TSS Technical Safety Services

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Hazardous Drug Compounding: USP<797> & <800> Requirements

USP<800> was published to establish national guidelines for both sterile and non-sterile compounding of hazardous drugs. The standard covers handling, storage and safety measures for the handling of hazardous drugs, and it is a companion for USP chapter <797>.

Hazardous drug residue sampling

USP<800> states that sampling for hazardous drug residue should be performed at least semi-annually as a way to verify containment over hazards and to assess the efficacy of the pharmacy's cleaning program. TSS offers the ability to sample for the residue of over 30 different common drugs used in hazardous compounding.

Recommended sampling areas include:

- Interior of the ISO class 5 hood
- Staging or work areas (e.g. carts and counter tops)
- Floor, walls, and the area surrounding the ISO class 5 hood
- Areas immediately outside of the compounding room
- Patient administration area

In addition to satisfying USP<800> recommendations, a routine hazardous drug monitoring regimen is an excellent way to evaluate and establish the effectiveness of your pharmacy's cleaning protocols.
Technical Safety Services has over forty years experience testing and certifying controlled environments for the pharmaceutical and medical device manufacturing industries. We've applied this experience to formulating comprehensive USP<797> & <800> compliance programs for compounding pharmacies. From gap analysis to CETA certified testing and certification, TSS does more than ensure your compliance, we help you maintain it.

For more information about our full suite of services or to schedule a consultation contact us at 800.877.7742 to discuss your specific needs and to schedule services.

For additional information, please visit us online at www.techsafety.com.