

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER FDA/CDER/OC/DMPQ/ICT Attn: Temeka Moore 10903 New Hampshire Ave Bldg. 51, Room 4234 Silver Spring, MD 20993 Phone : (301) 796-3275 Fax: 847-8738 E-mail: CDERICT@fda.hhs.gov	DATE(S) OF INSPECTION 12/7-12/2012
	FEI NUMBER 3002807979

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: **Mr. Naresh K. Gaur, Plant Head**

FIRM NAME Ranbaxy Laboratories Limited	STREET ADDRESS A41, Industrial Area, Phase-VIII A, Sector 76
CITY, STATE AND ZIP CODE S. A. S. Nagar 160071, Mohali, Punjab, India.	TYPE OF ESTABLISHMENT INSPECTED Solid Oral dosage form 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:

Observation 1

There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.

Specifically,

Firm's investigations and corrective and preventive actions were inadequate. For example,

On October 29th the site knew about the (b) (4) API (b) (4) particle contamination issues. Although the API lots # (b) (4) were available in significant quantities the API was not set aside and not used with increased sample sizes during the testing performed as part of the site investigation. The site used 30 grams of retained sample in its investigation protocol testing without assurance that the sample was a representative the API lots from which they were collected in non-uniform (b) (4) particle contamination.

Site decided to manufacture without implementing interim corrective and preventive measures such as enhanced efforts to detect (b) (4) particle contamination of the API lots were used and enhanced in-process controls. The site manufactured (b) (4) finished product lots # (b) (4) between October 29 through November 10th, 2012.

Observation 2

Laboratory records do not include complete data derived from all tests, examinations and assay necessary to assure compliance with established specifications and standards.

Specifically,

The raw material sampling SOP #OP003172 as described and implemented by the site did not assure that the API lots were sampled to be representative of the lots they were sampled from. Per Section 6.2.5, (b) (4) sampling spoons were used to collect samples from the API drums Note under section 6.2.5 of the SOP required sample to be taken from (b) (4). 6.3.15 requires sample to be collected from (b) (4). The sampling procedure lacked guidance to take representative samples from the raw material/API containers. The retain samples were sub-sample of the samples collected above.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE  	EMPLOYEE(S) NAME AND TITLE (Print or Type) Muralidhara B. Gavini, CSO Scott B. Laufenberg, CSO	DATE ISSUED 12/12/2012
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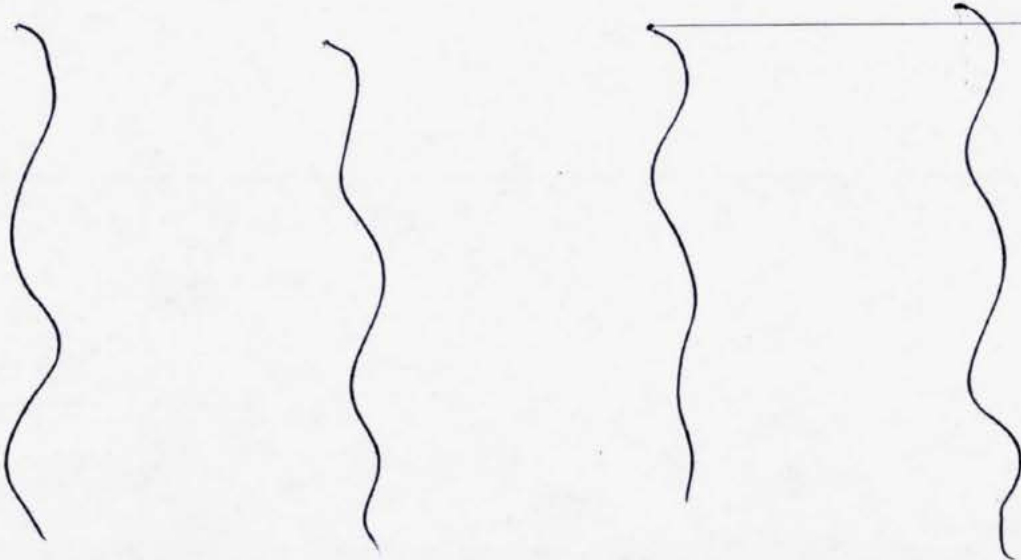
The API testing and release procedures were inadequate. The SOP #GP000040, Revision 2.0 required the analyst to examine for un-dissolved matter at the (b)(4) while the executed batch record only required comply/not comply comment. No comments were recorded on the executed record of analysis.

Observation 3

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

Specifically,

The SOP #OP003305 did not call for examining the (b)(4) retains for foreign matter and there was no other SOP that requires such examination. The site QA manager admitted that examining the (b)(4) retains was not performed as an in-process check during manufacturing of (b)(4) tablets. Review of the executed batch records revealed that no remarks were recorded in the executed batch records.



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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."