

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

DISTRICT ADDRESS AND PHONE NUMBER 12420 Parklawn Drive, Room 2032 Rockville, MD 20857	DATE(S) OF INSPECTION 12/08/2025-12/12/2025
	FEI NUMBER 3008654585

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED  
Mr. Ramesh Babu Potluri, Chairman & Managing Director

FIRM NAME SMS PHARMACEUTICALS LIMITED, Unit-VII	STREET ADDRESS Survey. No. 160, 161, 163 to 168, Kandivalasa Village, Poosapatirega Mandal
CITY, STATE, ZIP CODE, COUNTRY Vizianagaram District, Andhra Pradesh - 535 204, INDIA	TYPE ESTABLISHMENT INSPECTED API Manufacturer

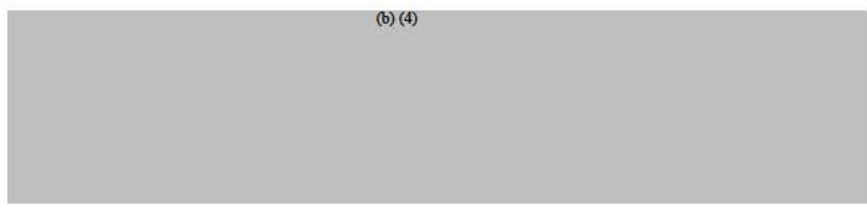
This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to 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 WE OBSERVED:  
LABORATORY**

**OBSERVATION 1**

Failure to ensure that all specifications are scientifically sound and appropriate to ensure that your API conform to established standards of quality and, or purity. Specifically,

The established criteria for extraneous matter testing is not followed. The General Test Procedure for extraneous matter (GTP/QC/018 Version 03 Effective 17OCT2025) has the established specifications below:



The procedure states to test (b) (4) and your firm tested (b) (4) for each batch. Your firm did not use the resulting particle count from (b) (4) to determine the particle count per (b) (4) for the established specifications.

For example, the in-house batch number (b) (4) for active pharmaceutical ingredient (b) (4) USP was tested for extraneous matter on 11DEC2025. The result for (b) (4) was reported as (b) (4) particles and passing. However, the result is (b) (4) particles for (b) (4) which would be a failing result. This batch was dispatched to the US market (b) (4)

<b>SEE REVERSE OF THIS PAGE</b>	Rowena S. Nguyen - Investigator	Rowena S. Nguyen Digitally signed by Rowena S. Nguyen-5 Date: 2025.12.12 02:51:19 -0800 X S	12/12/2025