Analytical Testing for Compounded BHRT Products

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Clinical Utility of Compounded BHRT
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ARL BIO PHARMA

Thomas C. Kupiec, PhD

- Independent Pharmaceutical Scientific and Technical Adviser
- President and CEO of ARL Bio Pharma, DNA Solutions, and the Kupiec Group
- Pharmaceutical and Toxicology Background in Chemical and Scientific Analysis for local and federal government for over 25 years
- Pharmaceutical and Chemical Testing for pharmaceutical companies, hospitals, raw material suppliers, pharmacies, and academia for over 20 years

Thomas C. Kupiec, PhD

- Scientific Consultation and Expert Witness for forensic toxicology and pharmaceutical sciences including litigation, patent infringement and medication errors
- Testified in over 100 cases in state and federal court involving civil and criminal, for prosecution and defense
- PhD in Pharmaceutical Sciences
- Graduate faculty member at the OU Health Sciences Center
- Published articles and abstracts in a variety of fields including pharmaceutical sciences, forensic sciences, and pharmacogenomics

Routine Analytical Testing of cBHRT

- Compounded BHRT are routinely analyzed by laboratories across the US without difficulty, using HPLC (High Performance Liquid Chromatography)

- Analytical testing criteria demonstrate not only that compounded BHRT products can be tested, but are frequently tested and there is data to show that it is not too difficult to compound, based upon potency results.

Compounded BHRT Preparations

- Of the 61,000 potency tests performed over the last two years, 22% were hormones and on average passed 93% of the time.

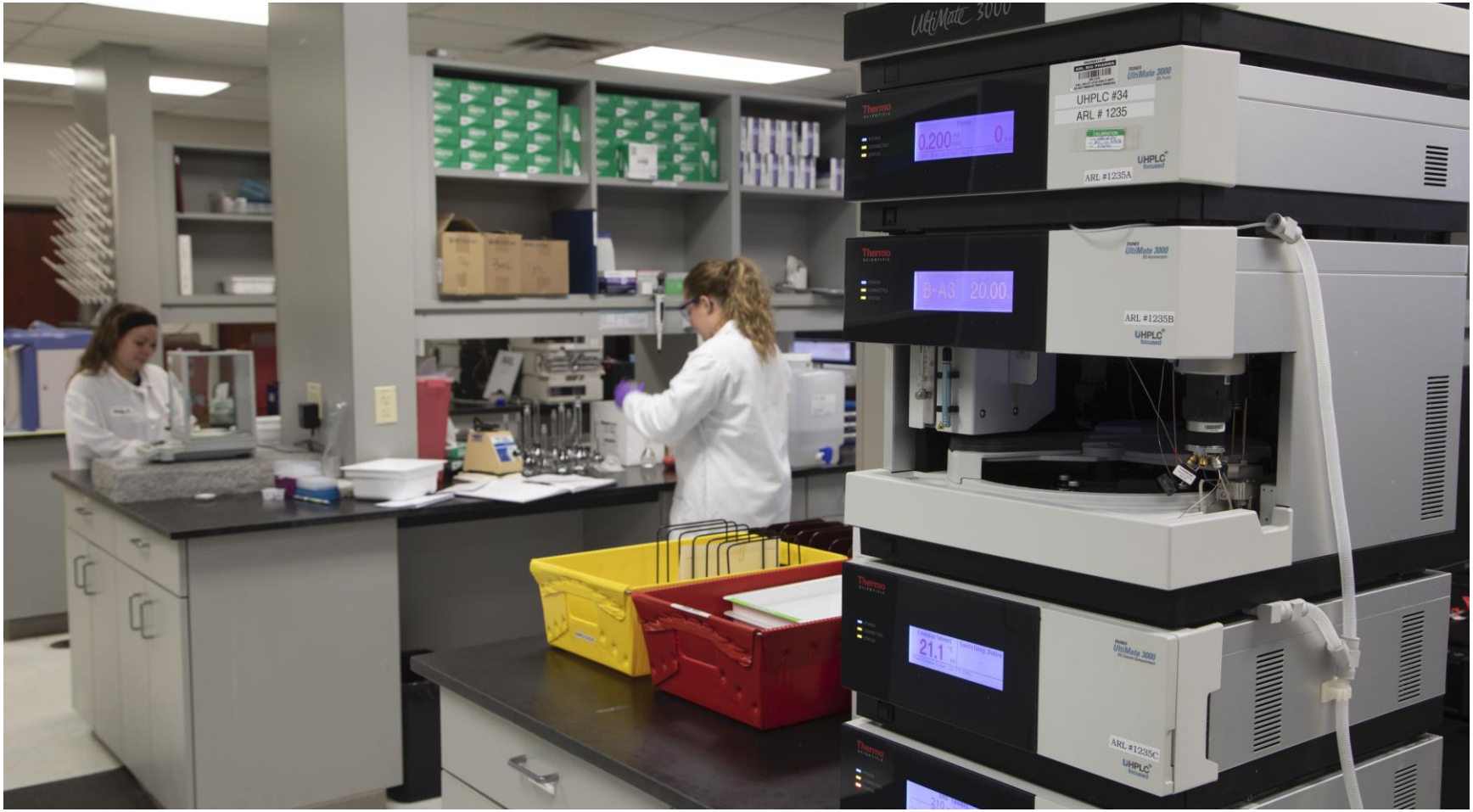
- Also, hormones are 57% less likely to be out of specification (OOS) than non-hormone formulations.

Compounded BHRT Preparations

Compounded Hormones Assays by HPLC

- 7-Keto DHEA
- DHEA
- Estradiol
- Estradiol Valerate
- Estradiol Cypionate
- Estradiol Benzoate
- Ethinyl Estradiol
- Estriol
- Estrone
- Progesterone
- Testosterone
- Testosterone Cypionate
- Testosterone Enanthate
- Testosterone Proprionate

HPLC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B-A3 20.00
21.1

BHRT Compounded Preparations

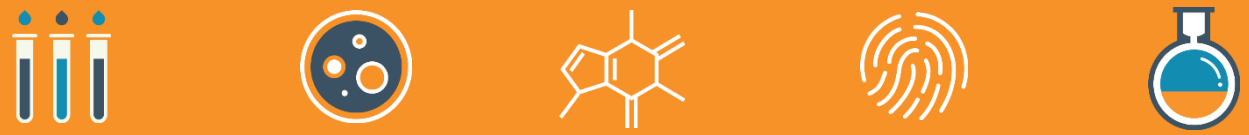
- BHRT Compounded Preparations (Estrogen, Progesterone, Testosterone) are **approximately 50% less likely to be Out of Specification for potency** than all other compounded preparations.

- Data was collected over a two-year period with over 61,000 potency tests from over 1,300 compounding pharmacies.

Drug Substance (API) versus Finished Drug Product Testing

API CHARACTERIZATION-TESTING	PRODUCT RELEASE TESTING
Infrared Spectroscopy	HPLC
Nuclear Magnetic Resonance	GC
Mass Spectroscopy	Dissolution
HPLC	Disintegration
GC	pH
Thermal Analysis (DSC, DTA, TGA)	Ion Chromatography
pH	Sterility
Heavy Metals	Pyrogenicity
Endotoxins	Titrimetry
Titrimetry	Particulate Matter
Loss on Drying, Loss on Ignition	Thermal Analysis (DSC, DTA, TGA)
Florescence Spectroscopy	
X-Ray Spectroscopy	
Optical Rotation	
Polarography	
Atomic Absorption Spectroscopy	
Density	
Others	Others

Summarized from USP 41, Pages 5866-5913.



API vs Product

Drug Substance
Active Pharmaceutical Ingredient

API vs Product

Drug Substance
Active Pharmaceutical Ingredient

Compounded BHRT Preparations

- The success rate for compounded BHRT samples is approximately 93%, compared to 89% for other compounded drugs tested in the same time period.

- At the minimum, these results indicated that compounded BHRT are prepared as successfully as other compounded drugs

Summary

- Compounded BHRT preparations **do not present demonstrably difficulties** for compounding

- Analytical testing criteria demonstrates not only that compounded BHRT can be tested, but are frequently tested and there is data to prove they are not “too difficult to compound”

- At the minimum, these results indicated that compounded BHRT are prepared as successfully as other compounded drugs

Contact Information

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