

**Inspection Report of M/s AnaZeal Analyticals & Research Pvt. Ltd.
Situating at C-404, TTC Industrial Estate, MIDC, Pawane, Navi Mumbai
400 705.**

Date of Inspection	11 & 12 October 2017			
Name & address of the Laboratory	AnaZeal Analyticals & Research Pvt. Ltd., C-404, TTC Industrial Estate, MIDC, Pawane, Navi Mumbai 400 705.			
Telephone Number	Fax Number	E-mail		
022-2763 3040 / 41 / 42 / 43 / 44	-	<u>info@anazeal.com</u>		
Names and designation of the Inspection Team Members	Name	Designation & Organisation		
	<u>Arun K. Nagarkat</u>	<u>Laboratory Expert, CDTL, Mumbai</u>		
	<u>Arvind R. Hiwale</u>	<u>Drugs Inspector, CDSCO, HQ, New Delhi</u>		
	<u>Rakesh Edlawar</u>	<u>Drugs Inspector, FDA, Maharashtra</u>		
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Purpose of inspection	To carry out Joint Inspection of Private Drug Testing Laboratories approved in Form-37 of Schedule A of D&C Rules, 1945			
Constitution of the Company	Private Limited Company			
License Number and Date	37/KD-TL-9 Valid up to 11.04.2021			
Approved For Chemical Testing	T-2692			
Approved For Microbiological Testing	T-2693			
NABL Accredited:	Yes			
		Total No. of samples analyzed	Samples declared NSQ	Samples declared Spurious
Total Number of Samples analyzed during last three years and no. of samples declared as Not of Standard quality (NSQ)/Spurious	2014-15	2235	NIL	NIL
	2015-16	1489	NIL	NIL
	2016-17	2098	NIL	NIL

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Observations	
General Requirements	<ol style="list-style-type: none"> 1. The management is responsible to ensure that the laboratory carries out its testing, calibration, validation, and all other technical activities in such a way as to meet Good Laboratory Practices (GLP) requirements 2. Qualified individual for carrying out all technical activities and for the implementation of documented quality system and which shall report to the top management directly, is available in the Laboratory
Premises:	<ol style="list-style-type: none"> 1. There are No sources of pollution in the neighborhood of the building. 2. There is No open drain, blocked sewer or public lavatory nearby. 3. The laboratories is designed, constructed and maintained so as to prevent entry of insects and rodents besides cross contamination
Personal:	<ol style="list-style-type: none"> 1. Staff in the laboratory possesses necessary qualification, proper training and has adequate, experience for the assigned duties 2. Training records of all the personnel are maintained. 3. Medical examination of Staff is conducted at least once a year and records maintained. 4. Head of the laboratory is of high professional standing with experience in drug analysis and laboratory management
Equipment :	<ol style="list-style-type: none"> 1. The laboratory is furnished with all types of equipments as may be necessary for carrying out the different activities within the laboratory. 2. The analytical instruments are housed in dust-free environment and whenever required, conditions of temperature and humidity are maintained and periodic checks on temperature and humidity are made and recorded. 3. Instruments requiring calibration calibrated at regular intervals and records of such calibration or maintenance is maintained and are there any written instructions in the form of Standard Operating Procedures for the operation, maintenance and calibration of instruments.
Chemicals and Reagents:	<ol style="list-style-type: none"> 1. The storage and handling of chemicals and reagents are done in a manner considering the physicochemical properties of these substances and the hazards involved in their use. 2. Period for reuse and scientific basis for this period is available

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Good housekeeping and safety:	<ol style="list-style-type: none"> 1. General and specific written down instructions for safety circulated to each staff member and the instructions revised periodically. However, poster displays, audio- visual material and by seminars/conferences are not available. 2. SOP for safety, house-keeping and loss prevention is prepared in accordance with the various rules, and regulations of the Government of India
Maintenance, calibration, and validation of equipments	<ol style="list-style-type: none"> 1. All equipments, instruments and other devices used in the laboratory have appropriate methods and procedures for all tests or calibrations and are regularly calibrated and validated. 2. SOP for calibration and calibration schedule of equipments and instruments prepared by the laboratory and whether logbook is also available and maintained for proper documentation of calibration results
Reference Materials:	Reference materials used for testing and, or Calibration, validation or verification of sample or of equipment, instruments or other devices and all such materials are traceable to agency authorized by Government of India
Microbiological Section	<ol style="list-style-type: none"> 1. Microbiological section separate from other activities with proper air-lock. 2. Access in sterile area is controlled, and if so the system followed in this regard. 3. Equipment used in the microbiological lab is placed logically and function accurately.
Quality system :	<ol style="list-style-type: none"> 1. The quality system is effective in providing necessary assurance that the activities or processes or techniques or practices comply with planned arrangements. 2. It has a documented quality policy for the organization.
Internal quality system audits:	<ol style="list-style-type: none"> 1. Internal audits are done to assure the integrity of the analysis and audits are conducted periodically with a predetermined schedule and procedure with appropriate checklist, to verify that the operations continue to comply with the requirements of quality system and requirements of regulatory authorities. 2. Head of the laboratory is responsible for initiation of the corrective action arising from audits and verification of corrective action.
Standard Operating Procedures:	SOPs are written in a chronological order listing different steps leading to an analysis of drugs or calibration of an instrument and include designation of the person responsible for intended activity
Protocols and specifications archive:	The laboratory has a specification archive and current versions of all necessary specifications are kept as per the requirements of the Act and the rules made there under and the National Pharmacopoeia (Indian Pharmacopoeia).

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Raw data:	Raw data is available. Laboratory work sheet having serial no., analysis sheet, records are available
Storage and archival:	Storage & Archival procedure are available. SOP's are in place.
Handling & Retention	Handling & Retention SOP is available
Certificates & Reports	Test Reports are issued on prescribed Form 39 containing the required information as prescribed
Data Integrity	The records are completed at the time of the operation and are legible maintained with raw data.

Remarks/ Recommendations:- M/s AnaZeal Analyticals & Research Pvt. Ltd. Situated at C-404, TTC Industrial Estate, MIDC, Pawane, Navi Mumbai 400 705 complies with Good Laboratory Practices (GLP) as specified under Schedule L-1 of Drugs & Cosmetics Rules, 1945

Name and signature of Inspecting team members

Arun
12/10/17
(Arun K. Nagarkar)
Laboratory Expert,
CDTL, Mumbai

Arvind
12.10.2017
(Arvind R. Hiwale)
Drugs Inspector
CDSCO, HQ,
New Delhi

Rakesh
12.10.2017
(Rakesh Edlawar)
Drugs Inspector
FDA, Maharashtra