PACKAGE INTEGRITY TEST – DYE PENETRATION AND LEAKAGE

Reference Document: ASTM F1929-12 (Method A) and NQCL/SOP/MDVS-014

Test Method A: Injection Method
Inject Dye solution within the sealed package and allow the dye to contact the sealed edge for a maximum of five seconds. Observe for leaks originating from inside edge of the package seal towards / through the outside edge of the package seal. The package is then rotated in order to expose the dye to the remaining sides of the package.

Specifications:
No leaks should be observed on any edge after 5 seconds.

Observation:

Remarks:

ACIDITY / ALKALINITY TEST

Reference Document: ISO 7886 – 1 (2ND Edition, 2017).

Test Method: Annex A
Fill enough syringes that make a minimum volume of 60 mL. Expel air bubbles and maintain the filled syringes at a temperature of 37 °C to 40 °C for 8 h to 8 h and 15 min. The control fluid (distilled water) should also be maintained at these temperatures.

After 8 h, eject the contents and combine them in a vessel made of borosilicate glass (beaker). Determine the pH of the solutions using a laboratory potentiometric pH meter using a general purpose electrode.

Specifications:
The pH value of the syringe assessment fluid is within one pH unit of the value of the control fluid (distilled water).

Observation:

pH of the Control solution : _____
pH of the Sample : _____

Remarks:

SYRINGE AND FUNCTION TEST – COMPRESSION AND PLUNGER TEST

Reference Document: ISO 7886 – 1 (2ND Edition, 2017).

Test Method: Annex E
Follow the setup and procedure outlined in this annex. Measure and note the forces required to initiate movement of the piston and sustain the travel of the piston. Carry out the testing on 10 syringes.

From the recording of plunger travel and force applied, the following should be determined:

1. Force required to initiate the movement of the plunger - F_s (Compression force).
2. Mean force during plunger travel – F
3. Maximum force during the plunger travel - F_{max}

NB: Attach a printout of the results of the test

Specifications:
Given in Table E.1, Annex E, page 24 ISO 7886-1

Observation: Summary of the results

Average F_s : _____
Average F : _____
Average F_{max} : _____

Remarks:

NEEDLE PENETRATION TEST

Reference Document: ISO 7864 (4TH Edition, 2016)

Test Method : Annex D
Follow the setup and procedure outlined in this annex. Carry out the testing on 10 needles. The two main outputs should be measured using the force profile.

1. Peak penetration force
2. Drag force

The test report should include the mean and standard deviation for the two outputs

NB: Attach a printout of the results of the test

Specifications:
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Observation:

Remarks: