1. The written procedure SOP/QCD/152/03 titled “Standard Chromatography Practice (HPLC and GC)” was not followed in that section 4.10.4 states “All the chromatograms which has no relevance with the analytical data due to non-achievement of system suitability parameters, distorted peaks, failure of system and improper integration shall be stamped as INVALID and attached with relevant record of analysis.” Specifically, the chromatograms of standard trial injections and aborted sequences were not submitted with test data or investigated. For example:

   a) Processed chromatogram of trial standard of tablet on 08.10.12 was not submitted with assay test data package of batch no. ____________

   b) ________ tablet one Assay, Disso_16.02.13_SQC133_SEQ rsrt processed chromatograms were not submitted with test data package for assay and dissolution analysis of ____________ tablets batch no. ____________ and ____________

   c) The following processed chromatograms of files were not justified: investigation_Trail_SQC.133.18.02.13._001.dat acquired time 2:10:17PM vial 31, investigation_Trail_SQC.133.18.02.13._002.dat acquired time 2:26:25PM vial 32

   According to QC manager there was no investigation performed.

d) A total of ________ trial standards of assay and dissolution were injected on 06/26/2013, however, only ________ chromatograms were submitted with batch ________

   ____________

   ____________
DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER
Food and Drug Administration, CDER/OC/OMPO/DIDQ/ICB
10903 New Hampshire Ave., Building 51, Room 4234
Silver Spring, MD 20993 PH: +1 301 796 3206 ATTN: Ms. Alicia Mozzachio

INDUSTRY INFORMATION: www.fda.gov/oc/industry

DATE(S) OF INSPECTION
December 11-19, 2014

FOE/NUMBER
3005977675

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Sujit Kumar Rath, Sr. General Manager - Operations

FIRM NAME
Ipea Laboratories Ltd.

STREET ADDRESS
Plot 65 & 99, Danudoyg Industrial Estate

CITY, STATE AND ZIP CODE
Piparia, Silvassa, India 396 230

TYPE OF ESTABLISHMENT INSPECTED
Drug Product Manufacturer

2. The documentation of laboratory tests and documentation result for plate did not include scientifically sound results for the growth promotion of microbiological culture media used for Microbial Limit Test of (b)(4) and finished products. Specifically, QC analyst entered results of (b)(4) positive growth on (b)(4) plate. This selective media for gram-negative bacteria should not show growth. The results entered on growth promotion test worksheet for media lot no. 099/14 and 0102/14 were not scientifically sound and could not be reproduced/qualified. This media batch was used for (b)(4) samples.

3. The laboratory test did not include scientifically sound results for the growth promotion of microbiological culture media used for the Microbial Limit Test of (b)(4). Specifically, lot no 0088/14 (b)(4) plates were inoculated with (b)(4) and showed no growth after five days incubation at 30-35°C. According to the written procedure CSOP/2014/015/R00 titled “Procedure for Media Management” annexure-V states that has growth promoting property for (b)(4) when incubated at 30-35°C.

4. Filters installed on the (b)(4) system holding tanks (which includes feed tank, tank, & tank) are not integrity tested as described in written procedure SOP/ENG/119/02 “Procedure for Integrity Test of Filter” and this procedure lacks details regarding the requirement and frequency for performance of pre and post filter integrity testing of the (b)(4) filters. In addition, no information is documented in the “Filter Replacement Record”, maintained for each of the (b)(4) system holding tanks, to identify the filter type & micron size and the filter manufacturer’s lot number for each (b)(4) filter.

5. Functionality tests are not performed using known weight control bottles (e.g. underweight and overweight bottles) during the packaging line set-up of Technofour Checkweigher, Model CW-1200 (which includes checkweigher ID No. PRD 220 and PRD 250), after the start up calibration has been performed, to assure that filled bottles of tablets or capsules that exceed the firm’s upper or lower weight limit of grams will be automatically rejected by the checkweigher.

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE

James MacLaughlin, Investigator
Parul Patel, Investigator

DATE ISSUED
12/19/2014

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