



MINISTRY OF HEALTH
NATIONAL AGENCY FOR MEDICINES
AND MEDICAL DEVICES
48, Av. Sănătescu St., 1st District
011478 Bucharest
Tel.: +40-21.317.11.02
Fax: +40-21.316.34.97

INDEPENDENT CONTROL UNIT AUTHORIZATION

1. Authorization number: **17L**
2. Denomination of the authorization holder: **MEDICINE QUALITY CONTROL LABORATORY of S.C. SARA PHARM SOLUTIONS S.R.L.**
3. Address of the control conduct site:
 - 266-268, Calea Rahovei, block 3, underground, Annexes A-B, poles 17 1/2-18, room 36, 5th District, Bucharest, zip code 050897
 - 266-268, Calea Rahovei, block 61, 3rd floor, Annexes A-B, poles 19-20, room 17, 5th District, Bucharest, zip code 050897
4. Head office of the authorization holder: **S.C. SARA PHARM SOLUTIONS S.R.L.**, 266-268, Calea Rahovei, block 61, 3rd floor, Annexes A-B, poles 19-20, room 17, 5th District, Bucharest, zip code 050897
5. Scope of authorization:
Appendix 1 to the independent control unit authorization
6. Legal bases of the authorization: Law no. 95/2006 on the reform in the field of health, Title XVII, Medicine, with the subsequent amendments and integrations and the Order of the Minister of Public Health no. 873/2006 for the approval of the Regulations on the contract-based medicine quality control, concluded between the production unit and a control unit outside the place of production, in case of special tests.
7. Name of the responsible person from the National Agency for Medicines and Medical Devices (the relevant authority in Romania granting the independent control unit authorization):
Marius Savu, M.D., President
8. Signature: *illegible signature*
Round stamp: National Agency for Medicines and Medical Devices, Ministry of Health, President
9. Date: July 13th, 2015
10. Enclosed appendices:
 - appendix no. 1
 - appendix no. 3
 - appendix no. 4



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APPENDIX No. 1
to the independent control unit Authorization no. 17L

SCOPE OF AUTHORIZATION

Site denomination and address: **MEDICINE QUALITY CONTROL LABORATORY of S.C. SARA PHARM SOLUTIONS S.R.L.**, 266-268, Calea Rahovei, block 3, underground, Annexes A-B, poles 17 1/2-18, room 36, 5th District, Bucharest, zip code 050897; 266-268, Calea Rahovei, block 61, 3rd floor, Annexes A-B, poles 19-20, room 17, 5th District, Bucharest, zip code 050897

- Medicines for human use
 Raw materials
 Packaging materials

TESTING ACTIVITIES

- Physical, physicochemical testing and instrumental, pharmaco-technical analyses (according to Part 1)
 Biological, microbiological testing (according to Part 2)
 Stability testing of medicine (according to Part 3)
 Other activities (according to Part 4)

**Part I PHYSICAL, PHYSICOCHEMICAL TESTING AND INSTRUMENTAL,
PHARMACOTECHNICAL TESTS**

1.1	Physical, psychical – chemical and chemical methods
	<i>1.1.1. Physical methods</i> 1.1.1.3 Melting point 1.1.1.5 Freezing point 1.1.1.11 Other methods: X-ray diffractometry
	<i>1.1.2 Physical-chemical methods</i> 1.1.2.1 Solubility 1.1.2.2 Aspect and coloration of solutions 1.1.2.4 Loss on drying 1.1.2.6 pH determination 1.1.2.7 Water determination 1.1.2.8 Potentiometric titration 1.1.2.9 Other methods: thermogravimetry (TGA), differential scanning calorimetry (DSC)



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1.2	Instrumental methods
	1.2.2 Chromatography
	1.2.2.4 High pressure liquid chromatography

Any restrictions or remarks clarifying the domain of these testing activities: -

Part 3 STABILITY TESTING OF MEDICINES	
3.1	Stability under long term conditions
3.2	Stability under accelerated conditions

Any restrictions or remarks clarifying the domain of these testing activities: in order to test the stability of medicines, sample storage under long term / accelerated conditions in the Memmert HPP110 constant climate chamber is not performed concomitantly.

Part 4 OTHER ACTIVITIES	
4.1	Control methodology development and validation

Any restrictions or remarks clarifying the domain of these testing activities:

Name and position of the responsible person: Marius Savu, M.D., President

Signature: *illegible signature applied*

Stamp and date: July 13th, 2015

round stamp: National Agency for Medicines and Medical Devices, Ministry of Health, President



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APPENDIX No. 3
to the independent control unit authorization no. 17L

Name of the person responsible for the quality control: PhD. Chemist Ovidiu Covaci

Name and position of the responsible person: Marius Savu, M.D., President

Signature: *illegible signature applied*

Stamp and date: July 13th, 2015

*round stamp: National Agency for Medicines and
Medical Devices, Ministry of Health, President*

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APPENDIX No. 4
to the independent control unit authorization no. 17L

Date of the inspection based on which the authorization was granted: May 04th-05th, 2015

Domain covered by the last inspection:

- physical – chemical testing activities
- stability testing of medicines
- control methodology development and validation

Name and position of the responsible person: Marius Savu, M.D., President

Signature: *illegible signature applied*

Stamp and date: July 13th, 2015

*round stamp: National Agency for Medicines and
Medical Devices, Ministry of Health, President*

Subsemnata BIRGHILĂ AIDA, interpret și traducător autorizat pentru limba Engleză Italiană, în temeiul autorizației nr. 36189 din data de 24.10.2013, eliberată de Ministerul Justiției din România, certific exactitatea traducerii efectuate din limba română în limba engleză, că textul prezentat a fost tradus complet, fără omisiuni, și că, prin traducere, înscrisului nu i-au fost denaturate conținutul și sensul.

Înscrisul a cărui traducere se solicită în întregime are, în integralitatea sa, un număr de 5 pagini, poartă denumirea de *Autorizație unitate de control* a fost emis de *Ministerul Sănătății* și mi-a fost prezentat în întregime.

Traducerea înscrisului prezentat are un număr 5 pagini și a fost efectuată potrivit cererii înscrise înregistrate cu nr. 3272/23.07.2015, păstrate în arhiva subsemnatului.

S-a încasat onorariul de 30 RON, cu bon fiscal nr. 5/23.07.2015.

I, the undersigned BIRGHILĂ AIDA, certified translator and interpreter for English, Italian, based on the authorisation no. 36189 issued on 24.10.2013, by the Romanian Ministry of Justice, hereby certify the accuracy of this translation from Romanian into English, that the presented text has been completely translated, with no omission, and that, through this translation, the content and the meaning of the document have not been distorted.

The document whose translation is required in full has, in its entirety, a number of 5 pages, bears the title of *Control Unit Authorization* it has been issued by *Ministry of Health* and it has been presented to me in full.

The translation of the presented document has a number of 5 pages and it was made according to the written application registered under no 3272/23.07.2015, kept in the archive of the undersigned.

The fee of RON 30 was collected by fiscal receipt no. 5/23.07.2015.

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Nr. 5536 Data 24.07.2015

AUTHENTICATION OF THE TRANSLATOR'S SIGNATURE

No. 5536 of 24.07.2015

DIACONU CRISTINA
NOTAR PUBLIC

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