DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	5/27/2019-6/4/2019*
	FEI NUMBER 3005124189

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Rajesh R. Dessai, Associate Vice President - Production

FIRM NAME	STREET ADDRESS
Indoco Remedies Limited	L 32 33 & 34 I D C Verna Industrial Road
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Vasco Da Gama, Goa, 403722 India	Manufacturer of Human Drug Products

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

Determinations of conformance to appropriate written specifications for acceptance are deficient for drug products.

Specifically,

Drug product (b) (4) Solution (b) (4) %, batch # (b) (4) failed the "any other individual impurities" specification during the related substances test conducted at the 24-months stability testing point (storage conditions: 25°C / 40% RH). The specification was NMT (b) (4) % and the result obtained was (b) (4) %. Investigation was documented in out-of-specification event report # OOS/G2/19/014. Batch # (b) (4) was produced in (b) (4) and expired in 12/18. It was placed in stability on 2/17/17 and was 24-months stability tested on 2/22/19 (i.e., testing completion date), one month and 22 days after the batch had expired. There is no assurance that this batch complied with specifications at its expiration date (12/18) because the batch was not tested when it expired (12/18). The stability testing protocol of this batch did not include an additional testing point to assure that the batch was tested upon expiration.

OBSERVATION 2

Investigations of a failure of a batch or any of its components to meet any of its specifications did not extend to other batches of the same drug product.

Specifically,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jose A Cruz Gonzalez, Investigator - Dedicated Drug Cadre	X Jose A Cruz Gonzalez Investigator - Dedicated Drug Cadre Signed By: Jose A. Cruz Gonzalez - S Date Signed: 06-04-2019 09:14:57	6/4/2019

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The firm failed to conduct an evaluation of the retain samples of the drug product (b) (4) (b) (4) Solution during the investigation of out-of-specification event # OOS/G2/19/014. The investigation confirmed out-of-specification results for "any other individual impurities" in the execution of the related substances test at the 24-month testing point during the stability testing of (b) (4) Solution (b) (4) %, batch # (b) (4) This lot was produced in (b) (4) (i.e., (b) (4) and expired in 12/18. It was placed in stability on 2/17/17 and was 24-months stability-tested on 2/22/19 (i.e., testing completion date), one month and 22 days after the batch had expired. At least one other product lot (# (b) (4)) was produced during 2017 and was represented by the stability study of batch # (b) (4)

OBSERVATION 3

There is no written testing program designed to assess the stability characteristics of drug products.

Specifically,

The current procedure for the stability testing of finished products (document # QC/016 – "Stability Testing of Finished Products", version # 23, effective date 1/19) was found inadequate in that:

a) The procedure does not include provisions to assure that products in stability studies are tested at their established expiration dates. For products with expiration periods of 24 or 36 months, the current procedure allows the testing of stability samples up to (b) (4) past their expiration date (i.e., because the procedures establish a time-line of (b) (4) for the testing of stability samples at storage-times / testing-points of 6, 9, 12, 18, 24, and 36 months). The procedures do not require the establishment of additional testing points in the stability testing protocols of stability batches to assure that these batches are tested at their expiration date.

b) The procedures do not define time frames to put the drug-product batches selected for stability studies in the stability chambers. The procedures do not establish a maximum number of (b) (4) to load the samples in the stability chamber to assure that stability samples are kept under

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controlled conditions of temperature and humidity during the products' indicated shelf-life (i.e., expiration period) and to assure that stability batches are tested at their expiration date. The following conditions were observed during the review of stability data summary reports and/or OOS investigation reports:

a. (b) (4) product (b) (4) Injection, batches # (b) (4) and # (b) (4) were produced on (b) (4) with expiration date of 3/17. The batches were placed in stability on 5/5/15 and 24-months stability-tested between 5/16/17 and 6/12/17.

b. (b) (4) product (b) (4) Injection, batches # (b) (4) (b) (4) were produced on (b) (4) with expiration date of 2/18. The batches were placed in stability on 4/15/16 and 24-months stability-tested on 5/2/18.

c. (b) (4) product (b) (4) Injection, batches # (b) (4) (b) (4) were produced between (b) (4) and (b) (4) with expiration date of 5/18. The batches were placed in stability on 7/4/16 and 24-months stability-tested between 7/14/18 and 7/28/18.

d. (b) (4) Solution (b) (4) %, batch # (b) (4) was produced on (b) (4) and expired in 12/18. It was placed in stability on 2/17/17 and was 24-months stability-tested on 2/22/19, one month and 22 days after the batch had expired.

OBSERVATION 4

Written procedures are not established that describe the examinations to be conducted on appropriate samples of in-process materials of each batch.

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There is no assurance that the amount of AQL samples visually inspected during the 100% visual inspection of (b) (4) drug products (b) (4) Injection (batches # (b) (4) and # (b) (4) (b) (4) Injection (batches # (b) (4) and (b) (4) Injection (batches # (b) (4) and # (b) (4)) were representative of the amount of samples needed to be collected as per a defined statistical sampling plan. During the 100% visual inspection of these batches, the AQL samples were inspected at a rate of (b) (4) (during the execution of the visual inspection process). AQL samples of these batches, collected as per a defined statistical sampling plan, were collected after packing operations, when the product vials had been labeled and packed. The AQL sample collected after packing operations was not inspected under the same conditions used for the 100% visual inspection because the collected units are labeled).

***DATES OF INSPECTION**

5/27/2019(Mon), 5/28/2019(Tue), 5/29/2019(Wed), 5/30/2019(Thu), 5/31/2019(Fri), 6/03/2019(Mon), 6/04/2019(Tue)

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