DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue, Building 51, Room 4225 (407) 475-4700 Fax:(307) 847-8738 Industry Information: www.fda.gov/oc/industry	11/29/2016-12/6/2016*
	FEI NUMBER 3004149463

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Kiran S. Divi, Director and President Operations

FIRM NAME	STREET ADDRESS
Divi's Laboratories Limited, Unit-II	Unit-2, Chippada Village, Annavaram Post Bheemunipatnam Mandal
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Visakhapatnam District Andhra Pradesh 531162 India	API 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 WE OBSERVED:

OBSERVATION 1

Proper controls are not exercised over computerized systems used for analytical testing to ensure drug products meet their specified quality attributes.

1. Your firm engages in extensive use of "Inhibit Integration" and other anomalous integration techniques for assessing US APIs such that unknown impurities are disregarded without scientific justification. Furthermore, unknown impurities are not accurately assessed or reported.

    a. For example, below lists some APIs for the US market with corresponding use of inhibit integration:

Inhibit Integration

SEE REVERSE OF THIS PAGE	Latorie S. Jones, Investigator Massoud Motamed, Investigator	DATE ISSUED 12/6/16

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue, Building 51, Room 4225 (407) 475-4700 Fax:(307) 847-8738 Industry Information: www.fda.gov/oc/industry	11/29/2016-12/6/2016*
	FEI NUMBER 3004149463

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Kiran S. Divi, Director and President Operations

FIRM NAME	STREET ADDRESS
Divi's Laboratories Limited, Unit-II	Unit-2, Chippada Village, Annavaram Post Bheemunipatnam Mandal
CITY, STATE, ZIP CODE, COUNTRY Visakhapatnam District Andhra Pradesh 531162 India	TYPE ESTABLISHMENT INSPECTED API Manufacturer

Product	Inhibition Start Time	Inhibition End Time
(b) (4)	(b) (4)	(b) (4)
(b) (4)		
(b) (4)		

SEE REVERSE OF THIS PAGE	Latorie S. Jones, Investigator Massoud Motamed, Investigator	DATE ISSUED 12/6/16

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue, Building 51, Room 4225 (407) 475-4700 Fax:(307) 847-8738 Industry Information: www.fda.gov/oc/industry	11/29/2016-12/6/2016* FEI NUMBER 3004149463

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Kiran S. Divi, Director and President Operations

FIRM NAME	STREET ADDRESS
Divi's Laboratories Limited, Unit-II	Unit-2, Chippada Village, Annavaram Post Bheemunipatnam Mandal
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Visakhapatnam District Andhra Pradesh 531162 India	API Manufacturer

(b) (4)	(b) (4)	(b) (4)
(b) (4)		
(b) (4)		
(b) (4)		

SEE REVERSE OF THIS PAGE	Latorie S. Jones, Investigator Massoud Motamed, Investigator	DATE ISSUED 12/6/16

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue, Building 51, Room 4225 (407) 475-4700 Fax:(307) 847-8738 Industry Information: www.fda.gov/oc/industry	11/29/2016-12/6/2016*
	FEI NUMBER 3004149463

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Kiran S. Divi, Director and President Operations

FIRM NAME	STREET ADDRESS
Divi's Laboratories Limited, Unit-II	Unit-2, Chippada Village, Annavaram Post Bheemunipatnam Mandal
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Visakhapatnam District Andhra Pradesh 531162 India	API Manufacturer

(b) (4)	(b) (4)	(b) (4)

SEE REVERSE OF THIS PAGE	Latorie S. Jones, Investigator Massoud Motamed, Investigator	DATE ISSUED 12/6/16

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue, Building 51, Room 4225 (407) 475-4700 Fax:(307) 847-8738 Industry Information: www.fda.gov/oc/industry	11/29/2016-12/6/2016*
	FEI NUMBER 3004149463

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Kiran S. Divi, Director and President Operations

FIRM NAME	STREET ADDRESS
Divi's Laboratories Limited, Unit-II	Unit-2, Chippada Village, Annavaram Post Bheemunipatnam Mandal
CITY, STATE, ZIP CODE, COUNTRY Visakhapatnam District Andhra Pradesh 531162 India	TYPE ESTABLISHMENT INSPECTED API Manufacturer

(b) (4)	(b) (4)	(b) (4)

SEE REVERSE OF THIS PAGE	Latorie S. Jones, Investigator Massoud Motamed, Investigator	DATE ISSUED 12/6/16

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue, Building 51, Room 4225 (407) 475-4700 Fax:(307) 847-8738 Industry Information: www.fda.gov/oc/industry	11/29/2016-12/6/2016*
	FEI NUMBER 3004149463

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Kiran S. Divi, Director and President Operations

FIRM NAME	STREET ADDRESS
Divi's Laboratories Limited, Unit-II	Unit-2, Chippada Village, Annavaram Post Bheemunipatnam Mandal
CITY, STATE, ZIP CODE, COUNTRY Visakhapatnam District Andhra Pradesh 531162 India	TYPE ESTABLISHMENT INSPECTED API Manufacturer

	(b) (4)	

This use of inhibit integration was used to mask unknown impurities for the (b) (4) and (b) (4)

(b) (4) lot (b) (4) was released with an individual unknown impurity of (b) (4)% against a specification of (b) (4)% (this individual impurity was in the inhibit integration region of the chromatogram. Your firm stated that this peak had not been quantified against the specification, as it was early eluting and a separate method is utilized for assessing those impurities. This statement remained unsubstantiated throughout the inspection. No investigation of this impurity had been conducted.

(c) (b) (4) lot (b) (4) was released with total impurities of (b) (4)% against a specification of not more than (b) (4)%; however, a review of the raw data revealed that a known impurity termed impurity (b) (4) had been integrated as a part of the desired peak, and therefore not considered in the calculation of total impurities. Your firm's Deputy General Manager QC acknowledged the presence of this impurity in the chromatogram, but declined the opportunity to explain how the product met specification.

(d) A review of chromatograms from your firm's last 30 batches of (b) (4) revealed that there is an unknown peak eluting at a slightly longer relative retention time than the desired peak. Specifically, approximately half of the last 30 batches display this unknown peak that is integrated as a part of the desired API. Your firm's Deputy General Manager QC stated this is an unknown and uninvestigated im-

purity. The chromatograms from your firm's forced degradation report (2-(b) (4) /HPLC/003) does not display this peak, suggestive of a process or cross-contamination related impurity.

(e) A review of chromatograms from your firm's last 30 batches of (b) (4) revealed that there unknown impurities are routinely integrated as a part of the desired API. Your firm's Deputy General Manager QC failed to explain why impurities would be as a part of the desired API peak.

2. 60 of (b) (4) of your R&D Division's chromatographic systems do not have audit trails enabled or enabled audit trails on November 27, 2016, the day before the initiation of the US FDA inspection.

These chromatographic systems are utilized for GMP functions including:

i. Providing data to address DMF deficiencies (For Example: (b) (4) (b) (4) and (b) (4))

ii. Performing investigations

Furthermore, we observed drug product from production at R&D. Moreover, we noted obscurely named chromatographic sequences contained in these same systems, such as:

a. "(b) (4)"- the name for (b) (4) (alternative process)

b. "(b) (4)"- the name for (b) (4)

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue, Building 51, Room 4225 (407) 475-4700 Fax:(307) 847-8738 Industry Information: www.fda.gov/oc/industry	11/29/2016-12/6/2016*
	FEI NUMBER 3004149463

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Kiran S. Divi, Director and President Operations

FIRM NAME	STREET ADDRESS
Divi's Laboratories Limited, Unit-II	Unit-2, Chippada Village, Annavaram Post Bheemunipatnam Mandal
CITY, STATE, ZIP CODE, COUNTRY Visakhapatnam District Andhra Pradesh 531162 India	TYPE ESTABLISHMENT INSPECTED API Manufacturer

c. '[(b) (4)]'- the name for [(b) (4)]

d. '[(b) (4)]'- the name for [(b) (4)]

e. '[(b) (4)]'- the name for [(b) (4)]

f. '[(b) (4)]'-the name for [(b) (4)]

g. '[(b) (4)]'-the name for [(b) (4)]

OBSERVATION 2

Facilities and equipment are not maintained to ensure the purity, quality, strength and identity of the API

Specifically, we observed the following deficiencies:

1. Unexplained [(b) (4)] colored product was observed on [(b) (4)] [(b) (4)] and [(b) (4)] [(b) (4)] in [(b) (4)] stages of API manufacturing (i.e. [(b) (4)] Block):

   a. On 11/29/16, we observed your [(b) (4)] [(b) (4)] [(b) (4)]-01 contained a [(b) (4)] [(b) (4)] colored residue inside the [(b) (4)] comingled with product. This coloration is inconsistent with the [(b) (4)] coloration of [(b) (4)], a US API manufactured in Block [(b) (4)], batch [(b) (4)]

SEE REVERSE OF THIS PAGE	Latorie S. Jones, Investigator Massoud Motamed, Investigator	DATE ISSUED 12/6/16

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue, Building 51, Room 4225 (407) 475-4700 Fax:(307) 847-8738 Industry Information: www.fda.gov/oc/industry	11/29/2016-12/6/2016*
	FEI NUMBER 3004149463

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Kiran S. Divi, Director and President Operations

FIRM NAME	STREET ADDRESS
Divi's Laboratories Limited, Unit-II	Unit-2, Chippada Village, Annavaram Post Bheemunipatnam Mandal
CITY, STATE, ZIP CODE, COUNTRY Visakhapatnam District Andhra Pradesh 531162 India	TYPE ESTABLISHMENT INSPECTED API Manufacturer

b. On 11/29/16, we observed your [redacted]-01 contained a [redacted] colored residue inside the [redacted] used to [redacted] a US API manufactured in Block [redacted]. Your firm stated these residues were a [redacted] on the [redacted]; however, wiping of the [redacted] surface with a white cloth displayed a [redacted] appearance. This equipment was being utilized in a campaign manufacturing [redacted], batch [redacted].

c. On 11/29/16, we observed [redacted] residue/staining on the product contact surface of the [redacted] of [redacted]-03. In addition, a build-up of white residue was observed in the piping of the [redacted] which contains no separation from the contents inside the [redacted]. This equipment was being utilized in a campaign manufacturing [redacted], batch [redacted]. The firm did not clarify how cross-contamination of the colored residue with API is avoided. [redacted] API is intended for the US Market.

d. On 11/29/16, we observed your [redacted] CP-01 contained a [redacted] colored material inside the [redacted] comingled with product. This [redacted] coloration is inconsistent with the [redacted] coloration of [redacted]. This [redacted] contained "[redacted] material" from the batch [redacted] which was intended for further [redacted] per SOP 2-PD/GEN/57.

SEE REVERSE OF THIS PAGE	Latorie S. Jones, Investigator Massoud Motamed, Investigator	DATE ISSUED 12/6/16

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue, Building 51, Room 4225 (407) 475-4700 Fax:(307) 847-8738 Industry Information: www.fda.gov/oc/industry	11/29/2016-12/6/2016*
	FEI NUMBER 3004149463

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Kiran S. Divi, Director and President Operations

FIRM NAME	STREET ADDRESS
Divi's Laboratories Limited, Unit-II	Unit-2, Chippada Village, Annavaram Post Bheemunipatnam Mandal
CITY, STATE, ZIP CODE, COUNTRY Visakhapatnam District Andhra Pradesh 531162 India	TYPE ESTABLISHMENT INSPECTED API Manufacturer

e. On 12/2/16, we observed (b) (4) material in 3 of (b) (4) being utilized in a (b) (4) campaign in (b) (4) Block. Per SOP 2-(b) (4) D/29a, only the exterior surface of the (b) (4) are cleaned during a campaign and therefore remains unclear how your firm avoids cross-contamination of batches manufactured.

For points a-e listed above, we observed your firm had complaints associated with abnormal colored/stained material. For example, complaint 2-IR/ILD-003/(b) (4)/2016/R was received for "Customer have found (b) (4) colored stain in (b) (4) API." Additionally, complaint 2-(b) (4) -001/(b) (4)/2015/R was received for "Customer has observed dark particles in sample of (b) (4) ."

2. (b) (4) used in product (b) (4) are not maintained

a. On 11/29/16, we observed particulates on the inner (b) (4) of the (b) (4) which were consistent with the color of the (b) (4) in (b) (4) -11. Additionally, white colored particulates were observed inside of the (b) (4) after manufacturing of batch (b) (4) . This (b) (4) , labeled "Last cleaned on 28/11/16 at 11:00", is used to manufacture (b) (4) for the US market.

b. On 11/29/16, we observed multiple areas of divets and chipping inside of (b) (4) (b) (4) -02. This (b) (4) labeled "Last cleaned on 29/11/16", is used to manufacture (b) (4) (b) (4) for the US market.

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue, Building 51, Room 4225 (407) 475-4700 Fax:(307) 847-8738 Industry Information: www.fda.gov/oc/industry	11/29/2016-12/6/2016*
	FEI NUMBER 3004149463

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Kiran S. Divi, Director and President Operations

FIRM NAME	STREET ADDRESS
Divi's Laboratories Limited, Unit-II	Unit-2, Chippada Village, Annavaram Post Bheemunipatnam Mandal
CITY, STATE, ZIP CODE, COUNTRY Visakhapatnam District Andhra Pradesh 531162 India	TYPE ESTABLISHMENT INSPECTED API Manufacturer

For points a and b, we were unable to ascertain where the (b) (4) particulates had gone. Furthermore, your preventative maintenance checks (Document 2-MT/OP/02/01) are silent with regards to testing the integrity of the (b) (4) of the (b) (4).

Additional equipment deficiencies similar to those listed above were observed throughout your facility.

OBSERVATION 3

Your R&D division guides quality and production to commence activities inconsistent with CGMPs.

1. We observed examples of product failing to meet specification for various stages of production in which R&D instructed onward processing of the product or alternative analysis. We discussed the contents of these memorandums with your firm and they confirmed the incorporation of failing material or alternative analysis for the product. For example,

   a. (b) (4)-OOS investigation reference 2-PLI/OOS/FP(b) (4)U/002 dated 08.10.15 states "From the above investigation no laboratory error is evident. Therefore, it is proposed to reject the sample B.No: (b) (4)" Subsequently, QA with a consult from R&D determined to re-sample and re-test, then instructed QC to re-sample the product which led to passing results being obtained and reported.

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue, Building 51, Room 4225 (407) 475-4700 Fax:(307) 847-8738 Industry Information: www.fda.gov/oc/industry	11/29/2016-12/6/2016* FEI NUMBER 3004149463

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Kiran S. Divi, Director and President Operations

FIRM NAME	STREET ADDRESS
Divi's Laboratories Limited, Unit-II	Unit-2, Chippada Village, Annavaram Post Bheemunipatnam Mandal
CITY, STATE, ZIP CODE, COUNTRY Visakhapatnam District Andhra Pradesh 531162 India	TYPE ESTABLISHMENT INSPECTED API Manufacturer

This was listed as a confirmed OOS per your document titled LIST OF CONFIRMED OUT OF SPECIFICATION (OOS) RESULTS REPORTED FOR APIs IN THE YEAR-2015 (REALTED TO US DMF PRODUCTS). This batch was deemed compliant on 15.10.15 and released as batch (b) (4) on November 2, 2015.

b. Inter Office Memorandum (IOM) between R&D and QA dated 15.06.15 states "***regarding (b) (4) B.No: (b) (4) higher (b) (4) content reported batch onward processing***proceed to (b) (4) synthesis with ~ (b) (4)% of (b) (4) (b) (4) no quality issues observed at (b) (4) (b) (4) . Hence, if the material met all (b) (4) quality specification you may give the clearance for further processing***"

c. Inter Office Memorandum (IOM) between R&D and (b) (4)-Block (a manufacturing block) dated 22.01.16 states "***regarding OOS result of (b) (4), test in (b) (4) (b) (4) analysis i.e. (b) (4) (b) instead of (b) (4) to (b) (4), we checked the lab data and not found this type of abnormal result in the lab experiments. Hence we have performed the user test with this batch and got the good yield and quality***you may proceed the batch to (b) (4) stage with the existing process***"

(b) (4) is the starting material for (b) (4) which is intended for the US market.

d. Manufacturing Deviation Investigation Report, reference no: 2-DIR/(b) (4)/V/001 dated 18/02/16, related to the discrepancy observed in (b) (4) (b) (4) result between

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue, Building 51, Room 4225 (407) 475-4700 Fax:(307) 847-8738 Industry Information: www.fda.gov/oc/industry	11/29/2016-12/6/2016*
	FEI NUMBER 3004149463

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Kiran S. Divi, Director and President Operations

FIRM NAME	STREET ADDRESS
Divi's Laboratories Limited, Unit-II	Unit-2, Chippada Village, Annavaram Post Bheemunipatnam Mandal
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Visakhapatnam District Andhra Pradesh 531162 India	API Manufacturer

first and second sample in (b) (4) by (b) (4) test, states "***based on R&D recommendation, batch was re-sampled (3rd time) for (b) (4) content by (b) (4) ***batch sequence was moved further as per BPR instructions without any deviations***R&D has opinioned that it may happen due to sample contamination at production or QC***No probable root cause was identified for the advent of this deviation but as per R&D the chance of getting such result is due to contamination of the sample***"

(b) (4) is the (b) (4) for (b) (4) and (b) (4) which is intended for the US market.

e. Inter Office Memorandum (IOM) between R&D and QA dated 22.01.16, related to (b) (4) (b) (4) (B.No: (b) (4)) in-process (b) (4) analysis deviation, states "***we have reviewed the all in-process results for (b) (4) batches in this campaign. Out of (b) (4) batches, (b) (4) batches completed with out any deviations, the remaining (b) (4) batches me the specification after additional IPC analysis based on R&D recommendations***unfortunately for the B.No: (b) (4) the (b) (4) is not reduced to desired level, but (b) (4) % reduction observed after the 2nd time analysis when compared to the 1st time analysis***R&D has recommended for 3rd time analysis. After 3rd time analysis batch met the desired specification***the reduction of the (b) (4) (b) (4) depends on the batch (b) (4) and (b) (4) (b) (4) ***to avoid the re-occurrence in the future, we recommend to minimize the storage time of the (b) (4) (b) (4) (b) (4) (b) (4) and also recommend to keep (b) (4)

SEE REVERSE OF THIS PAGE	Latorie S. Jones, Investigator Massoud Motamed, Investigator	DATE ISSUED 12/6/16

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue, Building 51, Room 4225 (407) 475-4700 Fax:(307) 847-8738 Industry Information: www.fda.gov/oc/industry	11/29/2016-12/6/2016* FEI NUMBER 3004149463

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Kiran S. Divi, Director and President Operations

FIRM NAME	STREET ADDRESS
Divi's Laboratories Limited, Unit-II	Unit-2, Chippada Village, Annavaram Post Bheemunipatnam Mandal
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Visakhapatnam District Andhra Pradesh 531162 India	API Manufacturer

at ~ (b)(4)°C (b)(4) until the usage. Based on the above discussions review and give clearance to the batch for further processing after attaining typical (b)(4) results***"

(b)(4) is the (b)(4) for (b)(4) and (b)(4) which is intended for the US market.

f. Manufacturing Deviation Investigation Report, reference no: 2-DIR/(b)(4)/U/001 dated 12/10/15, related to abnormal result of (b)(4)% was obtained for the parameter "(b)(4) (b)(4) content by (b)(4), states "R&D had issued an investigation report dated 24/09/14 for this***per R&D assessment, there is no chance/scope of (b)(4) of (b)(4) after completion of (b)(4) ***R&D has finally concluded that this descripency in result might have happened due to contamination of (b)(4) IPC sample***Batch quality***There is no effect on batch quality with this deviation***Investigation conclusion***The probable root cause for the advent of this event is not identified at this point of time***Since this is an isolated incident which could not occur frequently, no further investigation required on this at this point of time***" The status of the product was not included in the IOM, however, your Site Head stated there has been no rejection of any API.

(b)(4) is the (b)(4) for the intermediate (b)(4) which is intended for the US market.

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue, Building 51, Room 4225 (407) 475-4700 Fax:(307) 847-8738 Industry Information: www.fda.gov/oc/industry	11/29/2016-12/6/2016*
	FEI NUMBER 3004149463

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Kiran S. Divi, Director and President Operations

FIRM NAME	STREET ADDRESS
Divi's Laboratories Limited, Unit-II	Unit-2, Chippada Village, Annavaram Post Bheemunipatnam Mandal
CITY, STATE, ZIP CODE, COUNTRY Visakhapatnam District Andhra Pradesh 531162 India	TYPE ESTABLISHMENT INSPECTED API Manufacturer

g. Inter Office Memorandum (IOM) between R&D and (b)(4) Block (a manufacturing block) dated 05.11.16, related to (b)(4) (b)(4) (b)(4) states "***regarding (b)(4) (b)(4) (b)(4) by (b)(4) results***we have checked the analytical data and found one major (b)(4) merged with product (b)(4) (b)(4) (b)(4). As informed by QC the un-known (b)(4) (merged with product (b)(4)) (b)(4) is nearer to (b)(4), as the un-known (b)(4) is not separated clearly from product (b)(4) and as well as the suspected solvent (b)(4) is not used in the process and also not formed in the synthetic route of (b)(4) you may re-sample the (b)(4) (b)(4) (b)(4) and send for analysis***"

(b)(4) is starting material for (b)(4) which is intended for the US market.

h. Inter Office Memorandum (IOM) between R&D and (b)(4) Block (a manufacturing block) dated 23.11.16 states "***regarding (b)(4) (b)(4) (b)(4), we have reviewed the (b)(4) and noted the same (b)(4) which is observed recently in batch no (b)(4), however this batch was met the (b)(4) spec during the re-analysis***at this time also you may send the sample to re-analysis. If the sample met the spec. you may proceed further***Please note, if the sample met the specification during re-analysis, you may request QC to keep the batch sample which is having some deviation in any of the future batches***"

(b)(4) is the starting material for (b)(4) which is intended for the US market.

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue, Building 51, Room 4225 (407) 475-4700 Fax:(307) 847-8738 Industry Information: www.fda.gov/oc/industry	11/29/2016-12/6/2016* FEI NUMBER 3004149463

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Kiran S. Divi, Director and President Operations

FIRM NAME	STREET ADDRESS
Divi's Laboratories Limited, Unit-II	Unit-2, Chippada Village, Annavaram Post Bheemunipatnam Mandal
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Visakhapatnam District Andhra Pradesh 531162 India	API Manufacturer

i. Inter Office Memorandum (IOM) between R&D and The Sr. Manager (b)(4)-Block (a manufacturing block) dated 04.01.16, states "***regarding (b)(4) (b)(4) (b)(4) (b)(4) (b)(4) by (b)(4) results***we have checked the analytical data and found (b)(4) major (b)(4) i.e. (b)(4) **we are using these (b)(4) (b)(4) in the (b)(4) ***we have proposed the below specifications for (b)(4) (b)(4) (b)(4) So please revise all relevant documents as per the below specifications***".

(b)(4) is starting material for (b)(4) which is intended for the US market

We observed a similar trend of documentation throughout your facility. Your firm has (b)(4) R&D laboratories used to support (b)(4) APIs, approximately (b)(4) intermediates and approximately (b)(4) development products produced at your facility.

OBSERVATION 4

Failure to conduct a thorough investigation.

Your firm received complaints on 6-28-16 and 6-30-16 purporting the presence of (b)(4) in (b)(4) (b)(4) These complaints affected products (b)(4) (b)(4) (b)(4) (b)(4) (b)(4) (b)(4). As part of the investigation, your conclusion and root cause states "***the definite root cause for presence of such amount of (b)(4) in (b)(4) batches could not be identified from the investigation as the data related to (b)(4) batches are in line with requirement and no abnormali-

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue, Building 51, Room 4225 (407) 475-4700 Fax:(307) 847-8738 Industry Information: www.fda.gov/oc/industry	11/29/2016-12/6/2016*
	FEI NUMBER 3004149463

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Kiran S. Divi, Director and President Operations

FIRM NAME	STREET ADDRESS
Divi's Laboratories Limited, Unit-II	Unit-2, Chippada Village, Annavaram Post Bheemunipatnam Mandal
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Visakhapatnam District Andhra Pradesh 531162 India	API Manufacturer

ties/deviations reported***failure of heavy metals test of batches*** (b) (4) *** (b) (4) *** (b) (4) *** (b) (4) *** (b) (4) did not identify during release testing at QC because of analysts misinterpretation for (b) (4) comparison***". In addition to these complaints, your firm has known difficulty with removing (b) (4) such that interoffice memorandum dated 03.09.16 states "***there is suitable no alternative cleaning procedures available***However R&D will initiate lab work for alternate procedure for removal of (b) (4) deposits***" Subsequent interoffice memorandums highlighted this issue of cleaning (b) (4) has/could not be resolved. Given the aforementioned complaints and memorandums, your complaint investigation failed to suggest removing product from the market or conducting a comprehensive assessment for detecting the presence of (b) (4) and heavy metals across products and batches.

(b) (4) is used to manufacture the following products:

(b) (4) an intermediate for API- (b) (4)
(b) (4) an intermediate for a custom product
(b) (4) an intermediate for (b) (4)
(b) (4) a starting material for (b) (4)
(b) (4) (b) (4) starting material for (b) (4)
(b) (4) the name for technical grade API- (b) (4)
(b) (4) an intermediate for (b) (4)

SEE REVERSE OF THIS PAGE	Latorie S. Jones, Investigator Massoud Motamed, Investigator	DATE ISSUED 12/6/16

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue, Building 51, Room 4225 (407) 475-4700 Fax:(307) 847-8738 Industry Information: www.fda.gov/oc/industry	11/29/2016-12/6/2016*
	FEI NUMBER 3004149463

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Kiran S. Divi, Director and President Operations

FIRM NAME	STREET ADDRESS
Divi's Laboratories Limited, Unit-II	Unit-2, Chippada Village, Annavaram Post Bheemunipatnam Mandal
CITY, STATE, ZIP CODE, COUNTRY Visakhapatnam District Andhra Pradesh 531162 India	TYPE ESTABLISHMENT INSPECTED API Manufacturer

OBSERVATION 5

Documentation and records are either not maintained or inaccurate/falsified

1. Information pertaining to the IOM between QCD and (b) (4) -R&D dated 13/04/14 were falsified. The document provided for photocopy was not consistent with the copy received.

2. The file provided for the inspection titled "Customer complaint log" is not accurate. During the inspection, we identified an interoffice memo dated 11-04-15 which describes "comments received from customer (b) (4) about three unknown solvents" which was not included in this list titled "Customer complaint log."

3. On 12/1/16, we observed the incinerator contained several intact documents intermingled with ash which included documents signed from April 2016 as well as portions of interoffice memorandums. A trash bin was observed directly outside the incinerator.

4. Equipment status tag for (b) (4) (b) (4) -01 states last cleaned on 29/11/16, however, the equipment usage log fails to capture the indicated cleaning.

***DATES OF INSPECTION**

11/29/2016(Tue),11/30/2016(Wed),12/1/2016(Thu),12/2/2016(Fri),12/5/2016(Mon),12/6/2016(Tue)

SEE REVERSE OF THIS PAGE	Latorie S. Jones, Investigator Massoud Motamed, Investigator	DATE ISSUED 12/6/16