

**IoPP Medical Device Packaging  
Technical Committee  
Testing Survey Synopsis  
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# The Survey

*Please respond to this survey by Wednesday, 22 September (2004).*

(Indicate which standard or method is used by an "X" or fill in the blanks, where applicable):

--> ASTM D4169, distribution cycle \_\_\_\_\_ normally used, assurance level \_\_\_\_\_

--> ISTA 1A \_\_\_\_\_, 2A \_\_\_\_\_, or \_\_\_\_\_

--> In-house developed standard \_\_\_\_\_

--> Industry \_\_\_\_\_; examples: testing, university, pharmaceutical, medical device, supplier

--> Please return survey results \_\_\_\_\_

# Survey Synopsis

- There was an approximate split among survey participants for test usage:
  - 30% used ASTM D4169
  - 50% used ISTA  
(Primarily Procedure 1A used, but usually in conjunction with another test standard)
  - 20 % used in-house testing

# Survey Synopsis

- There was an approximate 50/50 split in using only one standard for distribution testing or a combination of standards.
  - Only one ASTM D4169 cycle or one ISTA standard used verses a mixture of ASTM and/or ISTA standards.

[The mixtures seen are shown on the following slides.]

# Survey Synopsis

- Some respondents combine test schedules from ASTM or ISTA
  - Example:  
ASTM Distribution Cycle 13, Assurance Level I for part of the testing and  
Distribution Cycle 13, Assurance Level II for other parts of the tests.

# Survey Synopsis

- Some respondents combined elements of ASTM and ISTA into one test protocol.

Example:

- ASTM Distribution Cycle 13, Assurance Level I for most of the testing with ISTA compression testing substituted.

# Survey Synopsis

- Some respondents combined elements of in-house test methods with ASTM and ISTA methods into one test protocol.

# Survey Synopsis

Some respondents have developed their own custom design distribution qualification test protocol.