

## *Label Testing for Pharmaceuticals*

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Imagine, if you will, the following frightening scenario: an elderly man with a history of heart problems as well as several other chronic health issues decides, as a safety precaution, to store a small supply of spare prescription medications in the glove compartment of his car, “just in case of an emergency.” No emergency occurs for some months – and then the fateful day arrives. Our subject reaches into the glove compartment of his car, pulls out several vials of medications, and discovers to his chagrin that the labels are no longer legible.

This scenario, or some variant on it, might happen somewhere every day - if strict quality control on labeling were not self-imposed by the retail pharmacist. Recognizing the implications of this potential problem, one major retail chain has taken it on themselves to conduct a broad-ranging series of tests of label durability. The tests involved labeling materials from nine different major suppliers.

MATCO Inc, an independent testing lab in Pittsburgh, PA, was engaged to develop and run a series of blind tests to mimic the environmental conditions to which prescription vials and their labels might conceivably be exposed. The labels were all submitted by the manufacturers to the retailer who printed them all identically, using the same in-house direct thermal printer. After printing, the samples were forwarded to MATCO for testing, identifying them only as group A, B, C, etc.

There are no industry-wide standards for label durability testing, so MATCO created a series of test protocols to compare the label materials against one another.

The tests involved the following characteristics:

1. Resistance to heat alone
2. Resistance to moisture, plus mild heat
3. Resistance to UV radiation
4. Resistance to atmospheric pollutants (sulfur and chlorine)
5. Resistance to common bathroom chemicals (shampoos, soaps, solvents etc), plus mild heat and moisture
6. Several combinations of the above.

The results of this rigorous testing were interesting and unexpected. Initially the labels appeared to be bright white with glossy black text. All but one type had an overcoat on the paper. After exposure to the various test

conditions, printing faded, backgrounds darkened, and colors washed out, all to varying degrees. No single material performed exceptionally well on all phases of the testing. In other words, all products had weak areas. Several major suppliers, startled by their failure to perform well, went quickly back and modified their submitted materials for re-testing. Some improved on the second round, some continued to perform poorly.

A weighted composite score was assigned to each sample, allowing an overall comparison for use by the retailer in qualifying suppliers.

The take-home messages to the industry are:

- \* To set high standards for your suppliers,
- \* To be skeptical of claims for all-around high quality for labeling materials, and
- \* To continue to educate your customers on the importance of keeping their medicines in well-ventilated, cool, dry, dark places, not only for the medicines themselves, but so that they can read the labels when they really need to! That glove compartment can get as hot as 190o F on a sunny July day!

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