

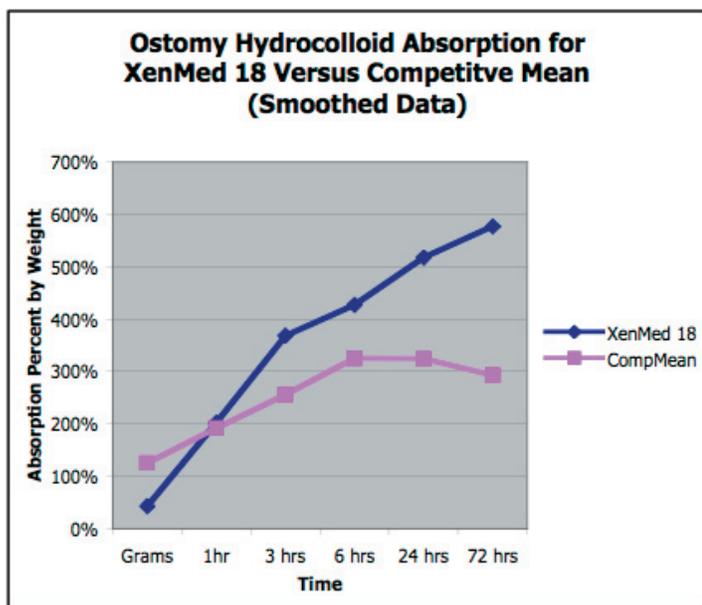


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### **XenMed 18 Study — Comparisons to Competitive Hydrocolloids for Ostomy Applications**

Several analytical studies were undertaken by Xennovate Medical LLC in early 2006 to validate the ostomy application advantages the Company believes its **XenMed 18** has over key competitors in the ostomy hydrocolloid skin barrier market segment. This report explains the studies and validates the moisture absorption advantages held by Xennovate Medical's **XenMed 18C** formulation versus the competitors studied. Our premise is that long-lasting, or continual, absorption is a good thing for the EndUser's skin, and our formula was created with this in mind. In the extreme alternative, no absorption, fluid will naturally flow into the gaps, including under the barrier and in contact with the EndUser's skin leading to skin maceration.

As our objective was to highlight **XenMed 18** and not to denigrate the competition, we have chosen to blind the competitive brands for this publication by coding them with a key held internally. Separately, then, we have aggregated all of the competitive samples and created a mean value ("CompMean") for all the competitive samples to compare to our **XenMed 18**. Our success can be seen in the chart nearby



comparing the performance of XenMed 18 directly to an aggregation of all the competitors studied. The disaggregated

competitive data can be found on page two. One further note regarding this graph is that the data for both curves has been smoothed using the simple mean of three adjacent data points. The first and last data points for each series are actuals.

### **Procedure for Absorption Study**

A test sample of each hydrocolloid under study was created. The samples were all two inches by two inches. Their thickness was a function of what the respective companies market, so you will find that the initial weights of the samples will differ. Xennovate Medical promotes the use of its ostomy skin barrier at a thickness of 25 mils (0.635 mm) versus the industry standard of 40 mils (~1 mm) because it provides a lower cost to our customers based on weight and a lower profile to the EndUser, while lasting as long or longer than competitive brands. This study validates this marketing claim.

Each 2x2 sample was then attached on one side to a 4x4 sheet of Mylar to maintain for as long as possible the integrity of the sample for the purpose of weighing it. Once the samples were prepared, they were subjected to full immersion (a rigorous test compared to actual applications) in a 0.9% normal saline solution for up to a maximum of 72 hours. The samples were removed from the saline bath periodically and weighed, until they were no longer viable due to complete disintegration into the wet bath. The data captured and recorded was the weight in grams of each sample. Subsequently, the weight at each time period was divided by the initial weight of the sample to enable rational comparisons across the data.



### **Results of the Study**

The details are reflected in the data included below and related graphs following. Data points are missing for one of two reasons: 1) the sample had disintegrated by the time period reflected by the "Ø" or 2) the researcher was not available to take the measurement. As there are a few sample data points missing and as our effort was to reflect the performance of **XenMed 18** against its key competition, the better comparisons are made against the overall average data ("MeanAll") or against the collective competitive averages ("CompMean").



From the data we can see that the two samples that rapidly absorbed moisture above the mean within three hours of application have disintegrated by the 24-hour reading. **XenMed 18's** early absorption is less than the mean at the three hour mark, but continues to ramp up over the entire 72 timeframe, and it is still absorbing when the measurements are discontinued. Of the remaining three samples only one fails to



absorb even two times its weight in moisture even at 72 hours, while the other two attain four and five times their weight in absorption in about 24 hours, although like all others, except **XenMed 18**, they lose absorptive capacity by the time the 72 hour mark is reached; this weight loss is typically do to partial disintegration. XenMed 18 continues to maintain its integrity and absorptive capacity even at the 72-hour mark.

Actual gram weights at measurement time						
	0	1hr	3 hrs	6 hrs	24 hrs	72 hrs
<b>XenMed 18</b>	0.43		1.31	1.86	2.34	2.48
<b>y75</b>	1.25		1.40		2.21	2.12
<b>z90</b>	1.28		2.92		4.99	3.98
<b>z95</b>	1.90		4.29		9.50	7.57
<b>y50</b>	0.92	2.99	4.12	2.81	0	
<b>z33</b>	0.91	1.77	3.78	4.10	0	

where  
0 → sample disintegrated prior to this reading

### Conclusion

**XenMed 18 outperforms all comparative samples in absorptive capacity and wet tack capabilities.**

### Hydrocolloid Adhesion Study

Clearly, the ability to adhere well to the skin defines a necessary ingredient of an effective skin barrier, especially as it relates to its absorptive capacity; in other words, having high absorptive capacity may be irrelevant if the barrier doesn't stay on the skin! Having formulated **XenMed 18** to have the properties required by ostomy EndUser's Company management felt compelled to demonstrate that its product meets this need well.

### Procedure for "Dry Tack" Study

A test sample of each hydrocolloid under study was created. The samples were all one-inch by one-inch strips. Their thickness was a function of what we acquired for ostomy applications. Xennovate Medical promotes the use of its ostomy skin barrier at a thickness of 25 mils (0.635 mm) versus the industry standard of 40 mils (~1 mm) because it provides a lower cost to our customers based on weight and a lower profile to the EndUser, while lasting as long or longer than competitive brands. This study validates this marketing claim. Where needed to maintain the tensile integrity of the sample, a 3M 1776 acrylic backed woven material was applied to one side of the hydrocolloid sample. The test subject's forearm was prepared by wiping with a saline moistened cloth and allowed to air dry. After application onto forearm, a 5 pound weight was applied perpendicular to the sample on the arm for 5 seconds.

At each respect time point, one edge of each hydrocolloid sample was lifted and a strain gauge (American Weigh®) with a gram scale was attached using an alligator

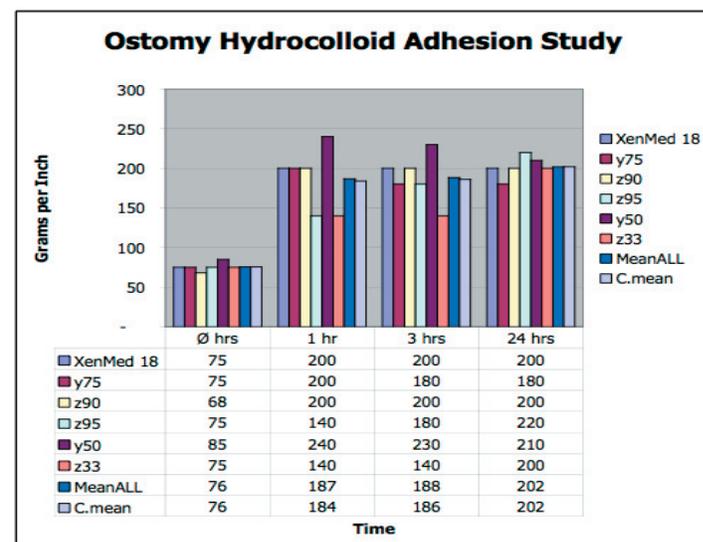
clip. A pull direction of 90 degrees to the arm was maintained while peeling each sample and the resulting removal force was measured by the strain gauge. The tabulated removal forces by respective sample are depicted nearby.

### Results of Adhesion Study

All products had significant initial tack. Samples designated as z95 and z33 maintained a lesser tack at one hour, and both left a significant residue upon removal. The peel of sample y50 was approaching a dangerous tack level of 240g per inch at one hour; in fact, subject's arm still has a red imprint of y50 HCD two days after removal, and it was the only one demonstrating that problem. The sample z95 disintegrated and had to be removed in clumps. As the hydrocolloids absorb over time in general, the adhesion levels fall, regressing as a group to around 200 grams by the third hour.

### Conclusion

**XenMed 18 demonstrated no significant improvements over most competitive samples, although all samples demonstrated superior results over samples y50 and z95 for the different reasons outlined above.**



**Test Conditions.** All testing was carried out at a temperature of 20° C ± 1° C and 40% - 60% relative humidity.