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SUMMARY

This surveillance GMP inspection of a non-sterile active pharmaceutical ingredient (API) and excipient manufacturer was conducted as part of CVM FY'21 surveillance GMP work plan and as per MARCS OP ID 131412. This inspection was conducted in accordance to compliance program 7371.001, Animal Drug Inspections. Guidance was also provided by ICH Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients.

The previous inspection of the firm was conducted from 07/31/2017 – 08/01/2017 and provided coverage of the firm's Quality, Production, Materials, and Laboratory Controls systems. No Form FDA 483, Inspectional observation, was issued.

The current cGMP inspection included coverage of the firm's Quality Management, Personnel Training, Building and Facilities, Materials Management, Production and In-Process Controls, and Laboratory Control systems. No FDA-483, Inspectional Observations was issued at the conclusion of the current inspection. [redacted]