How sticky is your transdermal patch?

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The Transdermal Drug Delivery System (TDDS) is the transport of therapeutic substances through the skin by means of diffusion in order to deliver the drug for its systemic effects at pre-determined and controlled rates. The TDDS system consists of an outer impermeable membrane, a reservoir containing the drug (patch), a rate-limiting membrane, and an adhesive frame. The adhesive frame used to help maintain contact between the transdermal system and the skin surface when the patch is worn on the skin for an extended period of time. The high concentration of drug in the patch means that a concentration gradient is developed into the blood stream therefore maintaining a constant drug concentration in the blood. The adhesiveness of the adhesive frame is therefore critical in the drug delivery mechanism, as well as for its safety, product quality, and efficiency. As such, a good adhesive should easily adhere to the skin with an applied finger pressure and be tacky enough to apply a strong holding force. The adhesive should also be removable from the skin without leaving a residue or causing discomfort.

TDDS has several advantages over traditional methods such as the limitation of hepatic first pass metabolism. This is particularly useful to drugs that would normally undergo extensive first pass metabolism and for drugs with a narrow therapeutic window or short half-life. The net effect with this system is therefore an enhanced therapeutic efficiency.

The tack performance of a transdermal delivery patch can be quantified by texture analysis that incorporates both compression and tension forces using a ball probe. The tackiness is quantified as the adhesive force required to break contact between the probe surface and adhesive frame; the reproducibility of this method means that the adhesiveness of the adhesive frame can be assessed to optimize product performance and for quality control.

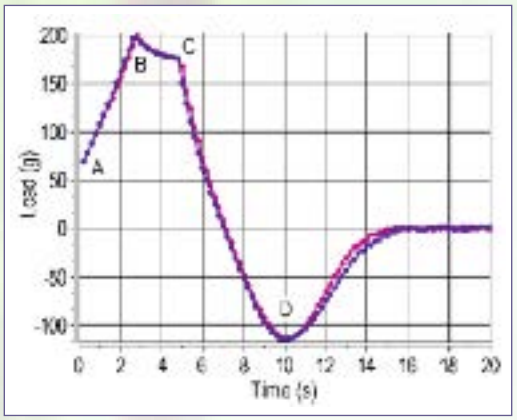

Figure 1 – A load/time graph for the adhesive force of two similar transdermal patches tested at room temperature.

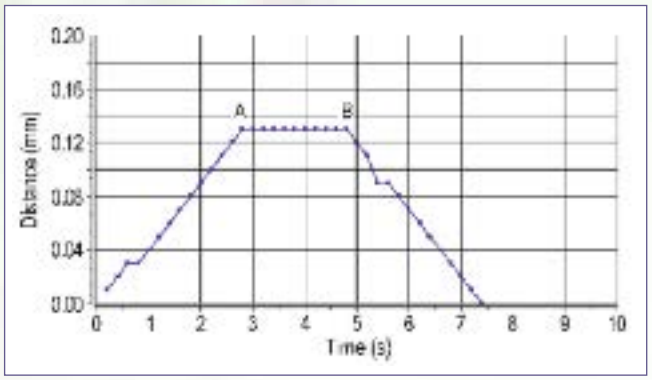

Figure 2 – A distance/time graph for a transdermal patch tested at room temperature.

Figure 1 is a typical example of the reproducibility of this test for the adhesive force (stickiness/tackiness) of two patches taken from the same batch. A high trigger load of 60 g is used to initiate the test, and a hold time of 2 seconds has been used in order to ensure full probe-sample contact before measuring the tackiness of the adhesive frame.

At point A, a trigger of 60 g is attained at

Sample	Adhesive Force (g)	Adhesiveness (mJ)
Transdermal Patches	126.5±1.1	0.27±0.01

Figure 3 – The average results taken from four transdermal patches.

the sample surface, and the ball probe (0.25 inches DIA) compresses the patch at a speed of 0.5 mm/s until a load of 200 g has been achieved (point B). At point B, the compression is stopped, and the patch is held at constant distance for a hold time of 2 seconds. At the 2-second hold time (point C), the ball probe begins to withdraw in the tensile direction at a post-test speed of 0.5 mm/s. The maximum tensile force (point D) is a measure of the adhesive force required to overcome the bonding forces between the probe and the adhesive frame. The higher the value, the more tacky is the adhesive frame.

Figure 2 shows the distance travelled to obtain a target load of 200 g (point A) followed by a hold time of 2 seconds during which the distance is held constant before probe withdrawal (point B).

Table I shows the average results taken from four transdermal patches. The adhesive force (force to overcome the bonding forces between probe and adhesive frame on probe withdrawal) and adhesiveness (energy expended when pulling the ball probe away from the adhesive frame) are shown.

These data show that the texture analyser can be used as an effective tool to quantify the adhesive properties of transdermal delivery systems. The test is quick, accurate, easy to perform and very reproducible.