

WHO PUBLIC INSPECTION REPORT

(WHOPIR)

Finished Product Manufacturer

Part 1: General information

Name of manufacturer	EISAI PHARMATECHNOLOGY and MANUFACTURING PVT.LTD
Physical address	Ramky Pharma City (SEZ), Plot No.96, 97, 98, 124 & 126, Parawada-531019, Visakhapatnam District, A.P India.
Postal address	As above
Telephone number	+91-891- 304 7100, +91 8924 660777
Fax number	+91-8924-660759
Summary of activities of manufacturer (e.g. manufacturing, packing).	Manufacturing, quality control and batch release of APIs and FPP: solid oral dosage form – tablets
Indicate dosage forms and type of products (e.g. tablets; cephalosporin containing products)	Hazardous or sensitizing products, including antibiotics, hormones and cytotoxins are not manufactured in facility
Focus of inspection – product formulations in WHO PQ program covered in the scope at the time of inspection	Tablets (immediate release)
Scope and type of inspection	Routine inspection, covering all aspects of GMP
Date of inspection:	21 – 24 January 2013
Project (if any):	Prequalification of Medicines Programme

Part 2: Summary

General information about the company and site

EISAI PHARMATECHNOLOGY and MANUFACTURING PVT.LTD further in the text EPM is a 100% subsidiary of Japan based Eisai Co., Ltd. for manufacturing of active pharmaceutical ingredients (API) and finished pharmaceutical products (FPP). This site started manufacturing operations in December-2009

Till the date of inspection commercial batches of Diethylcarbamazine citrate – 100 mg – tablets (DEC) were not manufactured.

History of WHO or regulatory agencies inspections

This was the first WHO inspection at this site.

The site had been inspected by the following authorities:

Date	Country
11 th January 2010	DCA, India
29 th April 2011	DCA, India
04 th July 2011	DCA, India
19 th July 2011	DCA, India
18 – 21 st October 2011	USFDA
13 th April 2012	DCA, India
21 st May 2012	DCA, India
10 – 11 th September 2012	South Korea
Paper Based Inspections	
June 2011	PMDA, Japan
May 2012 (API)	MHRA, UK

Focus of the inspection

The inspection focused on the production and control of NT002 Diethylcarbamazine citrate – 100 mg – tablets validation batches.

The inspection covered all the sections of the WHO good manufacturing practices: main principles for pharmaceutical products guideline, including quality assurance, premises,

equipment, documentation, materials, validation, sanitation and hygiene, production, quality control, utilities and manufacture.

Inspected Areas

- Quality Assurance
- Sanitization and hygiene
- Qualification and validation
- Complaints
- Recalls
- Self-inspection
- Personnel
- Training
- Personal hygiene
- Premises
- Equipment
- Materials
- Documentation
- Production
- Quality control

2.1 QUALITY ASSURANCE

A system for quality assurance in general was established. Production and control operations were clearly specified in written procedures, arrangements were made for the manufacture, supply and use of the correct starting and packaging materials. Necessary controls on materials, calibrations, and validations were carried out. There was a system for Quality Risk Management (QRM) in place as well as Corrective actions and preventive actions. Product quality reviews (PQR) were conducted for all products.

Product Quality Review

PQR for DEC three process validation batches (January – December 2012) was presented and reviewed by the inspector, no observations were made.

Another product PQR was also reviewed, no observations were made.

CpK calculation formula and excel sheet used for the calculation of process capability were reviewed, no observations were made.

According to company policy, the following excel sheet calculations were re-checked manually:

- SD
- Mean
- CP
- CPL
- CPU
- CpK

PQR was performed of acceptable standard.

Quality Risk Management (QRM)

QRM was implemented. Standard Operating Procedure (SOP) risk management was reviewed, no observations were made. Failure mode and effect analysis (FMEA) were used for risk assessment.

Risk assessment was carried out for each product before process validation. Risk assessment for DEC tablets report was reviewed. Risk assessment was very extensive and started from receipt of materials.

Till the date of inspection the following risk assessments were carried out:

- All products
- Stability chambers
- PW generation, storage and distribution system –document was spot checked
- HVAC - document was spot checked
- Nitrogen generation and distribution system
- Compressed air generation and distribution system
- IT infrastructure

QRM was performed of acceptable standard.

Change control (CC)

The SOP on change control and flow chart were spot checked. Changes were not classified. According to the SOP CC should be closed within 3 months.

CC registers were dedicated to the respective departments, e.g. QC, DP (drug product), and QA.

Drug product CC register was reviewed as well as two CC, no observations were made.

CC's were trended and trend results were presented to the inspector. Trending was carried out every 3 months.

Change control was performed of acceptable standard.

Deviation handling

The SOP on deviation handling was reviewed. Deviations were classified as:

- Planned
- Unplanned

Unplanned deviations were recorded in the Batch Manufacturing Records (BMR's). Registers were dedicated to the respective departments, e.g. QC, DP (drug product), and

QA. According to the SOP planned deviations should be closed within 60 days and unplanned within 30 days.

Planned deviation log for Drug product was reviewed, no observations were made.

Deviation management was performed of acceptable standard.

Corrective actions and preventive actions (CAPA)

According with the SOP CAPA's should be implemented within 30 days of initiation. Summary of the CAPA's including the trends was prepared by QA on monthly basis. Review summary of CAPA for period January – December 2012 and CAPA register was reviewed.

Two CAPA's were reviewed, no observations were made.

Fish bone diagram were used for Root Cause Analysis (RCA). CAPA's trending was carried out and trend results were presented to the inspector. Trends were reviewed every month, no observations were made.

Investigation SOP described how to conduct RCA. RCA was used for investigation of:

- Deviations
- Complaints
- Non-conformances
- Adverse trend (OOT)
- Deficiency
- Abnormality observed during manufacturing, packing, testing, storage and distribution of DP and DS.

Investigations trending was carried out and trend results were presented to the inspector. Trends were reviewed every month, no observations were made.

For RCA the following tools were specified:

- FMEA
- Brainstorming
- Cause and effect/ Fish bone diagram
- Flow charts
- Decision charts
- Why-why analysis
- 1H-5W (how, what, when, where, why, who)

Management review

Management review SOP was spot checked. According to the SOP review should be carried out once in 3 months.

Management review meeting records were presented to the inspector and were spot checked. No observations were made.

2.2 GOOD MANUFACTURING PRACTICES (GMPs) FOR PHARMACEUTICAL PRODUCTS

Good manufacturing practices generally were implemented. The necessary resources were provided. Manufacturing processes were clearly defined and systematically reviewed. Qualification and validation were performed. Operators were trained to carry out procedures correctly, and records were made during manufacture.

2.3 SANITATION AND HYGIENE

Premises and equipment were maintained at an acceptable level of cleanliness. The company had a standard operating procedure as the basis for its approach to personal hygiene and sanitation in its production facility.

Clean areas were cleaned frequently in accordance with an approved written programme and SOPs. Microbial monitoring was regularly undertaken.

2.4 QUALIFICATION AND VALIDATION

The company identified what qualification and validation work was required. The key elements of a qualification and validation programme were defined and are in the validation master plan (VMP).

VMP

VMP was spot checked. VMP was applicable for:

- Facility qualification
- Manufacturing equipment qualification
- Laboratory equipment qualification
- Process validation
- Cleaning validation
- Analytical method validation

Re-validation approach was described in the VMP. No observations were made.

Process validation

DEC process validation batches were manufactured in September 2012. Till the date of inspection the batches had not been packed because of the installation of the bottle packaging line. Bulk tablets were stored in quarantine area in the production department.

Bulk product hold time studies were completed for 90 days. 180 days studies were on going. It was also explained that clean equipment hold time studies were carried out. According to the company clean equipment hold time was specified 7 days. Clean equipment hold time studies records were not reviewed.

“Hold time study Protocol DEC 100 mg tablets” and “Interim report compressed tablet hold time study DEC WHO market” were presented to the inspector. Protocol and interim report were reviewed, no observations were made.

DEC 100 mg tablets process validation protocol and report along with BMR and analytical raw data were reviewed. Also API standard test procedure and analytical raw data were reviewed. Several re-calculations of analytical raw data were carried out and results were identical to initial results.

Cleaning validation

SOP and cleaning validation studies for specific product was spot checked.

Criteria applied for cleaning validation studies were:

- MACO
- NMT 01.% of minimum daily dose
- 10 PPM
- Visually clean
- Microbial limits

Cleaning validation studies were carried out for all manufactured products. Cleaning verification was carried out every 6 months using swab samples. Daily cleaning verification criteria was visually clean.

Swab recovery studies were carried out for SS and PVC surfaces. Cleaning validation studies was performed of acceptable standard.

HVAC qualification

HVAC system performance re-qualification of granulation area was carried out in January 2012 and December 2012. Both reports were reviewed.

The following checks had been done for HVAC re-qualification (December 2012):

- Particle counts – every 6 months
- Air velocity and air changes per hour - every year
- HEPA filter integrity, particle count recovery, airflow pattern – every 2 years

Calibration certificates of test equipment's were attached to the re-qualification protocol.

HVAC qualification was performed of acceptable standard.

Production equipment qualification

Compression machine Installation Qualification, Operational Qualification and Performance Qualification reports were available. Performance Qualification report was spot checked. No observations were made.

PW system qualification

PW system 3 phase validation was finished 31 March 2011.

Welder's qualification certificate was reviewed. Boroscopic video graphics had been taken for all weld joints. CD with boroscopic video graphics was available, but not checked during the inspection. Zero dead leg diaphragm valves were installed in the system.

PW tests trends (2012) were spot checked. No OOS results were obtained.

PW system qualification was performed of acceptable standard.

Equipment Qualification

Electronic Multi-Channel Counter machine Design Qualification, Installation Qualification, Operational Qualification and Performance Qualification protocols and reports were available and presented to the inspector. Operational Qualification and Performance Qualification protocols and reports were spot checked, no observations were made.

2.5 COMPLAINTS

Complaints and other information concerning potentially defective products were reviewed according to written procedure and the corrective actions were taken. Complaints concerning a product defect were recorded and investigated. Complaints should be completed within 30 calendar days.

Complaints trending and review of complaints were carried out every three months and submitted to the higher management for review. Trends were spot checked.

Specific complaint was reviewed, no observations were made.

Complaints register was spot checked. Complaints management was of acceptable standard.

2.6 PRODUCT RECALLS

The written procedure to recall products from the market was reviewed. The authorized person responsible for the execution and coordination of recalls was designated. Till the date of inspection there was not product recall carried out.

Recalls were classified as:

- Class I
- Class II
- Class III

According with the SOP mock recall should be carried out once in every 3 years. Mock recall was carried out on 16.01.2013. Recalls management was of acceptable standard.

2.7 CONTRACT PRODUCTION AND ANALYSIS

Production activities were not contracted out.

Four contract laboratories were used for excipients and HDPE bottles analysis.

Contract laboratory audit report was reviewed. Audit report observations were detailed and comprehensive. CAPAs were evaluated and found to be satisfactory.

According with the SOP evaluation and certification of contract testing laboratory re-evaluation should be carried out every two years.

Technical agreement (TA) with contract laboratory was reviewed. The main part of the TA consisted of check list explaining responsibilities for Contract giver and Contact acceptor. Contract was found to be comprehensive. Reviewed contracts were of acceptable standard.

2.8 SELF INSPECTION AND QUALITY AUDIT

Self-inspections were performed routinely. The frequency at which self-inspections were conducted was stated in the procedure and was specified as 6 months. The following departments were subject to self-inspections:

- Manufacturing department
- Warehouses department
- Engineering department
- QC department
- QA department
- Human resource & Administration department
- IT department

A report was made at the completion of a self-inspection.

Self-inspection was carried out according different check lists dedicated for the departments. Non-conformances observed should be investigated in accordance with SOP investigations. Approved Internal auditors list was presented to the inspector.

Observations were classified as:

- Critical
- Major
- Minor
- Recommendations

The system was in place for approving suppliers of starting materials - active and inactive and primary and secondary packaging materials.

Vendor's qualification was based on:

- Sample testing
- Vendor evaluation check lists
- On-site audits

According with SOP all vendors of API should be audited prior to adding them onto the approved supplier's list. Re-qualification audits should be carried out within 2 years ± 45 days. Approved list of external auditors were presented to the inspector.

On spot checks suppliers audit schedule was followed and reports were available.

One DEC API manufacturer audit was carried out. Audit report and CAPAs were reviewed. Audit report was found to be comprehensive. CAPAs were evaluated and found to be satisfactory.

Second DEC API manufacturer audit was carried out. Audit report was found to be comprehensive. CAPAs were not received till the date of inspections.

Printer of roll labels audit was carried out. Audit report was reviewed and found to be comprehensive. CAPAs were not received till the date of inspections.

Manufacturer of containers and closures audit was carried out. Audit report was reviewed and found to be comprehensive. CAPAs were evaluated and found to be satisfactory.

Self-inspection and approval of vendors were of acceptable standard.

2.9 PERSONNEL

The manufacturer had an adequate number of personnel with the necessary qualifications and practical experience. Responsible staffs, specific duties were recorded in written job descriptions. Personnel were aware of the principles of GMP and received initial and continuing training, including hygiene instructions, relevant to their needs. Steps were taken to prevent unauthorized people from entering production, storage and QC areas. SOP's washing and inspection of garments and cleaning of factory shoes and safety goggles were spot checked. Garments from different departments were washed separately.

The following Job Descriptions were reviewed:

- Assistance General Manager QA
- Assistance General Manager Formulation Manufacturing
- Senior manager QC

2.10 TRAINING

Training of Employees SOP was reviewed. The following types of training were specified in the SOP:

- Induction training
- On-job training
- cGMP training
- SOP training
- Training needs identifications
- Retraining
- External training

Training effectiveness was evaluated.

GMP training schedule for years 2012 and 2013 and GMP training tracker was spot checked and compared with presented schedule for 2012. On spot check schedule was followed.

cGMP training module was spot checked. Training Matrix for drug product department was presented to the inspector and SOP's training records were spot checked.

Separate training files for all employees were maintained by the QA.

Procedure for Analyst qualification was reviewed. Newly recruited analysts should be qualified within 3 months of joining the respective area of work. Each analyst should be re-qualified every 2 years and after long leave - more than 3 months. Analysts were qualified by having them retest already tested samples. Results were compared and allowed RSD was specified.

Analyst qualification matrix was available and presented to the inspector. Training was carried out of acceptable standard.

2.11 PERSONAL HYGIENE

The SOP personnel hygiene & cleanliness and SOP employee's health check-ups were spot checked. All employees should fill up medical self-declaration form and undergo medical check-up before employment. Regular health checks were carried out annually.

Direct contact was avoided between the operator's hands and starting materials, primary packaging materials and intermediate or bulk product. Smoking, eating, drinking, chewing, and keeping plants, food, drinks, smoking material and personal medicines was not permitted in production, laboratory and storage areas. Wrist-watches, cosmetics and jewelry were not

being worn in clean areas. High performance of personnel hygiene was observed during the inspection.

2.12 PREMISES

Exposed surfaces were smooth, impervious and unbroken. Changing rooms were designed as four cascade airlocks and used to provide physical separation of the different stages of changing. Photos explaining changing procedures were available in all changing rooms; changing rooms were equipped with mirrors. Additional changing rooms and separate material entry rooms were located before each production room where works with open products were carried out, for example granulation room, tablet compression rooms.

Premises were cleaned and disinfected according to written procedures. Records were maintained. API sampling room log book and cleaning procedure was reviewed. Cleaning was recorded in check list. Two types of cleaning were applied.

Ancillary areas

Rest and refreshment rooms were separate from manufacturing and control areas.

Storage areas

Storage areas were of sufficient capacity. Receiving and dispatch bays protected materials and products from the weather. Segregation was provided for the storage of rejected, recalled, or returned materials or products. All materials in the warehouse were stored in high racks. Separate sampling areas were provided for APIs, excipient's and packaging materials sampling. Primary packaging materials were sampled in separated room located in the production department.

Weighing areas

Dispensing was carried out in two dispensing areas. One dispensing area was used for APIs dispensing second one for excipient dispensing.

Quality control areas

QC laboratories were separated from production areas. Sufficient space was given to avoid mix ups and cross-contamination. Adequate storage space was provided for samples, reference standards, solvents, reagents and records.

Microbial laboratory was separated from production and QC laboratories. Separate air-handling units were provided for microbiological laboratories.

2.13 EQUIPMENT

Fixed pipework was clearly labeled to indicate the contents and the direction of flow. Balances and other measuring equipment of an appropriate range and precision were available for production and control operations and were calibrated on a scheduled basis. Balances were verified daily, full scale calibration was carried out every three months for the balances located in the warehouse and production areas and monthly for balances

located in QC. Standard weights were available in production and QC departments. Standard weights calibration certificates were presented to the inspector. Production equipment was cleaned on a scheduled basis.

Laboratory equipment and instruments suited to the testing procedures undertaken. HPLC columns were dedicated and were stored properly. Laboratory equipment calibration was carried out.

Major production and laboratory equipment were subject to planned preventive maintenance.

Preventive Maintenance (PM)

Three types of PM were specified in the SOP:

- Scheduled PM
- Breakdown maintenance
- Demand maintenance

PM planner & Tracker was spot checked. Several equipment PM schedules were checked. On spot checks, presented planner was followed. Equipment had separate PM SOPs and check lists.

The SOP of PM for tablet compression machine and check list was spot checked. No observations were made.

Calibration

Calibration master plan was applicable for measuring instruments. Master list of calibration process equipment drug facility year 2012 was spot checked. On spot checks calibration plan was followed. Calibration SOPs as well as calibration certificates were available for equipments.

Calibration procedure and calibration certificate for Digital Timer were reviewed, no observations were made.

SOP Management of Laboratory Instrument / Equipment and Master calibration planner for 2012 were spot checked.

Extensive HVAC systems were installed, with 30 separate AHU. Each unit contained appropriate filters, finishing with a 0.3 micron HEPA filter in manufacturing areas. Air quality report for Granulation area was reviewed and appeared generally satisfactory with grade D quality routinely achieved.

Purified water was produced by passing potable water through two RO units and EDI. Purified water was continuously circulated in a stainless steel loop at ambient temperature. Tank and loop were routinely sanitised by steam every 15 days.

Hydrophobic filter installed on the PW storage tank and its integrity test was carried out every 6 months. UV lamp intensity was monitored. The system appeared well constructed and controlled.

SOP “Quality monitoring of compressed air system” was spot checked. Oil content was monitored once in 6 months.

Compressed Air Generation, storage and Distribution system Performance re-qualification report was spot checked. Re-qualification was carried out once in a year. The following tests were carried out during the re-qualification:

- Microbial tests for bacteria and fungi
- Oil contamination check
- Particle counts – this test was contracted out
- Dew point (on-line)
- Pressure verification at user points

No observations were made.

2.14 MATERIALS

Incoming materials and finished products were quarantined after receipt until they were released for use or distribution. Materials and products were stored under the appropriate conditions. Food grade oil was used for punches and dies lubrications.

Temperature (T) and Relative Humidity (RH) distribution studies were carried out for all materials storage areas, stability chambers, incubators and refrigerators. Stability chambers and incubators were equipped with alarm system, connected to the engineering department. T in stability chambers were recorded continuously using 8 (T) sensors. Data-logger printouts were checked every day.

T mapping for the raw materials warehouse was carried out for 3 seasons (summer, winter and rain season). T mapping studies were spot checked. Minimum and maximum T was recorded once per day. Separate AHU’s were provided for the warehouse to control required storage conditions. No observations were made.

Starting materials

Starting materials were purchased from approved suppliers. Approved suppliers lists for starting materials (active and inactive) and packaging materials were available. For each consignment, the containers were checked for integrity of package and seal. Damage to containers and any other problem that might adversely affect the quality of a material were recorded and reported to the QA department. Check-lists were used for materials receipt. No observations were made.

Packaging materials

Packaging materials were purchased from approved suppliers. Printed packaging materials were stored in secure conditions. Each delivery of batch of printed or primary packaging material was given a specific reference number. No observations were made.

Finished products

Finished products were held in quarantine until their final release, and stored under conditions established by the manufacturer. Batch release SOP and check list were spot checked. No observations were made.

Recalled products

Recalled products were stored separately in a secure area. No observations were made.

Returned goods

Returned goods were stored separately in a secure area. No observations were made.

Reagents and culture media

Records for preparation of reagents and culture media were available. Reagents made up in the laboratory were appropriately labeled. Dry reagents expiry date was specified 3 years after opening the container, liquid reagents 2 years after opening the container.

Growth promotion tests were applied to verify the suitability of culture media. Autoclave validation reports were not reviewed during this inspection. No observations were made.

Reference standards

Only USP official reference standards were used. Standards were stored according with specified storage conditions and usage was recorded in log book as well as in Analytical Work sheets. No observations were made.

2.15 DOCUMENTATION

In general documents were designed, prepared, reviewed and distributed with care. Documents were approved, signed and dated by the appropriate responsible persons. Documents were regularly reviewed and kept up to date. Records were made or completed when any action was taken. Documents related to the production and QC were kept up to 10 years.

Labels

Labels applied to containers, equipment and premises were clear and unambiguous.

Specifications and testing procedures

Testing procedures were approved, signed and dated. Testing procedures and specifications were available for starting and packaging materials and for finished products as well as for intermediate and bulk products.

Batch processing records

Batch manufacturing records (BMRs) were kept for each batch processed. Before any processing begins, checks were made that the equipment and work station were clear of previous products, documents, or materials, and that the equipment was clean and suitable for use. Checks were recorded and were part of the BMR.

Assessment of the Site Master File

The Site Master File was available in electronic form before the visit was made to the manufacturing site. It included detailed schematic plans and drawings of the buildings and utilizes, such as the water systems. In general it complied with the guidelines on preparation of the SMF.

2.16 GOOD PRACTICES IN PRODUCTION

Handling of materials and products were carried out in accordance with written procedures. Checks on yields and reconciliation of quantities were carried out. During processing, all materials, bulk containers, major items of equipment and rooms were labeled. Equipment spare parts such as FBP filter bags, sieves, stereos and screens were stored securely in locked cabinets. Punches and dies were product dedicated and rotation was ensured.

Before processing operations was started, steps were taken to ensure that the work area and equipment are clean and free from any starting materials, products, product residues, labels or documents not required for the current operation. Necessary in-process controls and environmental controls were carried out and recorded.

Packaging operations

Packaging was not carried out during inspection. Primary and secondary packaging lines were dedicated to production of DEC tablets. IQ, OQ and PQ were finished 21.01.2013. Packaging lines had on-line bar code reader (scanner), labels presence sensor and bottle counter.

2.17 GOOD PRACTICES IN QUALITY CONTROL

The QC function was independent of other departments. Adequate resources were available to ensure that all the QC arrangements are effectively and reliably carried out. QC personnel had access to production areas for sampling and investigation as appropriate. Analytical work sheets were checked by the supervisor and approved by the QC Manager. CoA was approved by the QC Manager.

Control of starting materials and finished products

Tests followed the instructions given in the relevant written test procedure. The result was checked independently before the material or product was released.

In-process controls

In-process (IPC) laboratory was located in the production department and carried out IPC tests.

Batch record review

QC records were reviewed as part of the approval process of batch release. Retention samples from each batch of finished product were kept for one year after the expiry date. Finished products were kept in their final packaging and stored under the recommended conditions.

Out of Specification (OOS) and Out of Trends (OOT) results

Out-of-specification results were investigated in accordance with an approved procedure. OOS register and records were maintained. The OOS SOP was based on USFDA guideline. Three phase investigations were carried out for OOS:

- Phase I- Laboratory Investigation
- Phase II – Sampling Investigation
- Phase III – Manufacturing Investigation

Trending was carried out every 3 months and trends were spot checked.

Two OOS investigation reports were reviewed. Investigations were found to be well carried out, for the RCA 6M's Fish bone diagram was used.

OOT

“Trend monitoring and Handling of out of trend” SOP was applicable to:

- Key starting materials
- Isolated intermediates
- In-process samples
- Finished products samples
- Stability samples

Till the date of inspection one OOT was registered and report was spot checked.

Stability studies

Stability studies SOP, protocol and report for DEC 100 mg tablets were reviewed, no observations were made.

For validation batches 3 month accelerated ($40\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$ and $75\% \pm 5\%$) and long term ($30\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$ and $75\% \pm 5\%$ - zone 4) studies were completed by the date of inspection.

24 months expiry date was assigned to the product based on the Bio batch stability studies. Bio batch accelerated stability studies and 12 months long term stability studies were completed till the date of inspection. Bio batch accelerated stability studies 6 months analytical raw data was reviewed, no observations were made.

Microbiological laboratory

SOP “Microbiological Environmental Monitoring (EM) in Production facilities” along with EM trend data for 2012 were spot checked. The following tests were carried out once in a month for all production rooms starting the first air lock:

- Passive air sampling
- Active air sampling

No observations were made.

Part 3: Conclusion

Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection listed in the Inspection Report, EISAI PHARMATECHNOLOGY and MANUFACTURING PVT.LTD located at Ramky Pharma City (SEZ), Plot No.96, 97, 98, 124 & 126, Parawada-531019, Visakhapatnam District, A.P, India, was considered to be operating at an acceptable level of compliance with WHO GMP guidelines.

All the non-compliances observed during the inspection that were listed in the full report as well as those reflected in the WHOPIR, were addressed by the manufacturer, to a satisfactory level, prior to the publication of the WHOPIR

This WHOPIR will remain valid for 2 years, provided that the outcome of any inspection conducted during this period is positive.