DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
109 Holton Street Winchester, MA 01890 (781)587-7500 Fax:(781)587-7556	12/10/2025-12/22/2025* FEI NUMBER 3010785603

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Stephen Conlon, Plant Manager

FIRM NAME	STREET ADDRESS
Ashland Specialty Ingredients, G.P.	535 Main St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Fiskeville, RI 02823	Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Procedures for design verification have not been adequately established.

Specifically, the firm's *Design Controls Procedure, QP-09*, states, "The Design Verification process confirms that the (b) (4) " *Design Input, DIP-012,* identifies the Dose-map Blood Irradiator Dosimetry System's expiration date as 55 days past cassette assembly; however, the *Dose-map Film Aging Study*, dated 6/14/2023, only analyzed the effect of film aging on central dose measurements up to (b) (4) days after radiation exposure. Additionally, justification for the sample size of (b) (4) pieces of film from one lot was not documented. The Dose-map Blood Irradiator Dosimetry System is intended to measure the radiation dose administered by blood irradiators to ensure these devices deliver the correct dose when irradiating blood products.

OBSERVATION 2

Procedures for design input have not been adequately established.

Specifically, the firm's Design Control Procedure, QP-09, states, "The design input shall ensure that the design requirements relating to a device are appropriate and address the intended use of the device, including the needs of the user and patient, if applicable." However, documentation of design inputs for the Dose-map Blood Irradiator Dosimetry System are incomplete; as such, essential design outputs are

AMENDMENT 1

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	Sara M Onyango, Investigator X Sara M Onyango Investigator Signed By: SARA M. ONYANGO - S Date Signed: 12-23-2025 08:07:44	12/23/2025

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not adequately defined, and design validation has not been performed. For example, *Design Input, DIP-012*, Rev 1, effective 5/2/2023:

a)Does not address the need for a watertight seal, despite the Quality Manager stating this is a requirement for product functionality, as the device is submerged in water during use and the film inside the cassette must remain dry.

b)Does not address device accuracy, despite the intended use of the device being to verify the radiation dose delivered by a blood irradiator.

OBSERVATION 3

A process whose results cannot be fully verified by subsequent inspection and test has not been adequately validated according to established procedures.

Specifically, the operational and performance qualifications for the (b) (4), used to assemble the Dose-map cassette, are inadequate per the following:

a)The number of units tested within the Operational Qualification Report - (b) (4) (b) (4) (OQR-002) was not defined, nor was raw data available for review. OQR-002 identifies the (b) (4) on the (b) (4) was set to "(b) (4)" during the qualification but the setting defined within the *Dose-map Cassette Assembly and Labelling Procedure, WI-11-007* is "(b) (4)" A justification was not documented for why revalidation at the lower (b) (4) setting is not required.

b)The rationale for the sample size of (b) (4) Dose-map cassettes was not documented within the Qualification/Verification Protocol (PQP-013) or Report (PQR-013) or otherwise justified. Furthermore, the raw data documenting the Dose-map cassette's visual inspection on (b) (4) cassettes was not made available, the acceptance criteria for this inspection was not defined, and a justification for why objective (b) (4) testing methods were not performed or required was not documented.

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OBSERVATION 4

Procedures for corrective and preventive action have not been adequately established.

Specifically, the investigations, corrective actions, and/or verifications of effectiveness for six closed CAPAs reviewed were inadequate according to the firm's CAPA Process Procedure, WI-20-001, Rev 2, effective 05/31/2023 per the following:

i. The investigation for CAPA 23-003, initiated 3/17/2023 after becoming aware that the Dose-map process was not running consistent with defined parameters, identified that the affected film lot (#(b) (4)) may not have received (b) (4) treatment at the time of manufacture, possibly contributing to film delamination; however, the CAPA did not document the basis for this conclusion, such as review of batch records or interviews with operators. Furthermore, the corrective actions and verification of effectiveness did not address the (b) (4) treatment process.

ii. CAPA 23-017, initiated 9/27/2023 after becoming aware that the (b) (4) test method was not validated, identified that the root cause was "oversight for the need to validate this process…"; however, the corrective actions did not consider or evaluate other processes which may require validation. The (b) (4) measures the (b) (4) content of wet laminated films including MD-V3—which is incorporated into the Dose-map device.

iii. The effectiveness check for CAPA 23-007, initiated 3/31/2023 to address environmental monitoring in storage conditions, did not include a plan or acceptance criteria, nor did it include evidence that storage temperatures recorded by data loggers were reviewed following the completion of all corrective actions.

iv. An executed action within CAPA 23-005, initiated 3/30/2023 to address the supplier evaluation process, identifies that reference document QP-23 was created to generate an internal procedure specific for evaluation and re-evaluation of suppliers; however, review of supplier files during the current inspection revealed that a critical supplier providing the base material for gafchromic films—including the MD-V3 which is incorporated into Dose-map—was incomplete per QP-23, Supplier Management – Ashland Diagnostic Films Group.

v. The verification of effectiveness for CAPA 23-010, initiated 5/17/2023 to address

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distribution of RTQA2 and EBT3 film lots which were part of an ongoing validation states, "All further actions that are identified will be tracked through the continual improvement project" without defining acceptance criteria or evidence of a completed effectiveness check.

vi. The verification of effectiveness for CAPA 24-002, initiated 2/21/2024 after becoming aware that all applicable regulatory requirements were not covered during the firm's 2023/2024 internal audit cycle states, "None required" without further justification.

OBSERVATION 5

Procedures for the control of storage areas and stock rooms have not been adequately established.

Specifically,

a)The *Environmental Control - Storage Areas Work Instruction, WI -06-002*, Rev 1, effective 3/19/2024, does not specify the temperature range within the firm's storage areas, including the Drying Room which stores in-process materials, and the Tent, which stores **gafchromic films, including the MD-V3 which is incorporated into** finished Dose-map devices. However, the Quality Manager stated that the temperature of these areas should be less than 25 °C, identified as the storage requirement within the device's Instructions for Use.

b)The firm could not provide evidence that temperature data recorded by data loggers within the firm's storage areas have been reviewed. Data logger (b) (4) recorded temperature excursions within Fridge (b) (4) from 4/14/2023 – 4/18/2023; however, these temperature excursions were not evaluated.

OBSERVATION 6

A device history record has not been adequately maintained.

Specifically, six of six device history records reviewed for the Dose-map Blood Irradiator Dosimetry System did not include or refer to the location of the primary identification label.

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***DATES OF INSPECTION**
12/10/2025(Wed), 12/11/2025(Thu), 12/12/2025(Fri), 12/17/2025(Wed), 12/18/2025(Thu), 12/22/2025(Mon)

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Annotations to Observations

Observation 1: Promised to correct

Observation 2: Promised to correct

Observation 3: Promised to correct

Observation 4: Promised to correct

Observation 5: Promised to correct

Observation 6: Promised to correct

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."