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 Industry Information: www.fda.gov/oc/industry	10/22-26/2018
	FEI NUMBER 3004161218

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Janmejay R. Vyas, Chairman

FIRM NAME	STREET ADDRESS
Dishman Carbogen Amcis Ltd	Survey No. 47, Paiki Sub Plot No. 1, Lodariyal Sanand-Bavla
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Ahmedabad 382 220, Gujarat, India	API Manufacturer

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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

PRODUCTION SYSTEM

1.) Blending of in-specification with out-of-specification (OOS) intermediate batches is performed.

Specifically, (b) (4) ((b) (4) intermediate) batch (b) (4) tested OOS for impurity (b) (4) The batch was manufactured starting on 03/05/2018. QC testing of this batch yielded a result of (b) (4) % for the impurity against a specification of less than or equal to (b) (4) %. Deviation investigation DV/(b) (4) /1801, written for this incident, calls for this batch to be blended with other batches that have an in-specification result for (b) (4) manufacturing. The OOS batch was blended with in-specification material as follows:

A.) (b) (4) kg of batch (b) (4) blended with (b) (4) kg of batch (b) (4) to manufacture (b) (4) batch (b) (4)

B.) (b) (4) kg (b) (4) blended with (b) (4) kg of batch (b) (4) and (b) (4) kg of batch (b) (4) to manufacture (b) (4) batch (b) (4)

C.) (b) (4) kg of batch (b) (4) blended with (b) (4) kg of batch (b) (4) to manufacture (b) (4) batch (b) (4)

D.) (b) (4) kg of batch (b) (4) blended with (b) (4) kg of batch (b) (4) and (b) (4) kg of batch (b) (4) to manufacture (b) (4) batch (b) (4)

The manufactured (b) (4) batches were used in the production of packaged lots (b) (4) (b) (4) of (b) (4).

LABORATORY CONTROL SYSTEM

2.) Laboratory investigations for OOS intermediate batches are not conducted.

Specifically, according to SOP BDQC-311 for OOS investigations (effective 07/16/2018), OOS is to be conducted on "...all quantitative and qualitative tests of...intermediates..." An investigation of an OOS impurity result in the (b) (4) intermediate, batch (b) (4) for (b) (4) was not conducted.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Alan P. Kurtzberg -S Digitally signed by Alan P. Kurtzberg -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=20014031 0 2, cn=Alan P. Kurtzberg -S Date: 2018.10.26 10:40:31 +05'30'	Alan P. Kurtzberg, Investigator	10/26/2018