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Hand-Sectioning and Analysis of Pharmaceutical Patches

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It is sometimes necessary to obtain cross-sections of pharmaceutical patches for purposes of quality control, analysis of individual layers and contaminants within layers, or for forensic identification. A reliable method has been developed for preparing cross-sections of patches from samples as small as 1mm^2, which can then be analyzed by any suitable means, and compared to known reference samples.

The method involves immersing the sample briefly in liquid nitrogen, and cross-sections are cut by hand while the sample is still partially frozen. The process utilizes a series of specially modified glass slides that allow for ease of handling of small samples. Step-by-step instructions will be provided in the form of text and diagrams. Photomicrographs of cross-sections of various pharmaceutical patches will be displayed, along with infrared spectra of individual layers of some of the patches.

The advantage of this method is that the resulting specimens maintain their original cross-sectional dimensions, with little to no dragging or deformation. The cross-sections are comparable to specimens produced by cryo-microtomy, and are much thinner than those prepared by hand at room temperature. Typical cross-sections obtained by this method are on the order of 30 to 60 μm in thickness. The cross-sections can be used to examine the thickness of the individual layers, size distribution of particles within the layers, presence/absence of voids, separation of the layers, and contamination within or between layers.

A cross-section of a Nitro-Dur® nitroglycerin patch is shown in Figure 1, and illustrates the quality of the cross-sections that can be obtained with this method. Note the parallel layers and smooth surfaces of the sample, which would be impossible to achieve with a room-temperature preparation. The cross-section was then pressed with a cover slip to flatten it and cause the layers to spread out to at least twice their original size, providing thin specimens of each layer with areas that were large enough to obtain micro-FTIR spectra of good quality.

Figure 2 is a cross-section of an OrthoEvra® birth control patch, showing the structural details that can be seen in the cross-sections. Notice the fibers within the adhesive layer, and the small isotropic particles that can be clearly seen. The layer of plastic wrap that was used to stabilize the sample during the cross-sectioning process remains attached to the cross-section.

The hand-sectioning method is a reliable, quick, and relatively simple way to prepare cross-sections of good quality from pharmaceutical patches. With practice, multiple sections can be obtained from a patch in less than 30 minutes. This method will be especially useful for laboratories that do not have access to a cryo-microtome.

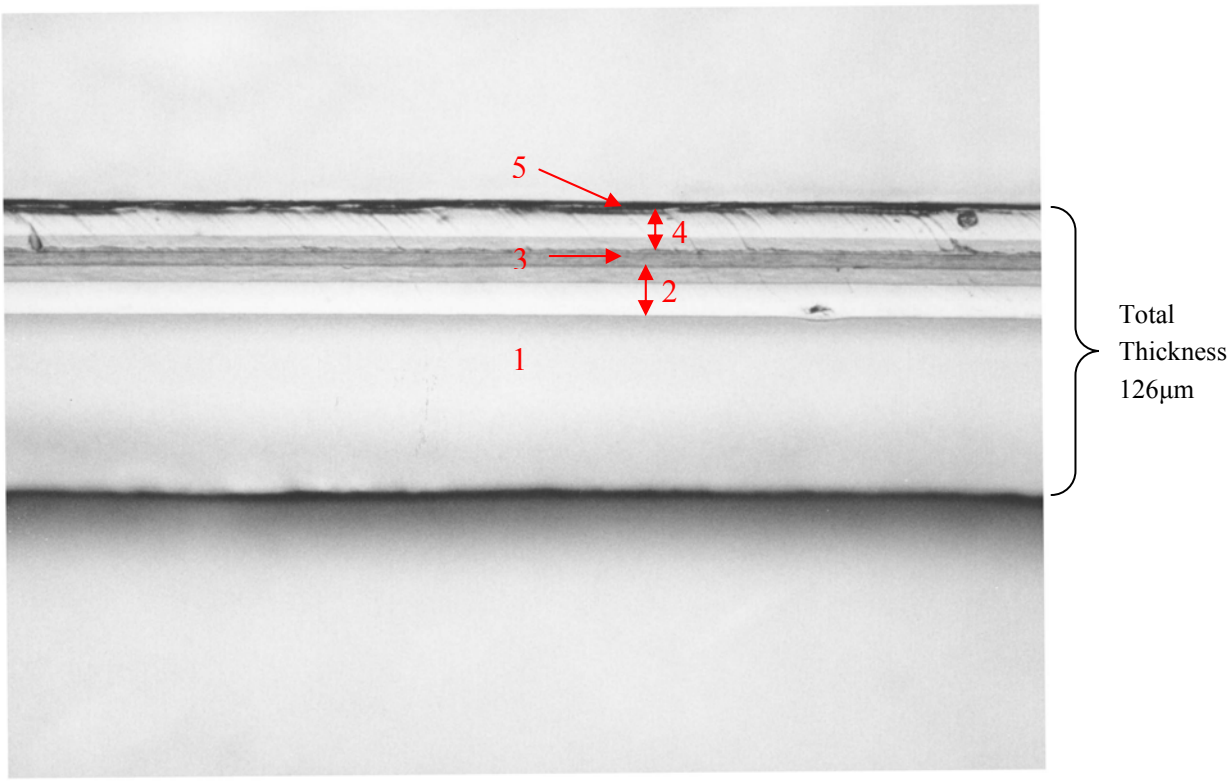

FIG. 1. Cross-Section of Nitro-Dur® Patch

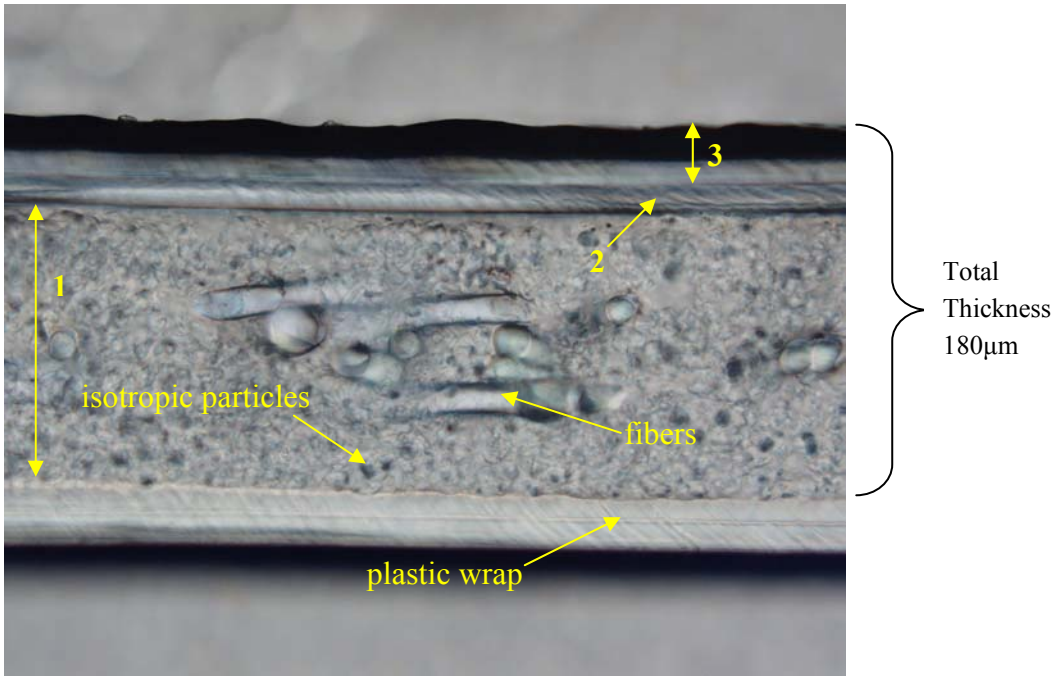

FIG.2. Cross-Section of OrthoEvra® Patch

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