Package Label Qualification
A Sample Plan

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Considerations in designing a package label testing/qualification procedure

- Face stock
  - Stock finish; gloss or matte
  - Stock strength; paper or synthetic
  - Print surface; laser, thermal transfer, inkjet, etc.

Considerations in designing a label testing / qualification procedure

- Print quality and durability
  - Printability of the design
  - Computer printer selection
  - Abrasion resistance; preprint and imprint
  - Chemical and solvent resistance

Considerations in designing a label testing / qualification procedure

- Adhesive properties
  - Adhesive composition, e.g. hot melt, emulsion acrylic, etc.
  - Adhesive initial tack and ultimate bond
  - Substrates adhered to and their shape
  - Application temperature
  - Operating temperature
  - Sterilization environment

Considerations in designing a label testing / qualification procedure

- Environmental conditions
  - Package composition
  - Shipping method and conditions
  - Storage conditions and length of storage
  - Chemical resistance

A Sample Testing/Qualification Plan

- Adhere samples to appropriate substrates at an accepted sample size.
- Peel tests after 24-72 hours
- Temperature and humidity conditioning
- Visual inspection and peel tests
- Abrasion testing
- Sterilization and final package tests
- ‘Shake, rattle, and roll’ tests

Common tests and standards

- ASTM D3330, Peel adhesion of PS material
- ASTM D5264, Sutherland abrasion and smudge resistance test
- ASTM F1319, Crockmeter abrasion and smudge resistance test
- ASTM F2252, Ink adhesion tape test
- ASTM F 2250, Chemical exposure, inks & coatings
- ASTM D4169, Distribution testing, “Shake, rattle, & roll”.
- ASTM F1980, Accelerated aging

Some common label adhesive conditioning cycles

- Low temp cycle, 48hrs, -30F, ambient RH
- Humid cycle, 48hrs, 90F, 85% RH
- High temp cycle, 48 hrs, 130F, 25% RH

Sample label stock 90 degree peel values on Tyvek lid stock, lbs/linear inch

Label stock	20 minutes	24 hours
Device Co A	.7	.95
Device Co B	.74	.98
Device Co C	1.5	1.8
Device Co D	1.2	fiber tear (label)
Device Co E	1.2	1.6

Summary and conclusions

- There are no standardized protocols for qualifying package labels.
- Design your protocol based on customer requirements, your process, package design, and environmental conditions.
- Develop rationale for sample size and test method.
- Develop your pass/fail protocols before testing begins.