **Capsules, soft shell (placement in blister and in box)** **Powder and solute for injectable solution**
INVESTIGATIONAL MEDICINAL PRODUCTS
STERILE PRODUCTS **Aseptically prepared** **Large volume liquids** **Small volume liquids (in vials)** **Terminally sterilized** **Large volume liquids** **Small volume liquids (in vials & in ampoules)**
NON-STERILE PRODUCTS **Capsules, hard shell: and antibiotics, sustained release** **Liquids for external use: and lotions, pharmaceutical shampoos** **Tablets: and coated, sugar coated, sustained release**
Packaging only : **Sterile products: eye drops (placement in carton)** **Capsules, soft shell (placement in blister and in box)**

IMPORTATION OF MEDICINAL PRODUCTS
Aseptically prepared in glass or plastic vials: large volume liquids, small volume liquids, powder for solution for infusion **Terminally sterilized in vials or ampoules (glass or plastic), or bags: large volume liquids, small volume liquids** **Oral solutions** **Tablets: and coated, sugar coated, sustained release, controlled release, chewable, orodispersable, soluble, dispersable, oral lyophilisate, sublingual, gastroresistant** **Capsules, hard shell: and antibiotics, sustained release, gastroresistant, controlled release** **Capsules, soft shell: and gastroresistant, chewable, sustained release, controlled release** **Eye drops: solution, suspension** **Liquids for external use: and lotion, pharmaceutical shampoos**
IMPORTATION OF INVESTIGATIONAL MEDICINAL PRODUCTS
<u>STERILE PRODUCTS</u> **<u>Aseptically prepared</u>** **Large volume liquids** **Small volume liquids (in vials)** **<u>Terminally sterilized</u>** **Large volume liquids** **Small volume liquids (in vials & in ampoules)** **<u>NON-STERILE PRODUCTS</u>** **Capsules, hard shell: and antibiotics, sustained release** **Liquids for external use: and lotions, pharmaceutical shampoos** **Tablets: and coated, sugar coated, sustained release, controlled release, chewable, orodispersable** **Eye drops** **Caspules, soft shell**

The Director of Production and Distribution Control