HELLENIC ACCREDITATION SYSTEM

ACCREDITATION CERTIFICATE
No. 244-8

The Hellenic Accreditation System S.A. (ESYD), as the national accreditation body of Greece in accordance with the Law 4468/2017,

ACCREDITS

the

Division of Laboratories

of the

National Organisation for Medicines

in Athens, Greece

under the terms of the ELOT EN ISO/IEC 17025:2017 Standard and the ESYD Criteria, to carry out tests, as specified in the attached Scope of the Accreditation, which may be revised by decisions of ESYD.

The initial accreditation was issued on 8 March 2006. This Certificate renews the accreditation, and it is valid until 7 March 2031, provided that the accredited body will comply with the above Standard and the ESYD Criteria.

Athens, 29 June 2026

Evangelos Apostolos Konstantinou
CEO of ESYD

ESYD is a signatory of the European co-operation for Accreditation (EA) Multilateral Agreement for the activities covered by this certificate.

HELLENIC ACCREDITATION SYSTEM

1st Annex F1A/17 to the Certificate No 244-8

SCOPE of ACCREDITATION

of the

Laboratory for Chemical Analysis of Medicines

of the

Division of Laboratories, National Organisation for Medicines

Tested materials / products	Types of test / Properties	Applied standards / Techniques
Chemical tests		
According to the monographs of current editions of European Pharmacopoeia (Ph.Eur.), Hellenic Pharmacopoeia (ΕΦ), British Pharmacopoeia (BP), United States Pharmacopoeia (USP) and approved validated methods of product files		
Pharmaceutical starting materials and pharmaceutical products	Identification and assay of active substance Test for related substances of active substance	High Performance Liquid Chromatography (HPLC) – (DAD/PDA) (MEE 9001)
	Identification and assay of active substance	Spectrophotometry UV-Vis (MEE 9003)
	Identification of active substance Test for related substances of active substance	Thin Layer Chromatography (TLC) (MEE 9005)
	Assay of active substance	Titrimetry (use of indicator) (MEE 9006)
	Potentiometric determination of pH	General method 2.2.3 Ph.Eur. of (MEE 9008)
Single-dose pharmaceutical products	Test for uniformity of content	General method 2.9.6 Ph.Eur. using High Performance Liquid Chromatography (HPLC) – (DAD/PDA)

Tested materials / products	Types of test / Properties	Applied standards / Techniques
Single-dose pharmaceutical products	Test for uniformity of dosage units	General method 2.9.40 Ph.Eur. using High Performance Liquid Chromatography (HPLC) – (DAD/PDA)
Pharmaceutical starting materials and pharmaceutical products	Semi-micro determination of water	General method 2.5.12 Ph.Eur. (MEE 9011)
Physical tests		
According to the monographs of current editions of European Pharmacopoeia (Ph.Eur.), Hellenic Pharmacopoeia (ΕΦ), British Pharmacopoeia (BP), United States Pharmacopoeia (USP) and approved validated methods of product files		
Single-dose pharmaceutical products	Test for uniformity of mass / Test for average mass	General method 2.9.5 Ph.Eur. by weighing / specification of the product dossier
Tablets and capsules	Test for dissolution	General method 2.9.3 Ph.Eur. and assay of active substance with HPLC-(UV-Vis) or Spectrophotometry UV-Vis (MEE 9002)
	Test for disintegration	General method 2.9.1 Ph.Eur. (MEE 9010)

Site of assessment: **Permanent Laboratory premises, Mesogeion 284, Holargos, Athens**
Approved signatories: **V. Violakis, E. Kyriakopoulou, E.Barmpagianni, P.Karava, A. Konstantara, K. Tsilafakis**

This scope of Accreditation replaces the previous one dated 06.03.2026.
The Accreditation Certificate No **244-8**, to ELOT EN ISO/IEC 17025:2017, is valid until 06.03.2031.

Athens, 29 June 2026

Konstantinou Evangelos Apostolos
CEO of ESYD

HELLENIC ACCREDITATION SYSTEM

2nd Annex F1B/17 to the Certificate No 244-8

SCOPE of ACCREDITATION

of the

Microbiological Laboratory

of the

Division of Laboratories, National Organization for Medicines

Tested materials / products	Types of test / Properties	Applied standards / Techniques
Microbiological tests		
Sterile pharmaceutical products and medical devices	Sterility tests	General methods Ph.Eur. 2.6.1, USP/NF <71> (MEE 7001)
	Test for bacterial endotoxins	General methods Ph.Eur. 2.6.14, Method A (gel-clot: limit test) and Method B (gel-clot: semi-quantitative test) USP/NF <85> and <161> (MEE 7006)
Non sterile pharmaceutical products and substances for pharmaceutical use	Test for microbial quality	General methods Ph.Eur. 2.6.12 and 2.6.13 (MEE 7002)
Foodstuffs intended for particular nutrition	Detection of *Salmonella* spp.	EN ISO 6579-1:2017/ Amd 1:2020 excluding Annex D (serovars *Typhi* and *Paratyphi*)
	Detection of *Cronobacter* spp .	EN ISO 22964:2017

Site of asseseement: **Permanent Laboratory premises, Mesogeion 284, Holargos, Athens**
Approved signatories: **V. Violakis, G. Bouziou, P. Ragias, I-A. Nikolaou**

This scope of Accreditation replaces the previous one dated 06.03.2026.
The Accreditation Certificate No **244-8**, to ELOT EN ISO/IEC 17025:2017, is valid until 06.03.2031.

Athens, 29 June 2026

Konstantinou Evangelos Apostolos
CEO of ESYD

HELLENIC ACCREDITATION SYSTEM

4th Annex F1D/17 to the Certificate No 244-8

SCOPE of ACCREDITATION

of the

Laboratory for Chemical Analysis of Feeding Stuffs, Dietary Products, Herbal Medicines

of the

Division of Laboratories, National Organization for Medicines

Tested materials / products	Types of test / Properties	Applied standards / Techniques
Chemical tests		
According to the monographs of current editions of European Pharmacopoeia (Ph.Eur.), Hellenic Pharmacopoeia (ΕΦ), British Pharmacopoeia (BP) and United States Pharmacopoeia (USP) and approved validated methods of product files		
Pharmaceutical starting materials used in veterinary medicinal products and veterinary medicinal products	Identification and Assay of active substance	Spectrophotometry UV-Vis (MEE 9003)
	Assay of active substance	Titrimetry (use of indicator) (MEE 9006)
	Identification and Assay of active substance	High Performance Liquid Chromatography (HPLC) – (DAD/PDA)
Physical tests		
According to the monographs of current editions of European Pharmacopoeia (Ph.Eur.), Hellenic Pharmacopoeia (ΕΦ), British Pharmacopoeia (BP) and United States Pharmacopoeia (USP) and approved validated methods of product files		
Single-dose veterinary medicinal products	Test of uniformity of mass	General method 2.9.5 Ph.Eur. by weighing

Site of assessment: **Permanent Laboratory premises, Mesogeion 284, Holargos, ATHENS**
Approved signatories: **V. Violakis, K.Fakinou.**

This scope of Accreditation replaces the previous one dated 06.03.2026.
The Accreditation Certificate No **244-8**, to ELOT EN ISO/IEC 17025:2017, is valid until 06.03.2031.

Athens, 29 June 2026

Konstantinou Evangelos Apostolos
CEO of ESYD

HELLENIC ACCREDITATION SYSTEM

5th Annex F1E/17 to the Certificate No 244-8

SCOPE of ACCREDITATION

of the

Biological and Toxicological Laboratory

of the

Division of Laboratories, National Organisation for Medicines

Tested materials / products	Types of test / Properties	Applied standards / Techniques
Chemical tests		
According to the monographs of current editions of European Pharmacopoeia (Ph.Eur.), Hellenic Pharmacopoeia (ΕΦ), British Pharmacopoeia (BP), United States Pharmacopoeia (USP)		
Pharmaceutical starting materials and pharmaceutical products	Identification and assay of active substance	Spectrophotometry UV-Vis (MEE 9003)
	Test for related substances of active substance	Thin Layer Chromatography (TLC) (MEE 9005)
Physical tests		
According to the monographs of current editions of European Pharmacopoeia (Ph.Eur.), Hellenic Pharmacopoeia (ΕΦ), British Pharmacopoeia (BP), United States Pharmacopoeia (USP)		
Single-dose pharmaceutical products	Test for uniformity of mass / Test for average mass	General method 2.9.5 Ph.Eur. by weighing / specification of the product dossier
Tablets and capsules	Test for dissolution	General method 2.9.3 Ph.Eur. and assay of active substance with HPLC-(DAD/PDA) or Spectrophotometry UV-Vis (MEE 9002)
Tablets and capsules	Test for disintegration	General method 2.9.1 Ph.Eur (MEE 9010)

Site of assessment: **Permanent Laboratory premises, Mesogeion 284, Holargos, Athens**
Approved signatories**: V. Violakis, G.Volikakis. P. Nikolaou.**

This scope of Accreditation replaces the previous one dated 06.03.2026.
The Accreditation Certificate No **244-8**, to ELOT EN ISO/IEC 17025:2017, is valid until 06.03.2031.

Athens, 29 June 2026

Konstantinou Evangelos Apostolos
CEO of ESYD

HELLENIC ACCREDITATION SYSTEM

6th Annex F1F/17 to the Certificate No **244**-8

SCOPE of ACCREDITATION

of the

Laboratory for Chemical Analysis of Cosmetics and Other Products

of the

Division of Laboratories, National Organisation for Medicines

Tested materials / products	Types of test / Properties	Applied standards / Techniques
Chemical tests		
Cosmetic products	Identification and determination of 2-phenoxy-ethanol, methyl-, propyl-, and butyl-4-hydroxybenzoate (parabens)	Annex /7th Commision directive 96/45/EC High performance liquid chromatographic (HPLC)-(DAD/PDA) (MEE 6005)
	Identification and determination of benzoic acid, 4-hydroxybenzoic acid, salicylic acid, sorbic acid	Annex/ 6th directive 95/32 EC High performance liquid chromatographic (HPLC)-(DAD/PDA) (MEE 6006)
Physical tests		
Medical gloves for single use	Requirements and testing for freedom from holes	ELOT EN 455-1:2020+A2:2024 (MEE 6011)
Natural rubber latex male condoms	Determination of bursting volume and pressure	ISO 4074:2026 (MEE 6003)

Site of assessment: **Permanent Laboratory premises, Mesogeion 284, Holargos, Athens**
Approved signatories: **V. Violakis, K. Venetsanou.**

This scope of Accreditation replaces the previous one dated 06.03.2026.
The Accreditation Certificate No **244**-8, to ELOT EN ISO/IEC 17025:2017, is valid until 06.03.2031.

Athens, 29 June 2026

Konstantinou Evangelos Apostolos
CEO of ESYD