	DEPARTMENT OF HEAI FOOD AND DRU	TH AND HUMAN SER G ADMINISTRATION	VICES			
DISTRICT ADDRESS AND PHONE NUMBER			DATE(S) OF INSPECTION			
12420 Parklawn Drive, Room 2032 Rockville, MD 20857			2/17/2020-2/21/2020 FEI NUMBER			
I ROOKVIIIC, III	ROCKVIIIe, MD 20057					
NAME AND TITLE OF INDIVIDU	AL TO WHOM REPORT ISSUED					
Mr. Rakesh Tripathi, Vice President - Operations						
FIRM NAME		STREET ADDRESS	D: 11 G 3			
CITY, STATE, ZIP CODE, COUN	tories Limited	Village- Thana, Distt Solan Type establishment inspected				
Baddi, Himacl	hal Pradesh, 173205 India	Drug 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: FACILITIES AND EQUIPMENT SYSTEM						
OBSERVATION 1 Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use.						
Specifically, you	r firm failed to perform a Performance	Oualification (PO)	of the (b) (4)			
rior to	use in the production of	(b) (4)	tablets, (5)(4)	(b) (A)		
o ensure the (b) (4) is capable of consistently inspecting (b) (4) drug products. The (b) (4)						
was used to perform the visual inspection of tablets tablets						
(b) (4)						
QUALITY SYSTEM						
OBSERVATION	ON 2					
	are not always made of investigation	ons into the failure	e of a batch or any of	its		
	meet specifications.		,			
1	-			(b) (4)		
Specifically, you	r firm failed to perform an Out-of-Spe	ecification (OOS) i	nvestigation when the	(b) (4)		
system had a bit of specified limi system had a bit						
January 30, 2020.						
<u> </u>	EMPLOYEE(C) CICNATURE			DATE ISSUES		
SEE REVERSE OF THIS PAGE	Jennifer L Huntington, Inve Dedicated Drug Cadre	stigator –	Jenniter I. Huntington Investigator - Dedicated Drug Cadre Signed by Jenniter I. Huntington - X Date Signed 02-21-2020 04 SS 06	2/21/2020		
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DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION							
DISTRICT ADDRESS AND PHON	we number Wn Drive, Room 2032		DATE(S) OF INSPECTION 2/17/2020-2/21/2020				
Rockville, MI		FEI NUMBER 3006370533					
			3000370333				
NAME AND TITLE OF INDIVIDUA	AL TO WHOM REPORT ISSUED						
Mr. Rakesh Tripathi, Vice President - Operations I STREET ADDRESS							
	tories Limited	Thana, Distt Solan					
CITY, STATE, ZIP CODE, COUN	JNTRY TYPE ESTABLISHMI		ENT INSPECTED				
Baddi, Himach	hal Pradesh, 173205 India Drug Manufacturer						
	EMPLOYEE(S) SIGNATURE			DATE ISSUED			
SEE REVERSE OF THIS PAGE	Jennifer L Huntington, I Dedicated Drug Cadre	investigator -	Jennifer I. Huntington	2/21/2020			
OI IIIIO PAGE			Investigator - Dedicated Drug Cadre Signed By Jenn fer L. Huntifigton - S Date Signed 02-21-2020 04 55 06				
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