**Quality Assurance of Compounded Pharmaceutical Formulations in Western Australian Pharmacies**

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**Background and Aims**

Compounded pharmaceutical formulations play a vital role in individualized patient care by providing customized medications that are not commercially available. Ensuring the safety and efficacy of these formulations is crucial to safeguard patient health and maintain confidence in pharmacy services. Medicine compounding services in Western Australia (WA) are largely self-regulated and, increasingly, pharmacies are relying on regular audits of staff competencies and the quality of compounded medicines for quality assurance. In response to requests for a WA-based analysis lab, we have set up an analytical laboratory focused on drug content and stability study.

**Methods**

In our analysis lab, we developed analytical techniques in accordance with guidelines established by the US Food and Drug Administration (FDA)¹,² and the Australian Therapeutic Goods Administration (TGA)³,⁴. High-Performance Liquid Chromatography (HPLC) was employed as the primary analytical tool for quantifying active pharmaceutical ingredients and assessing product quality, thereby supporting quality assurance (QA) in the preparation of compounded medications across WA pharmacies.

**Results**

Over the past five months, we conducted a comprehensive analysis of various compounded formulation types, including capsules, troches, creams, suspensions, and solutions. These formulations were prepared under pharmacist supervision using six different active pharmaceutical ingredients: estriol, estradiol, melatonin, omeprazole, progesterone, and testosterone. All compounded formulations tested were found to be within the acceptable potency range defined by the British Pharmacopoeia (BP), which sets limits of 95% to 105% of the labelled claim⁵.

**Discussion**

The analytical services we provide are an integral part of broader quality assurance (QA) practices in compounded formulations, which are essential for delivering safe, high-quality, and effective medications tailored to individual patient needs. The laboratory we have established and the methods we have developed are well-suited to support the QA efforts of WA pharmacies in alignment with the new guidelines of Pharmacy Board of Australia.

**References:**

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