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Document Title: West Global Specification for Aluminum Seals

Control ID: WPS-003

Rev. 3

MAY 30 2014

DATE EFFECTIVE:

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1. Scope

- 1.1 This specification provides product acceptance criteria for the manufacturing, inspection, labeling, packaging and shipping of aluminum seals. The process operates under applicable cGMPs.
- 1.2 This specification will be used in lieu of a customer specification or for those portions not covered within a customer's specification.
- 1.3 This specification applies to aluminum seals which have been developed, manufactured and marketed globally, with the exception of aluminum seals for emerging markets for which a separate specification has been established.

2. Applicable Documents: (Current Versions)

- 2.1. Policy on Change Notification
 - 2.1.1. A copy may be obtained on West's website, www.westpharma.com; (Support/Quality Assurance Support/References)
- 2.2. Size/Dirt Estimation Chart for use with TAPPI, T564, T213, T437 and ISO Standard 5350-3: Supplied by the Technical Association of the Pulp and Paper Industry.
- 2.3. ISO 2859: International Organization for Standardization: Sampling Procedure for Inspection by Attributes or ANSI/ASQ Z1.4: American National Standard: Sampling Procedures and Tables for Inspection by Attributes

3. Materials

- 3.1. Aluminum Seal:
 - 3.1.1. Aluminum alloy compositions
 - 3.1.1.1. Alloy 3003
 - 3.1.1.2. Alloy 8011(A)
- 3.2. Lacquer coating on outer surface is solely for cosmetic effect and maintains attractiveness of closure after processing. The lacquer will withstand a boil in D.I. water process for one hour or a normal autoclaving of one hour @ 250°F / 121.1°C.
- 3.3. Plastic Button
 - 3.3.1. Polypropylene
- 3.4. Dependent on component design and customer application:
 - 3.4.1. Seals are manufactured using applicable temper levels and lacquer levels. The exact metal grade designations and production control are maintained at the manufacturing facility level, and by internal and vendor specifications.
 - 3.4.2. Buttons are manufactured using applicable (e.g. gamma stable or low temperature storage) polypropylene grades. The specific grade designations and production controls are maintained at the manufacturing facility level, and by internal and vendor specifications.

4. Packaging

- 4.1. The primary package for the product will assure clean, acceptable delivery to the customer.
 - 4.1.1. Appropriate packaging configurations will be utilized for specific configurations.

5. Labeling/Markings

- 5.1. Each carton will contain at a minimum the following information:
 - 5.1.1. Product number / Item number
 - 5.1.2. Product description

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5.1.3. West batch number

5.1.4. Quantity

6. Certification

6.1. A Quality Certificate will accompany every shipment.

7. Sampling Plan

7.1. West will utilize sampling plans in accordance to the ISO 2859-1 or ANZI/ASQ Z1.4.

7.2. Visual evaluations will use General Inspection level II and dimensional evaluations will use Special Inspection Level S-4, Single Sampling Plan for Normal Inspection, unless otherwise specified in the plant's internal requirements.

7.3. Visual inspections will be unaided (naked eye). Magnification may be used to characterize visually observed defects; class segments are cumulative.

8. Classification of Defects**8.1. AQL% 0.01 (None Allowed)**

8.1.1. Mixed (intermixed) product within a carton

8.1.2. Mixed (intermixed) cartons or pallets within a shipment not matching the packing slip or certification

8.1.3. Carton label identification does not match product inside carton, packing slip or certification

8.1.4. Lacquer/coating not as specified

8.1.5. Absence of lacquer/coating

8.1.6. Missing liner

8.1.7. Wrong liner or laminated disc

8.1.8. Liner or laminated disc inserted the wrong way

8.1.9. Stamping or engraving not on buttons and/or seals

8.1.9.1. Not as specified per drawing

8.1.9.2. Incorrect text color

8.2. AQL% 0.258.2.1. Internal/external contamination, foreign bodies (including tape), slivers $\geq 0.05\text{mm}^2$ per TAPPI standards T564, T213 and T437 and ISO 5350-3

8.2.2. Defects impairing function of seal or processing machine operation

8.2.2.1. Malformed

8.2.2.2. Formation of burrs and sharp points

8.2.2.3. Dimensions out of specification

8.2.2.4. Holes, tears in material (stamping fault)

8.2.2.5. Number and/or width of bridges incorrect, bridges split at flange

8.2.2.6. Any hole off center by more than 1/32"

8.2.2.7. Embedded foreign particles, burnt plastic, particles stuck on surface

8.2.2.8. Coating partially detached

8.2.2.9. Double liners

8.2.3. Color of coating and/or plastic button not within normal color range

8.2.4. Illegible or incomplete imaging or embossing

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8.3. AQL % 0.65

- 8.3.1. All components must be present and secure in the assembly of the seal
- 8.3.2. Slight burrs or points – function or running of machine not impaired
- 8.3.3. Incomplete, flash/shorts at the plastic button
- 8.3.4. Incomplete liner
- 8.3.5. Severe scratches – going through lacquer and exposing aluminum
- 8.3.6. Seals must be free of machine oil, grease and/or other insoluble foreign material (a thin film of drawing lubricant is acceptable)

8.4. AQL % 1.0

- 8.4.1. Aluminum seal must activate per its described function

8.5. AQL % 4.0

- 8.5.1. Defects not impairing function or machine operation
 - 8.5.1.1. Slightly malformed
 - 8.5.1.2. Slight scratches, grooves – not going through coating and exposing aluminum

9. Change Notification

- 9.1. West will notify the customer of changes in accordance with the Policy on Change Notification.

10. Disposition of Non-Conforming Lots

- 10.1. Disposition of non-conforming lots shall not occur until West is notified.
- 10.2. West has the option to re-sample or, upon agreement with the customer, have the customer resample the product to a mutually agreed upon sampling plan pertinent to the applicable non-conformance.
- 10.3. Only agreed to product and quantity(s) can be returned to West after obtaining a Return Goods Authorization. This authorization must appear on all documentation and product shipping containers related to the return.
- 10.4. All returned products must be in the original West cartons with West traceability maintained.

11. Legal

- 11.1. The information contained in this specification is the property of West and will not be divulged to a 3rd party without first receiving written approval from West.



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2 Revision History On File

2.1 WPS-003 Rev 3 Rev History

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29 May 2014

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29 May 2014

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