

**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION**

<small>DISTRICT ADDRESS AND PHONE NUMBER</small> New England District Office One Montvale Ave. - 4 <sup>th</sup> Floor Stoneham, MA 02180 Ph. 781-587-7500 ORAPharm1_responses@fda.hhs.gov Industry Information: <a href="http://www.fda.gov/oc/industry">www.fda.gov/oc/industry</a>	<small>DATE(S) OF INSPECTION</small> 05/26/2021-07/06/2021*
	<small>FET NUMBER</small> 3012063246

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED  
 Mr. David YY. Light - CEO

<small>FIRM NAME</small> Valisure, LLC	<small>STREET ADDRESS</small> 5 Science Park
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<small>CITY, STATE, ZIP CODE, COUNTRY</small> New Haven, CT 06511 USA	<small>TYPE ESTABLISHMENT INSPECTED</small> Analytical Lab
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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.

**DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:**

**Laboratory System**

**OBSERVATION 1**

**The firm failed to adequately validate and/or verify analytical methods used in the evaluation of pharmaceutical products in that the firm failed to document the validation/verification process, acceptance criteria, and an evaluation of the validity of the method outlining its intended use.**

For example,

**(A). Inductively Coupled Plasma Mass Spectrometry (ICP-MS Test) PR-021 R1 (Verification of USP <233> Elemental Impurities):**

(a). Method Verification did not include justification for the removal of contaminants by (b) (4) (b) (4) Furthermore, there is no mention of (b) (4) (b) (4)

(b). Method Verification did not include an evaluation of the sample (b) (4) for a variety of pharmaceutical dosage forms (i.e., capsules, liquids, semi-solids).

(c). Method Verification did not include accuracy, precision, specificity, limit of quantitation, range, and linearity.

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(d). Method Verification did not include the outlined system suitability criteria. Furthermore, the ICP-MS Test does not include the USP <233> system suitability requirement prior to analysis.

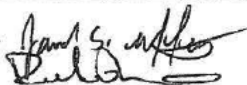
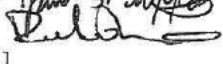
(e). On 01/13/2021, the firm had analyzed a sample of (b) (4) (b) (4) for Elemental Impurities, the laboratory identified an Out-of-Specification result for Lead at 17.749ppb (1.7µg lead/tablet, maximum adult dose 13.6µg lead/day) exceeding the firm's specification of (b) (4). On 01/14/2021, the firm had re-analyzed this sample in triplicate using a new sample preparation using (b) (4) (b) (4). The analysis confirmed the Lead results at 17.0 ppb. This process of using (b) (4) (b) (4) in order to rule out lead contaminated glass was not verified and/or validated.

**(B). Gas Chromatography Mass Spectrometry (GC-MS) Impurity Test – Nitrosamines PR-018 R4 (Verification of U.S. FDA Method: Combined N-Nitrosodimethylamine (NDMA) and Nitrosodiethylamine (NDEA) Impurity by (b) (4) in Valsartan Drug Substance or Drug Product):**

(a). Method Verification was performed on the Valsartan Drug Product for NDMA and NDEA impurities; however, the current method, PR-018 R4 is used to analyze a variety of drug products and dosage forms for the following impurities: NDMA, NDEA, N,N-Dimethylformamide (DMF), N-Nitrosoethylisopropylaminalar (NEIPA), N-Nitrosodiisopropylamine (NDIPA), and N-Nitrosomethylethylamine (NMEA). There was no documented validation process for analyzing the additional impurities on other drug products.

(b). Method PR-018 R4 contains no system suitability requirement as outlined within the FDA Method, which states the correlation coefficient (R) of the linear calibration curves should be ≥ 0.995.

**(C). Liquid Chromatography High Resolution Mass Spectrometry (LC-HRMS) Impurity Test PR-020 R1, which is a Verification of U.S. FDA Method: Liquid Chromatography – Electrospray Ionization – High Resolution Mass Spectrometry (LC-ESI-HRMS) Method for the Determination of Nitrosamine Impurities in Metformin Drug Substance and Drug Product:**

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(a). Method Verification was performed on Metformin Drug Product for impurities NDMA, NDEA, NMBA, NEIPA, N-nitrosodibutylamine (NDBA), DMF and N,N-diethylformamide (DEF); however, the FDA method only listed the following impurities NDMA, NDEA, NEIPA, NDIPA, NDPA, NMPA, NDBA and NMBA. There was no documented validation process for analyzing the additional impurities on other drug products.

(b). There was no validation/verification report as of the time of the inspection (May 26, 2021). The method has been routinely used since it's approval on 3/5/2020.

(c). Method PR-020 R1 contains no system suitability requirement as outlined within the FDA Method (%RSD of peak area for each nitrosamine impurity for the first six injections NMT 10% and cumulative %RSD of the peak area for each nitrosamine impurity NMT 15%).

**(D). Gas Chromatography Mass Spectrometry (GC-MS) Impurity Test – Residual Solvent PR-024 R0, which is a Verification of U.S. FDA Test Method: Direct Injection Gas Chromatography Mass Spectrometry (GC-MS) Method for the Detection of Listed Impurities in Hand Sanitizers; and USP <467> Residual Solvents:**

(a). Method Verification was performed on hand sanitizers and sunscreen products for the following impurities: Methanol, Benzene, Acetaldehyde and 1,1-diethoxyethane (Acetal); however, there was no verification report(s) for the analytical activities used to analyze Benzene via (b) (4) under USP <467> Residual Solvents and Methanol, Acetaldehyde, and Acetal via (b) (4) under the U.S. FDA Method. The firm's method was approved for routine use on March 24, 2021.

(b). Method PR-024 R0 contains no system suitability requirements as outlined within the FDA Method – Direct Injection, which states, %RSD of peak area for each listed impurity for all injections of standard solution NMT 10% and USP <467> Headspace Method, which states, S/N ratio for 1,1,1-trichloroethane in the Class 1 standard solution is NLT 5, the S/N of each peak in the Class 1 system suitability solution is NLT 3, and the resolution between acetonitrile and methylene chloride in in the Class 2 mixture A standard solution in NLT 1.0.

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c). Method PR-024 R0 does not require calibration daily or per use. According to the firm the GC-MS will be recalibrated (b) (4)

(E). High Performance Liquid Chromatography (HPLC) Test – Dosage PR-017 R3 (Verification of HPLC Dosage Test was conducted using the USP Monograph for selected product Active Ingredient):


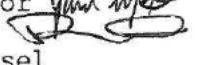
(a). The HPLC Method for Dextromethorphan Soft Gels Capsules was inconsistent with Dextromethorphan Bromide USP Monograph. The USP Monograph requires that the Mobile Phase be Docusate Sodium and Ammonium Nitrate in Acetonitrile and water (70:30); the UV Detector be set at 280nm; and the system suitability with a tailing factor of NMT 2.5 and RSD NMT 2.0% for the standard solution. However, the firm's method uses a Mobile Phase (b) (4) (b) (4)

and there is no system suitability requirement. There was no documented validation process for these changes to the USP Monograph. This method was used to analyze (b) (4) Dextromethorphan Soft Gel Capsules (lot number (b) (4))

(b). The HPLC Method for Fexofenadine Hydrochloride Tablets was inconsistent with USP Monograph in that the firm used an (b) (4) for Fexofenadine Hydrochloride Tablets and the method does not have a system suitability requirement. The firm failed to verify equivalency- of the (b) (4) and HPLC. Furthermore, according to the firm, analysts will conduct (b) (4) in order to demonstrate the system is suitable for a run. This method was used to analyze (b) (4) Allergy Relief Tablets (lot numbers (b) (4) and (b) (4)).

The above-mentioned methods are used routinely in Valisure, LLC's certificate program.

**OBSERVATION 2**

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**The firm's equipment qualification program is inadequate.**

For example,

The following Instrumentation used in analytical testing of pharmaceutical drug products have not been fully qualified.

Instrument Name	Manufacturer	Model Number	ID Number
(b) (4)	(b) (4)	(b) (4)	(b) (4)
(b) (4)	(b) (4)	(b) (4)	(b) (4)
(b) (4)	(b) (4)	(b) (4)	(b) (4)
(b) (4)	(b) (4)	(b) (4)	(b) (4)
(b) (4)	(b) (4)	(b) (4)	(b) (4)

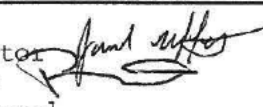
(a). The firm failed to perform or document IQ/OQ/PQ on their (b) (4) (b) (4) (b) (4). In addition, the firm did not establish an IQ/OQ/PQ protocol. The (b) (4) (b) (4) are used to perform NMDA, NDEA, DMF, and Benzene analytical testing.

(b). The firm failed to perform PQ for their (b) (4) used in Elemental Impurities Testing.

(c). The firm failed to perform OQ/PQ for their (b) (4). Additionally, the Quality unit did not sign off on the IQ "Installation and Customer Familiarization Procedure" and failed to have documentation that the IQ was assessed. The (b) (4) is used to perform NDMA, NDEA, NDIPA, NEIPA, NMBA, NDBA, DMF, and DEF analytical testing.

(d). The firm failed to establish a requalification frequency for their (b) (4) since original installation in 2019. The (b) (4) is used to perform Dosage Testing

**OBSERVATION 3**

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**The firm has failed to adequately control data access within analytical equipment used for the analysis of pharmaceutical products.**

For example,

The (b) (4), (b) (4), (b) (4), (b) (4), and the (b) (4), (b) (4) have no controlled access (i.e. no passwords required). Furthermore, each analyst has administrative access to these systems.

**Quality System**

**OBSERVATION 4**

**The firm's laboratory investigations are inadequate.**

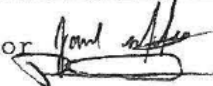
For example,

The firm's process for laboratory discrepancies and investigations is inadequate in the fact that the firm has had at least 45 out-of-specification events and failed to perform any documented Investigations from 06/07/2019-06/02/2021. In addition, the firm does not have an SOP instructing an employee to open an investigation when products do not meet their specifications.

**Drug Supply Chain Security Act**

**OBSERVATION 5**

**There are no systems in place to enable compliance with the requirements of the Food Drug and Cosmetic Act Section 582(c)(A) & (B) and (d)(A) & (B). Your firm has none of the verification**

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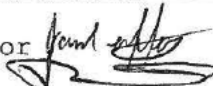

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**systems required by the Drug Supply Chain Security Act (DSCSA). When asked, your firm stated that it had not previously heard of the DSCSA.**

Specifically,

(a). Valisure has operated a pharmacy and wholesale distributor business which places them within the DSCSA definition of a trading partner (dispenser and wholesale distributor) and subjects them to the applicable requirements for those trading partners in the DSCSA. Under the DSCSA, covered product in the possession or control of a wholesale distributor or dispenser which is determined by that person to be a suspect product must be placed into quarantine and not processed further until a determination is made that the product is either cleared or illegitimate. In addition, when a product is determined to be a suspect product, prompt investigations must be conducted in coordination with trading partners, including validating the transaction history and transaction information. There is no documentation demonstrating that your firm appropriately identified products potentially subject to rejection by your laboratory as suspect products in your system(s). Examples include but are not limited to the following products: Bupropion XL lot NB900240 and Metformin lot MTSB19003-A. This Metformin lot was tested in September 2019. When the test results indicated that the lot may be rejected by the Valisure laboratory, your firm decided to reverse distribute the lot. In these examples, when initial laboratory testing showed that product potentially could be subject to rejection by your laboratory, your firm determined such product to be a suspect product when it concluded there was reason to believe that the product was unfit for distribution. In these situations, and others, your firm failed to coordinate with trading partners and conduct a robust investigation. In addition, your firm has no systems in place for determining and identifying a product as a suspect product in your system(s), and for quarantining and investigating suspect products generally.

(b). Your firm could not provide documentation that product rejected by the Valisure laboratory was appropriately identified as illegitimate in your system(s) and that the DSCSA verification

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requirements were complied with. Examples include but are not limited to the following products: Valsartan lot EVF804A and Metformin lot AM180405A. When additional testing by your lab resulted in Valisure's rejection of the lots, the lots at issue were identified as illegitimate because your firm had credible evidence that such product was unfit for distribution. Your firm was then required to make a determination, in coordination with the manufacturer, that the suspect products were illegitimate. Your firm was unable to provide evidence that the lots were appropriately identified as illegitimate in your system or that you sought to coordinate with the manufacturer on making the determination that those products were illegitimate. In addition, there is no documentation demonstrating that your firm has systems in place to identify illegitimate product in your system(s), and for quarantining and dispositioning illegitimate products generally.

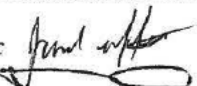

(c). Trading partners must also have systems in place to retain samples of illegitimate product at the request of the manufacturer or FDA. Your firm indicated that Valisure has no such procedures..

**OBSERVATION 6**

**Trading partners must have systems in place to make a notification of illegitimate product to FDA and immediate trading partners within 24 hours after making such a determination. There is no documentation to indicate that your firm has such procedures. Furthermore, your firm failed to make timely (within 24 hours) notifications to immediate trading partners or FDA once your firm became aware that it was in possession of an illegitimate product.**

Specifically,

(a). Your firm did not notify FDA within 24 hours after tests confirmed that product in your possession or control would be rejected by Valisure and was illegitimate product. Your firm has not filed nor submitted the required FDA 3911 form "Drug Notifications" via the established FDA mailbox in such cases. Examples include but are not limited to Metformin lot AM180405A and Valsartan lot EVF804A.

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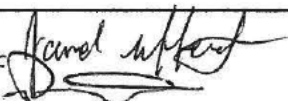

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(b). While your firm did notify some manufacturers when certain lots were rejected by your laboratory, your firm failed to identify such drug product as illegitimate in those notifications. In addition, your firm failed to notify the wholesale distributors from whom Valisure acquired the product within 24 hours after tests confirmed that product in your possession or control was illegitimate product. Examples include but are not limited to Metformin lot AM180405A and Valsartan lot EVF804A.

(c). After (b) (4) were conducted on Metformin lot AM180405A on February 23, 2020, the product was rejected by your laboratory for containing levels of NDMA above the acceptable (b) (4). At that time, your firm decided that the lot would not be dispensed or distributed and that it was to be sent to a reverse distributor. Your firm notified the manufacturer of the rejected Metformin lot in a March 2, 2020 letter but did not notify the manufacturer that the product was illegitimate product under the DSCSA. FDA was made aware of the issue with the product through a citizen's petition your firm filed with the Agency on March 2, 2020, rather than the required FDA Form 3911 for reporting illegitimate products to FDA. The citizens petition did not identify the product as an illegitimate product. The wholesale distributor from whom your firm purchased the lot was effectively notified at the same time and in the same manner as FDA.

**\*DATES OF INSPECTION**

05/26/21, 05/27/21, 6/1/21, 6/2/21, 6/3/21, 6/4/21, 6/7/21, 6/8/21, 6/9/21, 6/17/21, 7/6/21

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