DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857 OIIPHARMInternationalResponses@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	05/19/2025-05/22/2025
	FEI NUMBER 3009609117

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Vivek Bishnoi, Managing Director & Owner

FIRM NAME	STREET ADDRESS
Hy-Gro Chemicals Pharmtek Pvt. Ltd.	Plot 174 Progressive Industrial
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Bollaram Village, Narsapur Medak, Telangana, 500003, 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:

Quality System

OBSERVATION 1
Testing and release of drug product for distribution do not include laboratory determination of conformance to an appropriate final specification, prior to release.

Specifically,

Your facility is currently manufacturing products which utilize (b) (4) during the manufacturing process. Notably, these products utilize the solvent "(b) (4)" in said processes. Although your firm has incorporated release testing which includes residual solvent testing for (b) (4), your Quality Unit failed to conduct a complete risk assessment that accounts for the possibility of "(b) (4)" formation, a known carcinogen. For example:

1) Your firm does not test for the presence of (b) (4) prior to release of all finished products that may be at risk.
2) Your firm has not completed stability studies to ensure (b) (4) is not produced via (b) (4)
3) Your active pharmaceutical ingredients are non-sterile; no speciation has been conducted to exclude microbes capable of utilizing (b) (4) while in long term storage in accordance with your expiry period.

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	Bryan L. Mcguckin -S Digitally signed by Bryan L. Mcguckin -S Date: 2025.05.22 10:46:41 +05'30'	Bryan L. McGuckin, Investigator	05/22/2025

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Facilities & Equipment

OBSERVATION 2
Routine inspection of electronic equipment is not performed according to a written program designed to assure proper performance in lieu of power disruptions.

Specifically,

Your Quality Unit failed to conduct a power supply/disruption impact assessment to ensure power loss, voltage surges and fluctuations in said power supply, do not result in electronic equipment damage or loss of data generated by said equipment. There have been numerous, equipment failures or software discrepancies associated with voltage irregularities or power supply related interruptions which may have impacted your stability chambers, which have not been fully evaluated.

Laboratory

OBSERVATION 3
Your preventative maintenance program is inadequate.

Specifically,

Review of your HPLC "Error Logs" determined your current protocol "U1/QC-126 System Generated Errors, Rev. 1" is lacking specificity which determines when a qualified system engineer should be utilized to remedy repeated hardware/software generated failures. It is unclear to what extent these system errors may generate faulty data having never been assessed by a qualified 3rd party vendor. Numerous errors were observed without explanation from your Quality Unit as to their meaning or utility.

Furthermore, review of your facility "Invalid" generated data indicates repeated, ongoing failures of your analytical equipment without any assurances the equipment has been adequately repaired prior to further use.

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	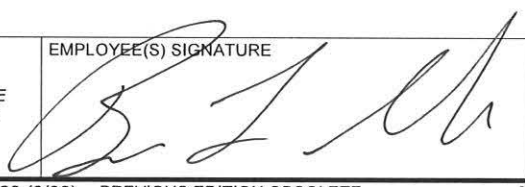	Bryan L. McGuckin, Investigator	05/22/2025