Title: Visual Inspection of Product

SOP Number: 22925

Revision Number: 03

Supersedes: Revision 02

Effective Date: AUG 02 2019

Originator/Date: [redacted]

Approval/Date:

Approval/Date:

Table of Contents

1.0 Purpose

This procedure describes the method for visual inspection of product.

2.0 Scope

This SOP specifies BOP requirements for the visual inspection of product. Biopharmaceutical Quality Control (BQC) personnel will perform these inspections. This procedure would apply to bulk, liquid, frozen, or lyophilized products.

3.0 Authority and Responsibility

3.1 The Process Analytics (PA) Technical Lead has the authority to define this procedure.

3.2 PA and Technical Operations personnel are responsible for the performance *ct* this procedure and documenting training on this procedure to Biopharmaceutical Quality Assurance (BQA).

3.3 PA and Technical Operations are responsible for reviewing the data and documentation of the results of this procedure.

3.4 BQA is responsible for quality oversight of this procedure.

4.0 Procedure

NOTE: This section outlines the information needed on Product Inspection Forms 22925- 01 (for vialed, bottled, bagged, boxed, or device-based products) or 22925-02 (used with IV-bagged patient-specific products). Products must be stored and handled in an approved manner to avoid product deterioration.

4.0 General Information

4.0.1 Record header fields on Form 22925-01 (Attachment 1) or Form 22925-02 (Attachment 2), as appropriate, including: Product name, Project No., Lot No., Storage Temperature, Number of Container(s) to be inspected, and Type/Description of container(s) on form. All information should be available on the QC Test request form submitted with the sample and the sample container itself.

NOTE: Do not record patient names or patient-specific identifiers on the Form.

4.0.2 Type/Description of container(s) should include manufacturer (if available), size, and fill volume.

4.0.3 If multiple containers of the same lot are submitted for testing, only one form is necessary. If there is a failure, separate forms must be filled out for all containers received.

4.1 Container Integrity

4.1.1 Bags: Inspect bag for evidence of tears or cracks. Inspect tubing for pliability and evidence of deterioration and inspect ends of tubing for caps. Record observations and/or anything unusual in the Comments section.

4.1.2 Bottles/Vials: Inspect for cracks, evidence of deterioration, and that the cap/crimp is securely closed. Record observations and/or anything unusual in the Comments section.

4.2 Lyophilized Product or Frozen Products

4.2.1 If the final product is not lyophilized or frozen, draw a line through the entire section and Initial/Date with N/A.

4.2.2 Record the color of the lyophilized product (cake) or frozen product.

4.2.3 Record whether product is uniform in color and texture. This does not apply to frozen products (N/A).

4.2.4 Document that the cake is not compressed or collapsed. This does not apply to frozen products (N/A).

4.2.5 Document Reconstitution Time (Lyophilized) or record how frozen product is to be thawed (place out at room temperature or water bath).

4.3 Clarity of Solution

4.3.1 Soluble product in liquid formulation must be free from any particulate matter by visual inspection. Swirl container and observe against white and dark background. Record the presence or absence of particles or anything unusual in the Comments section.

4.3.2 Note any opaqueness and/or tint of the fluid in the container. Record observations and/or anything unusual in the Comments section.

4.3.3 Note any turbidity (cloudiness) of the fluid in the container. Record observations and/or anything unusual in the Comments section.

4.4 Container Label

4.4.1 Confirm that each unit is labeled correctly and is securely applied. Record observations and/or anything unusual in the Comments section.

4.4.2 Confirm that required patient identifiers are on the labels if applicable.

4.5 Final Conclusion

4.5.1 A general statement will be provided about the overall appearance of the product. This may be worded to fit the product specification as appropriate.

4.6 Analytical Testing

4.6.1 Product release and stability testing shall be performed by PA personnel according to the requirements specified in the approved protocol. One sample may be used for several assays; however, visual inspection should be performed before aliquots are removed.

5.0 Acceptance/Release Criteria

5.1 Acceptance criteria are described on the product Assay Profile/Master Specifications or according to the product Stability Protocol.

5.2 Original Container

5.2.1 Products should meet all specifications for the visual inspection.

5.3 Secondary Container or Aliquot

5.3.1 Should material need to be transferred to secondary container in order to conduct the visual inspection, it is recommended that this procedure should be “For Information Only” (FIO) analysis. Should a failure occur, it cannot be determined if it was due to the “secondary” container.

5.4 Product or containers which fail visual inspection require an Out-of-Specification investigation be performed per ***SOP 22004, Managing Out-of-Specification Test Results or Unexpected Test Results***.

5.5 A digital picture will be taken for all products that fail visual inspection and be included with the test documentation.

6.0 Documentation

6.1 Document Product Inspection using Form 22925-01 (Attachment 1) or 22925-02 (Attachment 2).

This procedure is made available through federal funds from the National Cancer Institute, NIH, under contract HHSN261200800001E.

6.2 Attach the completed Product Inspection Form 22925-01 (Attachment 1) or 22925-02 (Attachment 2) (with digital picture[s] should a failure occur) to the QC Request Form (22002-01) and forward to PA for review.

NOTE: Do not include the patient name or patient-specific identifiers in the digital picture.

7.0 Material Disposition

7.1 Upon completion of testing, all samples shall remain under quarantine in the appropriate storage unit as determined by BQC accessioning per ***SOP 22007, Discarding QC Samples After Testing***.

8.0 References and Related Documents

8.1 **SOP 22002** *Request for Quality Control Testing*

8.2 **SOP 22004** *Managing Out-of-Specification Test Results or Unexpected Test Results*

8.3 **SOP 22007** *Discarding QC Samples After Testing*

9.0 Attachments

9.1 **Attachment 1** Form 22925-01, Product Inspection
9.2 **Attachment 2** Form 22925-02, IV-Bag Patient Specific Product Inspection

This procedure is made available through federal funds from the National Cancer Institute, NIH, under contract [redacted]

Attachment 1

Product Inspection

FNLCR
Form No.: 22925-01
SOP No.: 22925
Revision 03: AUG 02 2019

Product Inspection

Product: _____ Project No.: _____

Lot No.: _____ Storage Temperature: _____

Number of Containers Inspected: _____ QC Test Request #: _____

Type/Description of Container(s): _____

_____

Attributes	Criteria	Circle	Comments
Container Integrity	• No tears or cracks	Pass / Fail / NA	
	• No deterioration detected	Pass / Fail / NA	
	• Sealed and capped/crimped properly	Pass / Fail / NA	
Lyophilized Product or Frozen Products	Color	Pass / Fail / NA	
	Uniformity	Pass / Fail / NA	
	Not Compressed or Collapsed	Pass / Fail / NA	
	Reconstitution Time/Thawing Procedure	Pass / Fail / NA	
Clarity of Solution	Particulates or foreign matter	Pass / Fail / NA	
	Opaqueness or tint	Pass / Fail / NA	
	Turbidity / Cloudiness	Pass / Fail / NA	
Label	Labeled correctly and securely applied	Pass / Fail / NA	

Final Conclusion: _____

Inspected By: _____ Date: _____

Reviewed By: _____ Date: _____

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Attachment 2

IV-Bag Patient Specific Product Inspection

FNLCR
Form No.: 22925-02
SOP No.: 22925
Revision 03: AUG 02 2019

IV-Bag - Patient Specific Product Inspection

Product: _____ Project No.: _____

Lot No.: _____ Storage Temperature: _____

Number of Containers Inspected: _____ QC Test Request #: _____

Type/Description of Container(s): _____

_____

Attributes	Criteria	Circle	Comments
Container Integrity	• No tears or cracks	Pass / Fail / NA	
	• No deterioration detected	Pass / Fail / NA	
	• Sealed and capped/crimped properly	Pass / Fail / NA	
Label	• Clear and unique identification on IV bag labels	Pass / Fail / NA	
	• Patient specific information on bags	Pass / Fail / NA	

Final Conclusion: _____

Inspected By: _____ Date: _____

Reviewed By: _____ Date: _____

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