DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 Eighth Street NE Atlanta, GA 30309 (404)253-1161 Fax:(404)253-1202 ORAPHARM2_RESPONSES@fda.hhs.gov	3/7/2022-3/18/2022*
	FEI NUMBER 3001237796

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jody L Chastain, CEO

FIRM NAME	STREET ADDRESS
The Ritedose Corporation	1 Technology Cir
CITY, STATE, ZIP CODE, COUNTRY Columbia, SC 29203-9591	TYPE ESTABLISHMENT INSPECTED 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 OBSERVED:

OBSERVATION 1

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically, your firm detected mold species inside ISO 5 classified areas (b) (4) separate monitoring events between January 28, 2021 and November 05, 2021; six (6) of which recovered Aspergillus brasiliensis. Your firm did not thoroughly investigate these mold detection events and did not perform adequate actions to correct the issues and prevent recurrence.

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*DATES OF INSPECTION

3/07/2022(Mon), 3/08/2022(Tue), 3/09/2022(Wed), 3/10/2022(Thu), 3/11/2022(Fri), 3/14/2022(Mon), 3/16/2022(Wed), 3/18/2022(Fri)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jared P Stevens, Investigator	X Jared P Stevens Investigator Signed By: Jared P. Stevens -S Date Signed: 03-18-2022 14:55:32	3/18/2022

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."