DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn, Room 2032 Rockville, MD 20857 Attn: Hyosun Forman ORAPHARMInternational483responses@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	07/31/2023 - 08/04/2023
	FEI NUMBER 3007616930

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Marcelo Capanema Mansur, Chief Executive

FIRM NAME	STREET ADDRESS
Nortec Quimica, S.A.	Rua Dezessete, 200 - ABCD Distrito Industrial - Mantiquira
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Duque de Caxias - RJ - Brasil - CEP: 25250-612	Active Pharmaceutical Ingredient 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

Your firm's cleaning validation is not representative of current equipment usage.

Specifically, cleaning validation report NQPV432, approved 08/09/2019, updated cleaning (b) (4) dated 06/03/2022, for the group of equipment covered under (b) (4) which includes: (b) (4) (b) (4) and (b) (4) was validated using (b) (4) as the worst case scenario active pharmaceutical ingredient (API). However, your firm failed to conduct another cleaning validation for the equipment that is grouped in (b) (4) after (b) (4) .

The active pharmaceutical ingredient (API), (b) (4) which is marketed for U.S., is manufactured using equipment specified in (b) (4) such as but not limited to (b) (4) (b) (4) ; and (b) (4)

The following lots of the active pharmaceutical ingredient (API), (b) (4) were manufactured after the worst case scenario API, (b) (4) was discounted for (b) (4)

Product	Lot	Manufacturing Date	Expiration Date
(b) (4)			

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	John A. Gonzalez Demario L. Walls	John A. Gonzalez, Investigator Demario L. Walls, Investigator	08/04/2023