**Revision History for (PRC097514)**

|  |  |
| --- | --- |
| **SUMMARY OF CHANGES** | |
| Revision No. | Description of Change |
| A | Original Document |

|  |  |
| --- | --- |
| **OPERATIONAL QUALIFICATION PROTOCOL** | |
| Document Title: | Operational Qualification of Automated Label Applier E20172 |
| Document Number / Revision: | A |
| Site / Location: | Independencia: Ethicon Endo-Surgery, S.A. de C.V. Planta II, Calle Durango No. 2751, Colonia Lote Bravo, Ciudad Juárez, Chihuahua, 32575, México. |
| Project / Area: | Megadyne Packaging Line 174 |
| Equipment: | Automated Label Applier |
| Validation Assessment Reference: | DC003495 |
| N/A | |

# Document Approvals

The protocol will be approved per CP0160 Rev GY.

CSV-E representative to be added as required in line with Computer System Validation for Equipment Policy requirements where applicable.

| Function | Name | Signature | Date |
| --- | --- | --- | --- |
| **Originator** | Ricardo Miranda | eSig in Epicenter System | Electronic Date in Epicenter System |
| Lifecycle Quality Engineer | Ihsan Samara | eSig in Epicenter System | Electronic Date in Epicenter System |
| Franchise Package Development Engineer | Matthew Varga | eSig in Epicenter System | Electronic Date in Epicenter System |
| Plant Quality System Engineer | Victor Cantu | eSig in Epicenter System | Electronic Date in Epicenter System |
| Plant MEST Manager | Gabriel Herrera | eSig in Epicenter System | Electronic Date in Epicenter System |
| Business Unit Manager | Izza Rodriguez | eSig in Epicenter System | Electronic Date in Epicenter System |
| Planning | Marisol Vazquez | eSig in Epicenter System | Electronic Date in Epicenter System |
| Franchise Sterilization Sciences | Ravi Patel | eSig in Epicenter System | Electronic Date in Epicenter System |
| Plant QS Manager | Francisco Del Val | eSig in Epicenter System | Electronic Date in Epicenter System |
| Lifecycle Design Engineer | Brian Walter | eSig in Epicenter System | Electronic Date in Epicenter System |
| Approver | Luis Gutierrez | eSig in Epicenter System | Electronic Date in Epicenter System |

# Purpose

This is an initial and full Operational Qualification of the Automated Label Applier E20172 equipment located at Independencia Plant. PR-0000089 Rev. 14 Franchise Procedure for Validation (Shared) defines the requirements & approach for Operational Qualification.

The purpose of this Operational Qualification is to establish by objective evidence that the process control limits and action levels for Automated Label Applier E20172 result in product that meets all predetermined specifications SPE004695 Draft.

# Scope & Background

The scope of this Operation Qualification study for the label applier process at the Independencia site, using Automated Label Applier E20172 equipment. Table 1 lists the product families in scope of this process.

Table 1 - Products Applicable to this Operational Qualification.

| Mod Code | Product Code or Product Family Identifier | Description |
| --- | --- | --- |
| 02 and 03 | 0012 | EZ Clean 2.5" Blade |
| 02 and 03 | 0012A | EZ Clean 2.75" Blade |
| 02 and 03 | 0012AM | EZ Clean 2.75" Modified Blade |
| 02 and 03 | 0014 | EZ Clean 6.5" Blade |
| 02 and 03 | 0014A | EZ Clean Blade, 4.0" |
| 02 and 03 | 0014AM | EZ Clean Modified Blade, 4.0" |
| 02 and 03 | 0014M | EZ Clean Modified Flat Blade, 6.5" |
| 02 and 03 | 0012M | EZ Clean 2.5" Modified Blade |
| 02 and 03 | 0013 | EZ Clean 2.75" Needle |
| 02 and 03 | 0013M | EZ Clean Modified Needle, 2.75" |
| 02 and 03 | 0118 | EZ Clean Sharp Needle, 2.0" |
| 02 and 03 | 0118A | EZ Clean Sharp Needle, 2.5" |

Table 2 lists all of the equipment associated with the process under the scope of this study.

Table 2 - Equipment Applicable to this Operational Qualification.

| Equipment Name | Equipment Number | Maximo ID | Supplier | Serial # |
| --- | --- | --- | --- | --- |
| Automated Label Applier | E20172 | ES4457 | PROD Design | PROD-20145A |

# Definitions, Terms and Abbreviations

Refer to 100632965 Rev. 3 Franchise Glossary for Validation (Shared) for terminology and abbreviations used in the Ethicon, Ethicon Endo Surgery, and Cardiovascular and Specialty Solutions (CSS) validation program.

# Roles & Responsibilities

## Protocol Execution: Originator or designee.

## Cosmetic Inspections: Finished Good Quality Technician or designee.

## Legible Printed Information Inspection: Finished Good Quality Technician or designee.

## Machine Operation: Packaging Technician, Maintenance Technician or designee.

## Completion Report: Originator or designee

## Training: Originator or designee

## Set Up: Mechanic or designee

# Pre-requisites

The pre-requisites that must be fulfilled prior to OQ execution are shown in Table 3.

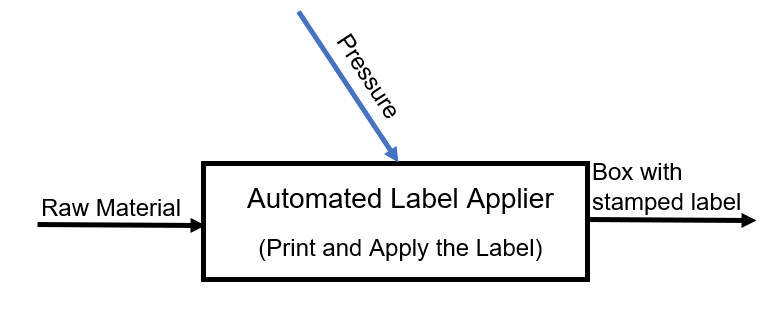
Table 3 - OQ Pre-Requisites

| Pre-Requisite | Document Title | Reference Doc. # or Attachment |
| --- | --- | --- |
| Installation Qualification Completion Report | [Completion Report for Automated Label Applier E20172](javascript:formsubmit('eds_open_generic_open_link?item_handle_param=MTIObjectHandle-0002-1%7ER%7EEerxNkdCinci-u_epipd-C0K%7Ex4CmpRpt%7Eu_epipd%7E%7E&rel_handle_param=&toggle=')) | PRC097511 Rev A |
| Software Validation Completion Report | Completion Report of Software Validation for Automated Label Applier E20172 | PRC097513 Rev A |
| Draft Procedures | Process Specification | PR001736 Draft |
| Draft Procedures | Control Plan | PR001754 Draft |
| Draft Procedures | I-Sheet | SPE004694 Draft |
| Draft Procedures | Bulk Packaging | TRP001934 Draft |
| Draft Procedures | Sales Unit Packaging | TRP001935 Draft |
| Draft Procedures | RSC Final Packaging | TRP001936 Draft |
| Draft Procedures | Loading of Components | TRP001937 Draft |
| Draft Procedure | Label Applying in Sales Unit Box | TRP001944 Draft |
| Draft Procedures | Packing area L-174 | TR011319 Draft |
| Draft Procedures | pFMEA | RMD001679 Draft |
| Drawing | Automated Label Applier | E20172 Rev A |

# Note: The operators involved in the execution of this protocol must be trained prior to execution.

# Manufacturing Process Flow

## The Process Specification PR001736 Draft, provides step-by-step instructions for process performed using E20172 Automated Label Applier Machine.



## Assembly manual training operation for Megadyne Line 174.

* Main Assembly training manual.
  + TR011319 Draft Packing area L-174.
* Manual training operations for Megadyne Line 174.
  + TRP001934 Draft Bulk Packaging.
  + TRP001935 Draft Sales Unit Packaging.
  + TRP001936 Draft RSC Final Packaging.
  + TRP001937 Draft Loading of Components.
  + TRP001944Draft Label Applying in Sales Unit Box.

# Process Parameters

The parameters used for this protocol will be in Low, Nominal and High equipment settings where applicable and those parameters are as per Process Specification in PR001736 Draft. Reference Table 4 for operational settings.

## Process Parameters / Inputs

Table 4 - Parameters

| Process Step | Parameter | *Range or Setting to be Validated* |
| --- | --- | --- |
| Label Applier | Pressure (Psi) | 60-80 Psi |

## Note: The pressure of equipment is the only variable parameter

## Other Critical Process Inputs and Controls Required

N/A

# Components Assessment

The materials/components that will be utilized for the Operational Qualification are listed on Table 5.

Components/materials to be utilized during the execution of this operational qualification will be referenced in the Bill of Materials of product codes stated in Table 1.

Table 5 – Materials

| **FG** | **Component Part ID** | **Description** |
| --- | --- | --- |
| 0012 | 3200023-02 | Unit Box, PrePrinted, 5 .875 x 4.375 x 1 |
| 0012 | 3100033-01 | Label Stock, Generic, Blank 2.5 x 5.5 |
| 0012 | 3100028-01 | Label Stock, Generic, 3.5 x 2.5 |
| 0012A | 3200023-02 | Unit Box, PrePrinted, 5 .875 x 4.375 x 1 |
| 0012A | 3100033-01 | Label Stock, Generic, Blank 2.5 x 5.5 |
| 0012A | 3100028-01 | Label Stock, Generic, 3.5 x 2.5 |
| 0012AM | 3200023-02 | Unit Box, PrePrinted, 5 .875 x 4.375 x 1 |
| 0012AM | 3100044-01 | Label Stock, Yellow, Blank 5.5 x 2.5 |
| 0012AM | 3100028-01 | Label Stock, Generic, 3.5 x 2.5 |
| 0012M | 3200023-02 | Unit Box, PrePrinted, 5 .875 x 4.375 x 1 |
| 0012M | 3100044-01 | Label Stock, Yellow, Blank 5.5 x 2.5 |
| 0012M | 3100028-01 | Label Stock, Generic, 3.5 x 2.5 |
| 0013 | 3200023-02 | Unit Box, PrePrinted, 5 .875 x 4.375 x 1 |
| 0013 | 3100033-01 | Label Stock, Generic, Blank 2.5 x 5.5 |
| 0013 | 3100028-01 | Label Stock, Generic, 3.5 x 2.5 |
| 0013M | 3200023-02 | Unit Box, PrePrinted, 5 .875 x 4.375 x 1 |
| 0013M | 3100033-01 | Label Stock, Generic, Blank 2.5 x 5.5 |
| 0013M | 3100028-01 | Label Stock, Generic, 3.5 x 2.5 |
| 0014 | 3200024-02 | Unit Box, PrePrinted, 8 3/4 x 5 7/8 x 1 |
| 0014 | 3100033-01 | Label Stock, Generic, Blank 2.5 x 5.5 |
| 0014 | 3100028-01 | Label Stock, Generic, 3.5 x 2.5 |
| 0014A | 3200024-02 | Unit Box, PrePrinted, 8 3/4 x 5 7/8 x 1 |
| 0014A | 3100033-01 | Label Stock, Generic, Blank 2.5 x 5.5 |
| 0014A | 3100028-01 | Label Stock, Generic, 3.5 x 2.5 |
| 0014AM | 3200024-02 | Unit Box, PrePrinted, 8 3/4 x 5 7/8 x 1 |
| 0014AM | 3100044-01 | Label Stock, Yellow, Blank 5.5 x 2.5 |
| 0014AM | 3100028-01 | Label Stock, Generic, 3.5 x 2.5 |
| 0014M | 3200024-02 | Unit Box, PrePrinted, 8 3/4 x 5 7/8 x 1 |
| 0014M | 3100044-01 | Label Stock, Yellow, Blank 5.5 x 2.5 |
| 0014M | 3100028-01 | Label Stock, Generic, 3.5 x 2.5 |
| 0118A | 3200023-02 | Unit Box, PrePrinted, 5 .875 x 4.375 x 1 |
| 0118A | 3100033-01 | Label Stock, Generic, Blank 2.5 x 5.5 |
| 0118A | 3100028-01 | Label Stock, Generic, 3.5 x 2.5 |
| 0118 | 3100028-01 | Label Stock, Generic, 3.5 x 2.5 |
| 0118 | 3100033-01 | Label Stock, Generic, Blank 2.5 x 5.5 |
| 0118 | 3200023-02 | Unit Box, PrePrinted, 5 .875 x 4.375 x 1 |

Note: The Automated Label Applier E20172 (Maximo ID: ES4457) uses a Ribbon (Item number: 35242) as raw material to print the information on the blank label.

# Additional details such as lot/batch number and expiration date (if applicable) will be included in the OQ report.

All components/materials used in this protocol will be received by Megadyne Plant and previously inspected by Megadyne RMI in Draper UT.

# Operating Procedures

The Manufacturing Procedure, PR001736 Draft, provides instructions on the processes performed on E20172 Automated Label Applier Machine.

The operating procedures are detailed in the following documentation and will be attached as supporting files:

* Control Plan (PR001754 Draft)
* pFMEA (RMD001679 Draft)
* I-Sheet (SPE004694 Draft)
* Set up (FRM004256 Draft)
* Instructions of process:
  + TRP001934 Draft Bulk Packaging.
  + TRP001935 Draft Sales Unit Packaging.
  + TRP001936 Draft RSC Final Packaging.
  + TRP001937 Draft Loading of Components.
  + TRP001944Draft Label Applying in Sales Unit Box.

# Training Requirements

## Training is required for operators, mechanics, technicians, engineers, and other personnel associated with running the protocol except the originator and approvers. See Section 7.2.

## Training will be documented by the protocol originator or designee and will consist of performing a review of this Operational Qualification Protocol PRC097514 Rev A and its requirements.

## Training will be documented using form FM-0000809 Rev. 15. The completed hard copies of the forms will be provided to the training department to be entered into the Compliance Wire System and one copy will be attached to the Completion Report PRC097515 Rev A.

# Requirements and Acceptance Criteria / CTQ List

## The Critical to Quality (CTQ) aspects of the products to be made during this Operational Qualification are shown below. Each of the OQ runs must meet the Acceptance Criteria following the Material Specification SPE004695 Draft and pFMEA RMD001679 Draft.

## Requirements and acceptance criteria are listed in Table 6 below.

Table 6 - CTQ List

| Attribute | Test Method | Specification | Acceptance Criteria |
| --- | --- | --- | --- |
| Cosmetic | Visual Inspection | Unit Box Pre-Printed free of damages | No damage on the Printed box or label |
| Legible | Visual Inspection | Information printed legible and correct | Legible and correct information |
| Integrity | Visual Inspection | Label correctly attached to the Unit Box Pre-Printed | Uniform label, firmly and securely attached to the Unit Box Pre-Printed |
| Location | Visual Inspection | Label located as per top assembly drawing | Label location matches specified location in drawing |

# Worst Case Condition Assessment

## The operation parameters for label applier machine will be defined by this operational qualification protocol. The ranges identified for the worst-case process setting conditions are listed in Table 7 below:

**Table 7- Worst-Case for Automated Label Applier Process Parameter**

|  |  |  |
| --- | --- | --- |
| **Process Parameter** | **Low Process Setting** | **High Process Setting** |
| Pressure (Psi) | 60 | 80 |

# OQ Test Plan

* 1. Different batches will be created for each setting parameter due to Megadyne production still being validated and transferring from Draper Utah to Ethicon Endo System. See Table below.

**Table 8: OQ Batches**

|  |  |  |
| --- | --- | --- |
| **Product** | **Parameter** | **Batch** |
| Any Product Code from Table 1 | Low | 97514L |
| Nominal | 97514N |
| High | 97514H |

* 1. Obtain all required material per Table 5.
  2. Manufacturing Engineer or designee will change parameters on the equipment for each process parameter setting (OQ Low, OQ Nominal and OQ High) and record loaded parameters in the setup sheet form FRM004256 Rev Draft.

The following parameters will be used during the validation.

**Table 9: OQ Process Parameters Settings**

| Parameter Name | OQ Low (Run 1) Setting | OQ Nominal (Run 2) Setting | OQ High (Run 3) Setting |
| --- | --- | --- | --- |
| Pressure | 60PSI | 70PSI | 80PSI |

* 1. Using a permanent marker, write the sample number on the Unit Box Pre-Printed, using L for low N for nominal and H for high condition followed by the sample number, i.e. L-15 for the 15th sample stamped with low parameters, H-8 for the 8th sample stamped with the high parameters.
  2. Run a minimum of one-hundred (100) stamped labels on Unit Box Pre-Printed for visual inspection to identify any possible defects such as illegible information printed on the label, integrity of the label placed on the box, cosmetic damage on the Unit Box Pre-Printed or improper label location on the Unit Box.
  3. Attribute testing only for cosmetic damage, integrity of the label placed on the box, information printed on the label defects and label placement on the box will be performed by the Quality Technician using the sample size shown in Table 10 to comply with the required 300 pieces sample size. No Unit Boxes Pre-Printed will be destroyed during this attribute test.

**Table 10- Quantity to produce and inspect**

|  |  |  |
| --- | --- | --- |
| **Parameter** | Qty to produce (Minimum) | Qty to inspect |
| OQ Run 1 Setting Low Parameters | 100 | 100 |
| OQ Run 2 Setting Nominal Parameters | 100 | 100 |
| OQ Run 3 Setting High Parameters | 100 | 100 |

Note: Only one product code will be selected for this operational qualification, because the system does not distinguish between one large box (0014) and one small box (0012) and the X-Y label location for both box sizes are the same.

* 1. Mark the Pass (Accept) column for Unit Box Pre-Printed that meet SPE004695 Draft. Mark the Fail (Reject) column for Unit Box Pre-Printed that do not meet SPE004695 Draft for cosmetic, legibility or location requirements and document defect classification in comments section for data collection. Record results in Attachment 1 ,2 and 3.
  2. Quality technician will visually inspect samples per section 12 for cosmetic defects and record results on inspection data sheet FMWE0311.1 Rev. G and will not tear down or destroy stamped samples for this inspection.

# Sampling Plan and Rationale

## 100% in-process visual inspection of the unit box pre-printed, and legibility of the label printed and stamped on the unit box will be performed by the line associates on the total quantity that will be produced per Table 10.

## This validation is intended to qualify the Automated Label Applier performance for product codes listed in Table 1.

## A sample size of 300 pieces of empty, non-erected, Unit Box Pre-Printed with label printed and stamped on the box are required to adequately perform testing for attribute data. The sample size is based on the Binominal Distribution (as defined below) assuming 99% reliability (process performance) at 95% confidence and with an acceptance number c=0 for Class 0 and Class I defects.

 where:

Pc = The probability of getting “c” defects in “n” samples with “p” percent defectives.

## The “Accept/Reject Numbers” listed below are calculated using the Binomial Distribution function shown above and the AQL’s stated in CP0030, section 4.2.6 for class II and III defects. The calculation for acceptance number “c” assumes 100% inspection, a sample size of n=300 and probability of acceptance of 95% for AQL. The reject number is defined as one number higher than the accept number. Please note the AQL listed below based on CP0030, section 4.2.6 and the “Accept/Reject” numbers truncated to the lower whole number.

**Table 11: Acceptance Criteria n=300**

|  |  |  |
| --- | --- | --- |
| Nonconformity Classification | Accept/Reject Numbers | Minimum required process performance |
| 0 | 0/1 | > 0.99 @ 95% confidence |
| I | 0/1 | 0.99 @ 95% confidence |
| II | 2/3 | 0.975 @ 95% confidence |
| III | 12/13 | 0.935 @ 95% confidence |

## Attribute testing only for cosmetics defects will be performed by the Quality Technician using the sample size shown in Table 10 to comply with the 300-sample size.

## In the event that the criteria for success are not met for this protocol, or any portion of this protocol, root cause and corrective action will be identified, however, analysis and corrective action must be documented under a Nonconformances in EtQ System per 100254122 Rev. 17

### In case there is a defect/rejection related with the changes addressed under this document, this protocol will fail.

### Defects not related to the execution of this protocol will be recorded as observational data but will not affect the outcome of the test.

# Material Disposition

Product used during this Operational Qualification will be disposed as scrap after validation has been completed. All the raw material will be labelled as “Not for Human Use”.

# Deviation Handling

If deviations occur during the execution of this Operational Qualification, they will be handled in accordance with PR-0000089 Rev. 14 Franchise Procedure for Validation (Shared) and documented in the Completion Report PRC097515 Rev A.

# Reference Documents

The following documents are used to develop, to support, or are referenced within this Operational Qualification Protocol.

| Document Number | Document Title | Revision |
| --- | --- | --- |
| CP0030 | Statistical Techniques Procedure | AJ |
| MS00003 | Packaging Defects | BV |
| PRC097511 | Completion Report for Installation Qualification of Automated Label Applier E20172 | A |
| PRC097513 | Completion Report for Software Validation for E20172 Automated Label Applier | A |
| PR001736 | Process Specification for Megadyne Packaging line 174 | Draft |
| 100646188 | Validation Deviation Form | 4 |
| WE0020 | Protocols and Engineering Studies | CH |
| WE0293 | Work Instruction for Packaging Process Validation | AW |
| CP0198 | Manufacturing Process Validation Procedure | BF |
| FRM004256 | Set-up Form for Line 174 | Draft |
| PR001754 | Manufacturing Process Control Plan Megadyne | Draft |
| SPE004695 | Material Specification for Megadyne E-Z Clean Electrosurgical Electrodes | Draft |
| FB003341 | Validation Master Plan for MIMAS project | A |
| TRP001934 | Bulk Packaging | Draft |
| TRP001935 | Sales Unit Packaging | Draft |
| TRP001936 | RSC Final Packaging | Draft |
| TRP001937 | Loading of Components | Draft |
| TRP001944 | Label Applying in Sales Unit Box | Draft |
| SPE004694 | [Finished Goods Specification for Megadyne E-Z CLEAN Electrosurgical Electrodes](javascript:formsubmit('eds_open_generic_open_link?item_handle_param=MTIObjectHandle-0002-1%7ER%7EEbwvytbCinci-u_epipd-xU0%7Ex3SpcDoc%7Eu_epipd%7E%7E&rel_handle_param=&toggle=')) | Draft |
| RMD001679 | [Project MIMAS pFMEA](javascript:formsubmit('eds_open_generic_open_link?item_handle_param=MTIObjectHandle-0002-1%7ER%7EEenpxThCinci-u_epipd-CGa%7Ex3RskMgt%7Eu_epipd%7E%7E&rel_handle_param=&toggle=')) | Draft |
| TR011319 | [Packing area L-174](javascript:formsubmit('eds_open_generic_open_link?item_handle_param=MTIObjectHandle-0002-1%7ER%7EEfilOsjCinci-u_epipd-Eb0%7Ex3AsmTrn%7Eu_epipd%7E%7E&rel_handle_param=&toggle=')) | Draft |
| 100254122 | Franchise Work Instruction for EtQ Nonconformance Process (Shared) | 17 |

# 

# Attachments

The following are appendices to this document.

| No. | Attachment Title |
| --- | --- |
| 1 | Cosmetic Inspection (In document) |
| 2 | Legible Information printed inspection (In document) |
| 3 | Label Location Inspection (In document) |
| 4 | Supporting File 1- I-sheet SPE004694 Draft |
| 5 | Supporting File 2 - Protocol Spanish version per WE0020 |
| 6 | Supporting File 3 – Process Specification PR001736 Draft |
| 7 | Supporting File 4 – Control Plan PR001754 Draft |
| 8 | Supporting File 5 – Set up Form FRM004256 Draft |
| 9 | Supporting File 6 – Bulk Packaging TRP001934 Draft |
| 10 | Supporting File 7 – Sales unit packaging TRP001935 Draft |
| 11 | Supporting File 8 – RSC Final Packaging TRP001936 Draft |
| 12 | Supporting File 9 – Loading of components TRP001937 Draft |
| 13 | Supporting File 10- PFMEA RMD001679 Draft |
| 14 | Supporting File 11- Material Specification SPE004695 Draft |
| 15 | Supporting File 12- I-sheet SPE004694 Draft ESP |
| 16 | Supporting File 13 – Process Specification PR001736 Draft ESP |
| 17 | Supporting File 14 – Control Plan PR001754 Draft ESP |
| 18 | Supporting File 15- Material Specification SPE004695 Draft ESP |
| 19 | Supporting File 16- TRP001944 Label Applying in Sales Unit Box |
| 20 | Supporting File 17- FGQA Results |

# APPENDIX 1 – Cosmetic Inspection

Check the appropriate test result below (Pass or Fail) and add comment if necessary or N/A.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Sample # | Acceptable Package (Pass) or Defective Package (Fail) | Comment | Sample # | Acceptable Package (Pass) or Defective Package (Fail) | Comment |
|  | Pass  Fail |  |  | Pass  Fail |  |
|  | Pass  Fail |  |  | Pass  Fail |  |
|  | Pass  Fail |  |  | Pass  Fail |  |
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| **Function**  (Include on Completion Report Approval Section) | **Name**  (type or print) | **Date Test Cases Complete**  (type or print) | **Signature** |
| **Test Conducted By** |  |  |  |

# APPENDIX 2 – Legible Information printed Inspection

Check the appropriate test result below (Pass or Fail) and add comment if necessary or N/A.

|  |  |  |  |  |  |
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| Sample # | Acceptable Package (Pass) or Defective Package (Fail) | Comment | Sample # | Acceptable Package (Pass) or Defective Package (Fail) | Comment |
|  | Pass  Fail |  |  | Pass  Fail |  |
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|  | Pass  Fail |  |  | Pass  Fail |  |

Batch:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |  |  |  |
| --- | --- | --- | --- |
| **Function**  (Include on Completion Report Approval Section) | **Name**  (type or print) | **Date Test Cases Complete**  (type or print) | **Signature** |
| **Test Conducted By** |  |  |  |

# APPENDIX 3– Label location inspection

Check the appropriate test result below (Pass or Fail) and add comment if necessary or N/A.

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| Sample # | Acceptable Package (Pass) or Defective Package (Fail) | Comment | Sample # | Acceptable Package (Pass) or Defective Package (Fail) | Comment |
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| **Function**  (Include on Completion Report Approval Section) | **Name**  (type or print) | **Date Test Cases Complete**  (type or print) | **Signature** |
| **Test Conducted By** |  |  |  |