SCOPE OF ACCREDITATION TO ISO/IEC 17025:2005

ELEMENT MATERIALS TECHNOLOGY PHARMA US LLC.
9240 Santa Fe Springs Rd.
Santa Fe Springs, CA 90670
Jihye Jang-Lee Phone: (562) 948-2225 x 70300

CHEMICAL

Valid To: March 31, 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:

Test(s) / Technology	**Test Method(s)**
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>

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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	ASTM E 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	ASTM E 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>

[1]*There 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 P112 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.

Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 3248.01
Valid to March 31, 2020
Revised May 8, 2019

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

SCOPE OF ACCREDITATION TO ISO/IEC 17025:2005

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ENVIRONMENTAL

Valid To: March 31, 2020 Certificate Number: 3248.02

In recognition of the successful completion of the A2LA evaluation process, (including an assessment of the laboratory's compliance with ISO/IEC 17025:2005 and the 2009 TNI Environmental Testing Laboratory Standard) accreditation is granted to this laboratory to perform recognized EPA methods using the following testing technologies and in the analyte categories identified below:

Testing Technologies: Gas Chromatography-Mass Spectrometry, High Performance Liquid Chromatography, and Ion Chromatography

Parameter/Analyte	Potable Water	Non-Potable Water	Hazardous Waste	
			Aqueous	Solid
Carbonyl Compounds				
Acetaldehyde	EPA 8315A MOD – Exova SOP 4010	EPA 8315A MOD – Exova SOP 4010	EPA 8315A MOD – Exova SOP 4010	EPA 8315A MOD – Exova SOP 4010
Formaldehyde	EPA 8315A MOD – Exova SOP 4010	EPA 8315A MOD – Exova SOP 4010	EPA 8315A MOD – Exova SOP 4010	EPA 8315A MOD – Exova SOP 4010
Metals				
Chromium (VI)	EPA 218.6	EPA 218.6	EPA 3060A/7199	EPA 3060A/7199
Purgeable Organics				
Ethyl Acetate	----------	EPA 1666	----------	----------
Isobutyraldehyde	----------	EPA 1666	----------	----------
Isopropyl Acetate	----------	EPA 1666	----------	----------
Methyl Formate	----------	EPA 1666	----------	----------
n-Amyl Acetate	----------	EPA 1666	----------	----------
n-Butyl Acetate	----------	EPA 1666	----------	----------
n-Heptane	----------	EPA 1666	----------	----------
n-Hexane	----------	EPA 1666	----------	----------
Tetrahydrofuran	----------	EPA 1666	----------	----------

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Parameter/Analyte	Potable Water	Non-Potable Water	Hazardous Waste	
			Aqueous	Solid
Xylenes	----------	EPA 1666	----------	----------

Accredited Laboratory

A2LA has accredited

ELEMENT MATERIALS TECHNOLOGY PHARMA US LLC.

Santa Fe Springs, CA

for technical competence in the field of

Environmental 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 the 2009 TNI Environmental Testing Laboratory Accreditation Standard in accordance with the A2LA *R206 – Specific Requirements – Environmental 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.

Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 3248.02
Valid to March 31, 2020
Revised May 8, 2019

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

Joint ILAC-ISO Communiqué on the recognition of ISO/IEC 17025 during a Three-Year Transition

Laboratories wishing to demonstrate their technical competence can do so via conformity with the international standard ISO/IEC 17025 '*General requirements for the competence of testing and calibration laboratories*'. Conformity with this standard also means that the laboratory generally operates a management system in accordance with the principles of ISO 9001.

In 2017, ISO published a revision to ISO/IEC 17025 (previously published in 2005) to ensure that requirements continue to meet the demands of the modern market place. As a consequence, it has been agreed that laboratories that demonstrate conformity through third-party accreditation will need to transition their processes to the new version within a defined timeframe. ILAC, in consultation with ISO, agreed that a three year period from the date of publication shall be allowed for this transition.

During this transition period, it is important to note that both ISO/IEC 17025:2005 and ISO/IEC 17025:2017 are equally valid and applicable. Formal accreditation to either standard granted by an accreditation body that is a signatory to the ILAC Arrangement should be recognised by the market place, and it is strongly recommended that specifiers equally recognise both versions until after the 3-year transition period has closed.

ILAC Chair

ISO/CASCO Chair

November 2017