# Redesign of the Syringe Inspection Process

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## INTRODUCTION

Drug product presentations manufactured at X-company in 1-mL glass syringes undergo 100% inspection process prior to the final assembly and secondary packaging. Currently, this inspection process is performed using the manual inspection system and the Syringe Automatic Inspection Line. During the manual inspection process inspectors hold four (4) syringes in their hands against white and black backgrounds in illuminated work stations/booths. The inspection is performed at a pre-established pace.

## Objective

In order to minimize inspector contact with the pre-filled syringe, X-Company is in the process of incorporating a syringe inspection holder that will hold up to five 1mL syringes simultaneously for manual inspection. Figure 1 provides an illustration of the proposed holder. Figure 1 shows the empty holder and Figure 2 show the holder loaded with five syringes for inspection.

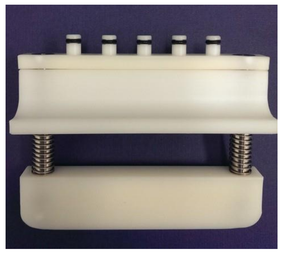

Figure 1
Proposed Holder

Figure 2
Proposed Holder with Syringes

## ANALYSIS

The methodology at the beginning and at the end of the manual inspection process light intensity was measured on each booth following procedure and documented on the corresponding form. The instrument used to measure the light intensity was documented and its calibration verified.

For non-particle defects, the inspection was performed at a pace of sixty (60) seconds per syringe set for one (1) hour, with ten (10) minutes break. For visible particle defects, the inspection was performed at a pace of forty (40) seconds per syringe set for one (1) hour, with ten (10) minutes break. For this test the following tasks will be performed:

- Five (5) syringes were carefully removed from the Tub using the holder.
- The holder (loaded with syringes) was positioned against the white background and black background.
- The stopwatch was activated.
- The Inspection was performed by scanning the syringes from top to bottom.
- After the inspection, the defect detection rate and false reject rates were calculated and compared against the established acceptance criteria.

## Non-particle defects inspection

The following steps for the non-particle defects test with the new tool in the inspection station:

- The syringes were turned by the flange. The holder was rotated on its vertical axis to facilitate the inspection.
- The holder was tilted backward and then forward to inspect the following points: Needle Cone, Needle Shield, Syringe Body, Stopper, Product in or over the stopper and Flange.
- The inspection procedure was repeated against the black background, until completing the established inspection time.

## VISIBLE PARTICLE DEFECTS INSPECTION

The following steps for the visible particle defects test with the new tool in the inspection station:

- The syringes were turned by the flange.
- The holder was tilted sideways as to displace the product inside the syringe and then returned to the upright position.
- The side of the holder was gently tapped to release any particle and/or bubble that may have become adhered to the stopper.
- The visible particle inspection process was repeated against the black background.

## ACCEPTANCE CRITERIA

Tables 1 and 2 present the acceptance criteria used to validate the tool for the non-particle and particle cases, respectively

**Table 2**
**Non-particle defects**

| Non-particle defects: | |
|---|---|
| Critical defects: | 100% defect detection |
| Major Defects: | NLT 90% defect detection |
| Minor Defects: | NLT 85% defect detection |
| False Rejects: | NMT 5% |

**Table 3**
**Visible particle-related defects**

| Visible Particle-related defects: | |
|---|---|
| Defect Detection: | NLT 85% |
| False Rejects: | NMT 5% |

## DEVIATION REPORTS

No deviations were occurred during the protocol execution.

## CONCLUSIONS

The technical protocol was executed without deviations. A total of 36 inspectors (29 packaging and 7 QA inspectors) were evaluated for certification following the methodology established on the Technical Protocol.

Syringes with non-particle defects (152 defects) were evaluated 5,472 times; (2,520 times the critical defects, 2,088 the major defects, and 864 the minor defects). Syringes with visible particle defects were evaluated 540 times (36 times per visual particle defects).

The non-particle defect detection rate met the certification requirements for critical, major and minor defects. The average defect detection rate for Critical non-particle defects was 100%, meaning that inspectors were capable of identifying every critical defect in the test set every single time.

The average defect detection rate on Major defects was 97%, exceeding the protocol's requirement of NLT 90%. The average defect detection rate on Minor defects was 97%, exceeding the protocol's requirement of NLT 85%. The overall detection rate by all the inspectors was 98% for all the Non-Particle defects. This defect detection rate was achieved while maintaining a false rejection rate of 0%, which is significantly below the protocol's recommended false reject rate of NMT 5%.

Syringes with visible particle defects were evaluated 540 times (36 times per visible particle defects). Particle defects were detected 518 times out of the 540 for a 96% overall detection. The overall false reject rate was 1%. The false reject rate by inspector met the protocol's requirement of NMT 5%.

Based on the results obtained during the execution of the Technical Protocol, it is concluded that all the inspectors that were evaluated for certification met the defined acceptance criteria and can be considered certified on the manual inspection using the manual holder. In the next graphic show the increment in the production by shift.