

Hellenic Accreditation System



1st Annex F1A/9 to the Certificate No 244-4

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 (EP), 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) – (UV-Vis) (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 EP of (MEE 9008)

Tested materials/products	Types of test/Properties	Applied standards/Techniques
Single-dose pharmaceutical products	Test for uniformity of content	General method 2.9.6 EP using high performance liquid chromatography (HPLC) – (UV-Vis) (MEE 9007)
	Semi-micro determination of water	General method 2.5.12 EP (MEE 9011)
Physical tests		
According to the monographs of current editions of European Pharmacopoeia (EP), Hellenic Pharmacopoeia (EΦ), 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 EP by weighing (MEE 9009) / specification of the product dossier
Tablets and capsules	Test for dissolution	General method 2.9.3 EP and assay of active substance with HPLC-(UV-Vis) or Spectrophotometry UV-Vis (MEE 9002)
	Test for disintegration	General method 2.9.1 EP (MEE 9010)

Site of assessment : **Permanent Laboratory premises, Mesogeion 284, Holargos, Athens**

Approved signatories : **V. Violakis, E. Kyriakopoulou.**

This scope of Accreditation replaces the previous one dated 21.06.2012.

The Accreditation Certificate No **244-4**, to ELOT EN ISO/IEC 17025:2005, is valid until 7.03.2018.

Athens, 9th April 2014

Ioannis Sitaras
Director of the Laboratories Accreditation Division

Hellenic Accreditation System



2nd Annex F1B/9 to the Certificate No 244-4

SCOPE of ACCREDITATION

of the

Microbiological Laboratory

of the

Division of Laboratories, National Organisation for Medicines

Tested materials/products	Types of test/Properties	Applied standards/Techniques
Microbiological tests		
According to the monographs of current editions of European Pharmacopoeia (EP), Hellenic Pharmacopoeia (ΕΦ), British Pharmacopoeia (BP) and United States Pharmacopoeia (USP)		
Sterile pharmaceutical products and medical devices	Sterility tests	General method 2.6.1 EP (MEE 7001)
	Test for bacterial endotoxins	General methods 2.6.14 EP, Method A (gel-clot: limit test) and Method B (gel-clot: semi-quantitative (MEE 7006)
Non sterile pharmaceutical products and substances for pharmaceutical use	Test for microbial quality	General methods 2.6.12 and 2.6.13 EP (MEE 7002)
Foodstuffs intended for particular nutritional uses	Detection of Salmonella spp	ISO 6579:2002
	Detection of Enterobacter sakazakii	ISO/TS 22964:2006

Site of assessment : **Permanent Laboratory premises, Mesogeion 284, Holargos, Athens**

Approved signatories : **S. Gazi, V. Birtsas.**

This scope of Accreditation replaces the previous one dated 21.06.2012.
The Accreditation Certificate No **244-3**, to ELOT EN ISO/IEC 17025:2005, is valid until 7.03.2018.

Athens, 9th April 2014

Ioannis Sitaras
Director of the Laboratories Accreditation Division

Hellenic Accreditation System



3rd Annex F1C/9 to the Certificate No 244-4

SCOPE of ACCREDITATION

of the
Section for Pharmacopoeia and Other Laboratory Standards
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 (EP), Hellenic Pharmacopoeia (ΕΦ), British Pharmacopoeia (BP) and United States Pharmacopoeia (USP)		
Pharmaceutical starting materials and pharmaceutical 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) – (UV-Vis) (MEE 9001)

Site of assessment : **Permanent Laboratory premises, Mesogeion 284, Holargos, Athens**

Approved signatories : **E. Georgiadou, A.Makritis**

This scope of Accreditation replaces the previous one dated 21.06.2012.

The Accreditation Certificate No **244-4** , to ELOT EN ISO/IEC 17025:2005, has been extended up to 7.03.2018.

Athens, 9th April 2014

Ioannis Sitaras

Director of the Laboratories Accreditation Division

Hellenic Accreditation System



4th Annex F1D/9 to the Certificate No 244-4

SCOPE of ACCREDITATION

of the

Laboratory for Chemical Analysis of Feeding Stuffs, Dietary Products, Herbal 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 (EP), Hellenic Pharmacopoeia (ΕΦ), British Pharmacopoeia (BP) and United States Pharmacopoeia (USP) and approved validated methods of product files		
Veterinary pharmaceutical starting materials and formulations	Assay of active substance	Spectrophotometry UV-Vis (MEE 9003)
	Assay of active substance	Titrimetry (use of indicator) (MEE 9006)
	Assay of active substance	High Performance Liquid Chromatography (HPLC) – (UV-Vis)
Physical tests		
According to the monographs of current editions of European Pharmacopoeia (EP), Hellenic Pharmacopoeia (ΕΦ), British Pharmacopoeia (BP) and United States Pharmacopoeia (USP) and approved validated methods of product files		
Single-dose formulations	Test of uniformity of mass	General method 2.9.5 EP by weighing (MEE 9009)

Site of assessment : **Permanent Laboratory premises, Mesogeion 284, Holargos, ATHENS**

Approved signatories : **A. Tsigouri, K.Fakinou.**

This scope of Accreditation replaces the previous one dated 21.06.2012.

The Accreditation Certificate No **244-4**, to ELOT EN ISO/IEC 17025:2005, is valid until 7.03.2018.

Athens, 9th April 2014

Ioannis Sitaras

Director of the Laboratories Accreditation Division

Hellenic Accreditation System



5th Annex F1E/9 to the Certificate No 244-4

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 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 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 EP by weighing (MEE 9009) / specification of the product dossier
Tablets and capsules	Test for dissolution	General method 2.9.3 EP and assay of active substance with HPLC-(UV-Vis) or Spectrophotometry UV-Vis (MEE 9002)
Tablets and capsules	Test for disintegration	General method 2.9.1 EP (MEE 9010)

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

This scope of Accreditation replaces the previous one dated 21.06.2012.
The Accreditation Certificate No **244-4**, to ELOT EN ISO/IEC 17025:2005, is valid until 7.03.2018.

Athens, 9th April 2014

Ioannis Sitaras
Director of the Laboratories Accreditation Division

Hellenic Accreditation System



6th Annex F1F/9 to the Certificate No 244-4

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	Determination of 2-phenoxy-ethanol, methyl-, propyl-, and butyl-4-hydroxybenzoate (parabens)	High performance liquid chromatographic (HPLC) method based on directive 96/45/EC (MEE-6005)
	Physical tests	
Medical gloves for single use	Requirements and testing for freedom from holes	ELOT EN 455-1:2000

Site of assessment : **Permanent Laboratory premises, Mesogeion 284, Holargos, Athens**

Approved signatories : **S. Gazi.**

This scope of Accreditation replaces the previous one dated 21.06.2012.

The Accreditation Certificate No **244-4**, to ELOT EN ISO/IEC 17025:2005, is valid until 7.03.2014.

Athens, 9th April 2014

Ioannis Sitaras

Director of the Laboratories Accreditation Division