B167 Overview of Pharmaceutical Tablet Manufacturing and Counterfeiting Considerations

Anna E. Plumley, BA, BS, West Virginia University Forensic Science Initiative, University Services Center, Suite 3102, 3040 University Avenue, PO Box 6217, Morgantown, WV 26506-6217*

The goal of this presentation is to provide attendees with an understanding of the manufacturing process of pharmaceutical tablets, noting aspects that are significant for detection of counterfeit products. Knowledge of the manufacturing process will allow examiners to make informed analyses and accurate inferences.

This presentation will impact the forensic community and/or humanity by demonstrating a comprehensive, detailed as a guide to those interested in the outcomes of the manufacturing process on the finished product. These concepts can then be applied to improve drug analysis and intelligence investigations.

Increased awareness of manufacturing processes will benefit the community by addressing the questions of why and how a product is developed. As an illustration, fiber analysts benefit from an understanding of the textile industry. Likewise, knowledge of manufacturing processes should precede examinations of physical evidence.

In addition to tableting techniques, attendees will also receive an overview of the tooling manufacturing process. The tableting process begins with tablet press tooling, which may be laser-etched or hobbed (cut, as the teeth of a gear). Depending on the machinery used, tablets may be produced one at a time, in batches of millions, or any quantity in between. In the Tableting Specification Manual, the American Pharmaceutical Association (APA) suggests guidelines for tooling, which are voluntarily followed by tablet press manufacturers in the United States and some international manufacturers. Tooling wear varies between products; some formulations are more abrasive than others. Fixed compression rates promote consistency between batches; therefore, preformulation studies strive for uniform formulations.

Formulations are composed of the active ingredients, binders, and excipients. A formulation is considered optimal if compression does not require a force that is abnormally high or low and the formulation does not stick to the punch face or abrade the tooling. The formulation is tested extensively before the product is manufactured in commercial quantities. In addition to the physical design, the tablet must also be pharmaceutically effective. The tablet ingredients must bind well enough to produce a functional tablet that will not easily fracture while maintaining bioavailability of the active drug upon dissolution of the tablet.

According to the Food and Drug Administration's (FDA) Counterfeit Drug Task Force Report—2006 Update, "Counterfeit prescription drugs are illegal, generally unsafe, and pose a serious threat to the public health. Many are visually indistinguishable from authentic drugs." According to the Pharmaceutical Security Institute, the number of incidents involving drug counterfeiting rose 27% from 2004 to 2005, while the number of products affected rose 25% and the number of countries involved increased 17%. Domestically, the FDA issues safety regulations and must approve all products before they may be placed on the market. Consistency and reputation are critical in the commercial industry, therefore tolerance levels are minimized. However, illicit manufacturers operate under a different set of standards. Economics, risk, and availability of components determine the characteristics of these products. This presentation will address factors of production that may be valuable in distinguishing illicitly produced tablets.

There are many phases in the production of compressed tablets, all of which must work in unison to create an effective product. A comprehensive, detailed presentation will be provided as a guide to those interested in the outcomes of the manufacturing process on the finished product. These concepts can then be applied to improve drug analysis and intelligence investigations.

Drugs, Manufacturing, Tablets

 ** Presenting Author*