



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2005

ELEMENT MATERIALS TECHNOLOGY PHARMA US LLC.
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CHEMICAL

Valid To: September 30, 2020

Certificate Number: 3248.01

In recognition of the successful completion of the A2LA evaluation process (including an assessment of the laboratory's compliance with the A2LA Food Testing Program Requirements, containing the 2015 "AOAC *International Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food, Dietary Supplements, and Pharmaceuticals*"), accreditation is granted to this laboratory to perform the following tests on drugs, excipients, raw materials, dietary supplements, consumer products, textiles, polymers, foods, feeds, and biological materials using the following chemical tests identified below:

<u>Test(s) / Technology</u>	<u>Test Method(s)</u>
Acid Value	EP 2.5.1; USP <401>
Chloride and Sulfate	EP 2.4.4, 2.4.13; USP <221>
Chromatography (GC)	USP <621>
Chromatography (GC/MS)	EP 2.2.43; USP <621>, <736>
Chromatography (HPLC)	EP 2.2.29; USP <621>
Chromatography (IC)	EP 2.2.29; USP <621>
Chromatography (LCMS)	EP 2.2.43; USP <621>, <736>
Ethylene Dioxide and Dioxane	EP 2.2.28, 2.4.25; USP <228>
Fluoride by Ion-Selective Electrode	Exova SOP 8300
Hydroxyl Value	EP 2.5.3; USP <401>
Identification by TLC	EP 2.2.27; USP <201>
Identification Tests, General	EP 2.3; USP <191>
Loss on Drying	EP 2.2.32; USP <731>
Loss on Ignition	USP <733>

Test(s) / Technology	Test Method(s)
Melting Range or Temperature	EP 2.2.60; USP <741>
Metals by ICP-MS Al, Sb, As, Ba, Be, B, Cd, Ca, Cr, Co, Cu, Ir, Au, Fe, Pb, Li, Mg, Mn, Mo, Hg, Ni, Pd, Pt, K, Rh, Rb, Ru, Se, Si, Ag, Na, Sr, Tl, Sn, Ti, W, U, V, Zn	ASTME 1613-94, F963; EPA 200.8, 6020; EP 2.2.58, 2.4.20; Exova SOP 7040; USP <233>, <730>
Metals by ICP-OES Al, Sb, As, Ba, Be, B, Cd, Ca, Cr, Co, Cu, Au, Fe, Pb, Li, Mg, Mn, Mo, Hg, Ni, K, Se, Si, Ag, Na, Sr, Tl, Sn, Ti, U, V, Zn	ASTME 1613-94; EPA 6010C; EP 2.2.57, 2.4.20; Exova SOP 7191; USP <233>, <730>
Method Validation and Verification	ICH Q2; USP <1225>, <1226>
Nuclear Magnetic Resonance	EP 2.2.33; USP <761>
Optical Rotation	EP 2.2.7; USP <781S>
Ordinary Impurities	USP <466>
Peroxide Value	EP 2.5.5; USP <401>
pH	EP 2.2.3; USP <791>
Residual Solvents (GC/GC-MS)	EP 2.4.24, 2.4.28; USP <467>
Residue on Ignition Limit Test	EP 2.4.14; USP <281>
Saponification Value	EP 2.5.6; USP <401>
Specific Gravity	USP <841>
Spectrophotometric ID – FTIR	EP 2.2.24; USP <197>, <851>, <854>
Spectrophotometric ID – UV-Vis	EP 2.2.25; USP <197>, <851>, <857>
Titrimetry	EP 2.2.20; USP <541>
Viscosity	EP 2.2.8, 2.2.9, 2.2.10; USP <911>, <912>
Water by Karl-Fischer	EP 2.5.12; USP <921>

¹There are circumstances in which this laboratory must perform testing activities not covered on their fixed scope of accreditation, such as for additional matrices (flexibility concerning sample type) or additional parameters (flexibility concerning analytes). The following activities are covered under A2LA's Flexible Scope policy for analysis in drugs, excipients, raw materials, dietary supplements, consumer products, textiles, polymers, foods, feeds, and biological materials:

Analysis of Metals in drugs, excipients, raw materials, dietary supplements, consumer products, textiles, polymers, foods, feeds, and biological materials using ICP with the following detection systems:

- Mass Spectrometry (MS)
- Optical Emission Spectroscopy (OES)

Analysis of Organic Compounds in drugs, excipients, raw materials, dietary supplements, consumer products, textiles, polymers, foods, feeds, and biological materials using Gas Chromatography with the following detection systems:

- Flame Ionization Detector (FID)
- Nitrogen-Phosphorus Detector (NPD, “TSD”)
- Thermal Conductivity Detector (TCD)
- Mass Spectrometry (MS)

Analysis of Organic Compounds in drugs, excipients, raw materials, dietary supplements, consumer products, textiles, polymers, foods, feeds, and biological materials using Liquid Chromatography with the following detection systems:

- Ultraviolet Detection (UV, DAD)
- Pulsed Amperometric Detection (PAD)
- Refractive Index Detection (RI)
- Mass Spectrometry (MS Quadrupole, MS-MS Triple Quadrupole)

¹ This portion of the scope meets the A2LA P1 12 Flexible Scope Policy.



Accredited Laboratory

A2LA has accredited

ELEMENT MATERIALS TECHNOLOGY PHARMA US LLC.

Santa Fe Springs, CA

for technical competence in the field of

Chemical Testing

This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2005 *General requirements for the competence of testing and calibration laboratories*. This laboratory also meets the requirements of A2LA's *R204 - Specific Requirements - Food and Pharmaceutical Testing Laboratory Accreditation Program*. This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system (*refer to joint ISO-ILAC-IAF Communiqué dated April 2017*).



Presented this 10th day of September 2018.

A blue ink signature of the Vice President of Accreditation Services.

Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 3248.01
Valid to September 30, 2020
Revised August 28, 2020

For the tests to which this accreditation applies, please refer to the laboratory's Chemical Scope of Accreditation.