

The University of Iowa Dezii Translational Vision Research Group

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TITLE: Raw Material and Packaging Component Specification Sheets

SOP Number: D-GLO-PRO-015

Revision Number: 0

Effective Date: 09 Aug 2015

- d. Purchasing specifications will be listed. These specifications may include, but are not limited to: requirement for a certificate of analysis / compliance (if the material is to be used in the manufacture or packaging of an HCT/P or GT product), a requirement that the entire shipment have the same lot number, requirement that the item ordered matches the item description in LabGuru, minimum expiration/retest dating for the material, a requirement that a Material Safety Data Sheet be on file or supplied with the shipment, if it is a chemical, and a requirement that a BSE/TSE statement be supplied with each lot or be on file.
6. Upon Receipt of the product QA will inspect using the following receiving specifications.
 - a. Inspection - All incoming materials will be subject to an inspection which will be a visual examination of shipping container(s) for integrity and proper labeling. If the incoming goods appear to have damage an incident report must be created following SOP D-GLO-PRO-013.
 - b. If materials are received with a temperature tail, DTVR personnel will return the tail to the sender and request confirmation that the shipment did not exceed the range required. Special storage conditions will be noted.
 - c. Incoming materials purchased by DTVR shall be matched to their respective purchase order in LabGuru. If the purchase orders do not match, check with purchasing to determine if it is the correct material or needs to be returned.
 - d. QA personnel will obtain a specification sheet, if available, for each material. The QA Officer shall verify that each material's expiration date (if preset) meets the specification sheet.
 - e. QA will examine container labels for special storage conditions. If there is no SDS on hand, the manufacturer will be contacted and a request submitted for the SDS. If the SDS is not available, the materials will be sampled in a controlled environment.
 - f. Update LabGuru Material name, Item no., quantity received, date received, Vendor name, and Manufacturer lot no.
 7. QA will release the product to the DTVR using the following release specifications.
 - a. For raw materials a C of A may be required prior to release. If the C of A does not arrive with the shipment, then the QA Officer will contact the manufacturer to obtain the C of A. The certificate will be entered into LabGuru when it arrives.
 - b. Refer to forms F-GLO-PRO-012 and F-GLO-PRO-013 to verify that a BSE/TSE statement is required. If a BSE/TSE statement is required and is not present on the C of A, for DTVR ordered material, then the QA Officer will contact the manufacturer to obtain the BSE/TSE statement. The BSE/TSE statement will be entered into LabGuru when it arrives.
 - c. When materials do not have compendial specifications, the raw material specification sheet will be compared to documentation supplied to DTVR by the manufacturer.
 - d. Approved or Rejected labels will be generated based on all results of quality control inspection testing.
 - e. For materials that can be dispensed directly from the primary container, then one label is to be made for each container of material.
 - f. For materials that are packaged in cardboard boxes with separate packages inside the boxes, one label is to be placed on the outside of the cardboard box for storage in the DTVR storage area, and a second label placed on the separate packages inside the cardboard boxes in order to have a release label on the items that will be taken out of the original container for transferring the materials into production.

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Approved Label Text

- 7.1 Name of material
- 7.2 Raw material lot number
- 7.3 Item Number
- 7.4 Repass Date

Rejected Label Text

- 7.5 Name of material
- 7.6 Raw Material lot number
- 7.7 Manufacturer's/supplier's name
- 7.8 Manufacturer's/Supplier's lot number
- 7.9 Date Received
- 7.10 If lot was sampled

- 8. Once the Quality Assurance review is completed, approved raw materials will be moved the QA officer to the appropriate location within the DTVR.
- 9. Rejected materials will be clearly marked and moved to an appropriate area until their disposition is determined.

E. History

Effective Date	Revision	Change
09 Aug 2015	0	Original document