DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Use this check box to generate the required 483 statement on page 1 for medical device observations. ☐

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
United States Food and Drug Administration 12420 Parklawn Drive, Room 2032 Rockville, MD 20857 Industry Information: www.fda.gov/oc/industry	06/15/2026-06/19/2026
	FEI NUMBER 3003520162

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Maneesh Goyal, Director

FIRM NAME	STREET ADDRESS
Shashi Phytochemical Industries	329 Delhi Road
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Alwar, Rajasthan, 301001, India	API 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 (I) (WE) OBSERVED:

OBSERVATION 1

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance for the identity and strength of the active ingredient.

Specifically,

Your firm failed to perform product release and stability testing per current USP monograph (which became effective in (b) (4) for:

A) Identification Testing by HPLC for (b) (4) API batches shipped to the US.

B) Content of (b) (4) for (b) (4) API batches shipped to the US, using a (b) (4) LC method.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	KARISHMA G. GOPAUL -S Digitally signed by KARISHMA G. GOPAUL -S Date: 2026.06.19 05:18:20 -04'00'	Karishma G. Gopaul, Investigator	06/19/2026