



ΕΛΛΗΝΙΚΗ ΔΗΜΟΚΡΑΤΙΑ  
ΥΠΟΥΡΓΕΙΟ ΥΓΕΙΑΣ &  
ΚΟΙΝΩΝΙΚΗΣ ΑΛΛΗΛΕΓΓΥΗΣ  
**ΕΘΝΙΚΟΣ ΟΡΓΑΝΙΣΜΟΣ  
ΦΑΡΜΑΚΩΝ**

Μεσογείων 284, 155 62  
Χολαργός  
[www.eof.gr](http://www.eof.gr)

**Διεύθυνση** : Ελέγχου Παραγωγής  
& Κυκλοφορίας Προϊόντων  
**Τμήμα** : Επιθεωρήσεων  
**Πληροφορίες:** Δ. Δήμας  
**Τηλέφωνο** : 210 6507373  
**Fax** : 210 6549591

Χολαργός: 8-8-07  
Αρ. Πρωτ.: 48099

✓ **ΠΡΟΣ: BOEHRINGER INGELHEIM  
ΕΛΛΑΣ Α.Ε.**  
5<sup>ο</sup> χλμ. Παιανίας-Μαρκοπούλου  
194 00, Κορωπί

**Θέμα : Άδεια Δυνατότητας Παραγωγής**

Κύριοι,

Σας διαβιβάζουμε Άδεια Δυνατότητας Παραγωγής σύμφωνα με το Κοινοτικό Πρότυπο (Αριθμός Αδείας Παραγωγής 0000000003/07/2) στα Αγγλικά

**Η ΑΝΑΠΛΗΡΩΤΡΙΑ  
ΔΙΕΥΘΥΝΤΡΙΑ ΕΠΚΠ**

**Συνημμένη:**

Η Άδεια Δυνατότητας Παραγωγής ( 7 σελίδες)

**ΕΣΩΤ. ΔΙΑΝΟΜΗ**

Τμήμα Επιθεωρήσεων

**Α. ΚΥΡΙΑΚΟΥ**



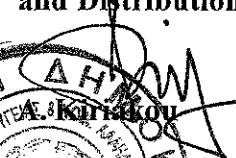

ΘΕΩΡΗΘΗΚΕ ΓΙΑ ΤΗΝ ΑΚΡΙΒΕΙΑ  
Ο ΠΡΟΪΣΤΑΜΕΝΟΣ  
ΓΕΝΙΚΗΣ ΓΡΑΜΜΑΤΕΙΑΣ  
και α.α.

Ηλ. Τριανταφυλλόπουλος



MINISTRY OF HEALTH AND SOCIAL SOLIDARITY  
NATIONAL ORGANIZATION FOR MEDICINES  
DIVISION OF PRODUCTION AND DISTRIBUTION CONTROL  
DEPARTMENT OF INSPECTION

COMMUNITY FORMAT FOR MANUFACTURER'S AUTHORISATION

1	Authorisation number	000000003/07/2
2	Name of authorisation holder	BOEHRINGER INGELHEIM ELLAS A.E.
3	Address(es) of manufacturing site(s)	5 <sup>th</sup> km Paiania – Markopoulo 194 00 Koropi Greece
4	Legally registered address of authorisation holder	Ellinikou 2 167 77, Elliniko Attiki, Greece
5	Scope of authorisation and dosage forms	ANNEX 1
6	Legal basis of authorisation	Law 1316/83, article 3, paragraph d Ministerial Decision ΔΥΤ3(α)/83657/24.1.06, article 54
7	Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	Deputy Head of the Production and Distribution Control Division
8	Signature	
9	Date	
10	Annexes attached	Annex 1, 3, 5, 6 and National Annex

**SCOPE OF AUTHORISATION**

ANNEX 1

Name and address of the site:

**BOEHRINGER INGELHEIM ELLAS A.E.**5<sup>th</sup> km Paiania – Markopoulo

194 00 Koropi

Greece

<input checked="" type="checkbox"/>	<b>Human Medicinal Products</b>
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**AUTHORISED OPERATIONS**

<input checked="" type="checkbox"/>	<b>Manufacturing Operations (according to part 1)</b>
<input checked="" type="checkbox"/>	<b>Importation of Medicinal Products (according to part 2)</b>

<b>Part 1 - MANUFACTURING OPERATIONS</b>	
<b>1.2</b>	<b>Non-sterile products</b>
	<i>1.2.1 Non-sterile products (list of dosage forms)</i> 1.2.1.6 Liquids for internal use 1.2.1.13 Tablets
<b>1.5.</b>	<b>Packaging only</b>
	<i>1.5.1 Primary packing</i> 1.5.1.1 Capsules, hard shell 1.5.1.17 Other non-sterile medicinal products: Herbal products (Capsules, soft shell)
	<i>1.5.2 Secondary packing</i>



<b>Part 2 - IMPORTATION OF MEDICINAL PRODUCTS</b>	
<b>2.1</b>	<b>Quality control testing of imported medicinal products</b>
	2.1.2 Microbiological: non-sterility 2.1.3 Chemical/Physical
<b>2.2</b>	<b>Batch certification of imported medicinal products</b>
	2.2.2 <i>Non-sterile products</i>

**Address(es) of Contract  
Manufacturing Sites**

**- FAMAR S.A.  
Agiou Dimitriou 63  
174 56, Alimos  
Attiki, Greece**

**- FAMAR S.A.  
Anthousas Avenue, 7  
153 44, Anthousa  
Attiki, Greece**



**ANNEX 5**

**Name(s) of Qualified  
Person(s)**

**- SOFRA PINELOPI  
Chemist**

**- MAZONAKIS NIKOLAOS  
Chemist**



**ANNEX 6**

**Name(s) of person(s)  
responsible for quality  
control**

**SOFRA PINELOPI  
Chemist**

**Name(s) of person(s)  
responsible for production**

**PITSOS CHARALAMBOS  
Chemist**



<b>NATIONAL ANNEX</b>
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<b>MANUFACTURING ACTIVITIES</b>
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<b>HUMAN MEDICINAL PRODUCTS</b>
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<b><u>NON-STERILE PRODUCTS</u></b>
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Liquids for internal use: syrups, suspensions, oral drops, elixirs  
Tablets: coated, sugar coated, sustained release

**Packaging only:**

**Primary packaging:**

Capsules, hard shell

**Secondary packaging**

Aerosol for inhalation (standard dose)

Nasal sprays (standard dose)

Solution for inhalation

**Herbal medicinal products:**

Primary and secondary packaging: Capsules, soft shell

<b>FOOD SUPPLEMENTS</b>
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Primary and secondary packaging: Capsules, soft shell

<b>IMPORTATION ACTIVITIES</b>
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<b>HUMAN MEDICINAL PRODUCTS</b>
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<b><u>NON-STERILE PRODUCTS</u></b>
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Tablets: film coated, sugar coated, enteric sugar coated, controlled release, prolonged release

Capsules: Soft shell, controlled release

Syrups, suspensions, oral drops

Nasal solutions

Aerosol for inhalation

Solution for inhalation

Ointments, gels

Granules for oral solution (single dose)

Powder for inhalation, capsule hard shell and HandiHaler device