

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 EudraGMPD 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
	<i>1.1.1 Aseptically prepared (processing operations for the following dosage forms)</i> 1.1.1.1 Large volume liquids 1.1.1.4 Small volume liquids
	<i>1.1.2 Terminally Sterilised (processing operations for the following dosage forms)</i> 1.1.2.1 Large volume liquids 1.1.2.3 Small volume liquids
	<i>1.1.3 Batch certification</i>
1.2	Non-sterile products
	<i>1.2.1 Non-sterile products (processing operations for the following dosage forms)</i> 1.2.1.1 Capsules, hard shell 1.2.1.5 Liquids for external use 1.2.1.13 Tablets
	<i>1.2.2 Batch certification</i>
1.3	Biological medicinal products (list of product types)
	<i>1.3.2 Batch Certification (list of product types)</i> 1.3.2.6 Human or animal extracted products
1.5	Packaging
	<i>1.5.1 Primary Packing</i> 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
	<i>1.5.2 Secondary packing</i>



1.6	Quality control testing
	<i>1.6.1 Microbiological: sterility</i> <i>1.6.2 Microbiological: non-sterility</i> <i>1.6.3 Chemical/Physical</i>

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
	<i>2.1.1 Microbiological: sterility</i> <i>2.1.2 Microbiological: non-sterility</i> <i>2.1.3 Chemical/Physical</i>
2.2	Batch certification of imported medicinal products
	<i>2.2.1 Sterile products</i> 2.2.1.1 Aseptically prepared 2.2.1.2 Terminally sterilised
	<i>2.2.2 Non-sterile products</i>
2.3	Other importation activities
	<i>2.3.1 Site of physical importation</i>

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
	<i>1.1.1 Aseptically prepared (processing operations for the following dosage forms)</i> 1.1.1.1 Large volume liquids 1.1.1.4 Small volume liquids
	<i>1.1.2 Terminally Sterilised (processing operations for the following dosage forms)</i> 1.1.2.1 Large volume liquids 1.1.2.3 Small volume liquids
	<i>1.1.3 Batch certification</i>
1.2	Non-sterile products
	<i>1.2.1 Non-sterile products (processing operations for the following dosage forms)</i> 1.2.1.1 Capsules, hard shell 1.2.1.5 Liquids for external use 1.2.1.13 Tablets
	<i>1.2.2 Batch certification</i>
1.5	Packaging
	<i>1.5.1 Primary Packing</i> 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
	<i>1.5.2 Secondary packing</i>
1.6	Quality control testing
	1.6.1 Microbiological: sterility 1.6.2 Microbiological: non-sterility

	1.6.3 Chemical/Physical
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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 <i>Sterile products</i> 2.2.1.1 Aseptically prepared 2.2.1.2 Terminally sterilised
	2.2.2 <i>Non-sterile products</i>
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

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, controlled release, chewable, orodispersable

Eye drops

Caspules, soft shell

The Director of Production
and Distribution Control

