SOP Title: **Visual Inspection of Product**
SOP Number: **22925**
Revision: **04**

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1. PURPOSE

This procedure describes the method for visual inspection of product.

2. 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. RESPONSIBILITIES

3.1 Technical Lead / Process Analytics (PA)

- Defines the procedure.

3.2 PA and Technical Operations personnel

- Trains personnel.
- Performs procedure.
- Reviews data.

3.3 Biopharmaceutical Quality Assurance (BQA)

- Provides quality oversight.

4. PROCEDURE

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

4.1 General Information

4.1.1 Record header fields on **Form 22925-01** or **Form 22925-02**, 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.

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

4.1.3 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.

4.2 Container Integrity

4.2.1 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.

4.2.2 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.

4.3 Lyophilized Product or Frozen Products

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

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

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

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

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

4.4 Clarity of Solution

4.4.1 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.

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

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

4.5 Container Label

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

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

4.6 Final Conclusion

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

4.7 Analytical Testing

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. 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

Products should meet all specifications for the visual inspection.

5.3 Secondary Container or Aliquot

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 Result**s.

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

6. MATERIAL DISPOSITION

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.**

7. DOCUMENTATION AND RECORDS

7.1 Document Product Inspection using **Form 22925-01** or **Form 22925-02**.

7.2 Attach the completed Product Inspection **Form 22925-01** or **Form 22925-02** (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's name or patient-specific identifiers in the digital picture.

8. REFERENCES AND RELATED DOCUMENTS

Document Number	Title
22002	Request for Quality Control Testing
22002-01	QC Request Form
22004	Managing Out-of-Specification Test Results or Unexpected Test Results
22007	Discarding QC Samples After Testing
22925-01	Product Inspection
22925-02	IV-Bag Patient Specific Product Inspection