DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	4/20/2026-4/27/2026*
	FEI NUMBER 1000110034

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jure Batur, CEO

FIRM NAME	STREET ADDRESS
Similasan AG	Chriesiweg 6
CITY, STATE, ZIP CODE, COUNTRY Jonen, Aargau, 8916 Switzerland	TYPE ESTABLISHMENT INSPECTED Homeopathic Pharmaceutical 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.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Determinations of conformance to appropriate written specifications for acceptance are deficient in that they are not made for each lot within each shipment of components used in the manufacture, processing, packing or holding of drug products.

Specifically, (b) (4) used in homeopathic formulations are not tested at raw material stage and/or at finished product stage for (b) (4) test to demonstrate their suitability for intended use.

The site manufactures numerous homeopathic formulations (including but not limited to (b) (4) (b) (4) using (b) (4) On 4/23/2026, the QA Manager stated these (b) (4) are not tested for (b) (4) test when received at the site. The QA Manager confirmed the firm does not test (b) (4) (Finished Products) for (b) (4) test as well.

OBSERVATION 2

Your firm failed to establish adequate written procedures for production and process controls designed to assure that the drug products have the identity, strength, purity, and quality that they are purported or represented to possess.

Specifically, process validation performed as per Validation Report QUAL VAL 124124 (effective date

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Matthew B Casale, Investigator - Dedicated Drug Cadre Saleem A Akhtar, Investigator	X Matthew B Casale Investigator - Dedicated Drug Cadre Signed By: Matthew B. Casale -S Date Signed: 04-27-2026 10:40:52	4/27/2026

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6/27/2023) for (b) (4) products including (b) (4) (b) (4) is deficient as the batch size of the validation batches is not representative of the commercial batch size. For example:

The process validation was performed by manufacturing (b) (4) batches using (b) (4) material code (b) (4) and by manufacturing (b) (4) other batches using (b) (4) material code (b) (4) The batch size of all (b) (4) validation batches was (b) (4) each.

However, the review of the Master Batch Records of (b) (4) products indicated the commercial batch size ranges from (b) (4) to (b) (4). For example, in June 2025, the firm manufactured (b) (4) (b) (4) batch (b) (4) batch size (b) (4). The firm's Master Batch records allow the commercial batch size up to (b) (4). The firm failed to perform process validation studies covering the upper batch size range i.e., (b) (4) to demonstrate process robustness.

Additionally, following deficiencies were observed in Room (b) (4) that was being used for (b) (4) (b) (4) for (b) (4) batch (b) (4)

A. Some of the (b) (4) were not (b) (4) step that is performed in the (b) (4) were observed (indicating (b) (4) material inside) at the (b) (4) step.

B. After (b) (4), the (b) (4) are transferred into the (b) (4) bags for (b) (4) (approximately for (b) (4) It was observed the (b) (4) were not (b) (4)

After (b) (4), the (b) (4) are filled and packed for commercial distribution.

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OBSERVATION 3

Routine checking of mechanical and electronic equipment is not performed according to a written program designed to assure proper performance.

Specifically, adequate controls are not exercised over filling machine (equipment ID: (b) (4) that is used to fill numerous homeopathic formulated drugs including but not limited to (b) (4) (b) (4) (b) (4) for the US market.

The filling machine (b) (4) was qualified at the filling speed of (b) (4) units (b) (4) The filling speed can be modified by the manufacturing personnel. The machine does not retain any batch data, and the actual filling speed is not documented on the batch records. Under these circumstances, if the filling speed is modified, it can go undetected. Similar deficiencies were also observed in Filling Machine (equipment ID: (b) (4) used to fill homeopathic (b) (4)

Additionally, in-process fill weight checks for filling line (b) (4) are deficient as it does not include statistically sound sampling plans. For example, weight verification is performed for (b) (4) (b) samples (b) (4) sample is checked for fill weight (b) (4) (b) (4) units filled (b) (4)

*DATES OF INSPECTION

4/20/2026(Mon), 4/21/2026(Tue), 4/22/2026(Wed), 4/23/2026(Thu), 4/24/2026(Fri), 4/27/2026(Mon)

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Investigator - Dedicated Drug Cadre
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