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Prequalification Team Inspection services
WHO PUBLIC INSPECTION REPORT
(WHO PIR)
Bio-Equivalence Study

Part 1	**General information**
Company details	
Name of company	Sun Pharmaceutical Industries Limited
Corporate address of company	Sun Pharmaceutical Industries Limited SUN HOUSE CTS No. 201 B/ I, Western Express Highway Goregaon (E), Mumbai 400063; India
Inspected site	
Name & address of the inspected site	**Clinical site:** Sun Pharmaceutical Industries Limited CPU Sun Pharma Road, Tandalja Vadodara - 390 012 Gujarat, India
GPS coordinates	Latitude 22,2809 Longitude 73,1497
Inspection details	
Date of inspection	14-15 January 2019
Type of inspection	Initial
Introduction	
Brief description of Activities performed at the site	The site had an aim to provide clinical pharmacokinetic studies in healthy human volunteers for approval of drug candidate for marketing in domestic and international markets. The source of formulated drug candidate was the formulation and development unit of SPIL or any other manufacturer of finished product under cGMP conditions. The aim of the Clinical Research facilities was to assess the bioavailability and conclude bioequivalence between the test drug and a similar Reference Listed Drug from innovator or the equivalent form of any other manufacturer. The centers also carried out bioavailability studies of newly formulated drug candidate to study the pharmacokinetic parameters of the drug candidate.

General information about the company and site	Sun Pharmaceutical Industries Limited established in 1983 and headquartered in Mumbai, India, is an international, integrated pharmaceutical company, with 45 global manufacturing facilities. Sun Pharma acquired Ranbaxy in March 2015. Approximately 2000 products were produced by the company around the world and the company was ranked as number One in India. In addition to manufacturing and bioanalytical sites, the company, in India consisted of three CPU units located in New Delhi and Vadodara. The clinical site in Vadodara was in the Research and Development Center of Sun Pharmaceuticals Industries Limited, Tandalja, Vadodara with facilities required for proper conduct of studies.
History of previous inspections	The Cooperate was inspected by various regulatory authorities, including USFDA, MHRA (UK), ANVISA (Brazil), ANSM (France), NPRA (Malaysia) and CDSCO (India). The site was not previously inspected by WHO.
Brief report of inspection activities undertaken – Scope and Limitations	
Areas inspected	The scope of the inspection included a review of the following study-related activities: The company's history, clinical study performance, informed consent process, ethics committee approvals and correspondence, test product accountability, dispensation and storage, processing and handling of plasma samples collected during the study, equipment calibration, employee training, computer controls. Tours of the facilities were also conducted.
Restrictions	Not applicable
Out of scope	Not applicable
WHO product covered by the inspection	**Study no. PKD_15_326** Bioequivalence study of Abacavir and Lamivudine tablets, 600 mg / 300 mg
Abbreviations	**Meaning**
ADR	adverse drug reaction
AE	adverse event
ALCOA	attributable, legible, contemporaneous, original and accurate
BE	bioequivalence

BDL	below detection limit
CAPA	corrective actions and preventive actions
CC	calibration curve
CPU	clinical pharmacology unit
CRA	clinical research associate(e)
CRF	(electronic) case report form
CRO	contract research organization
CoA	certificate of analysis
CS	calibration standard
CSR	clinical study report
CSV	computerized system validation
ECG	electrocardiogram
F/T	Freeze thaw study
GCP	good clinical practice
GLP	good laboratory practice
HPLC	high-performance liquid chromatograph
HQC	high concentration quality control standard
IB	investigator's brochure
ICF	informed consent form
ICH	International Conference on Harmonization
IEC	(independent) ethics committee
IMP	investigational medicinal product
IS	internal standard
ISR	incurred sample reanalysis
ISV	internal standard response variation
JD	job description
LC-MS/MS	liquid chromatography–mass spectrometry
LIMS	laboratory information management system
LLOQ	lowest limit of quantification
LOD	limit of detection
LTS	long term stability
MVR	monitoring visit report
OQ	operational qualification
P&A	precision and accuracy
PIS	patient information sheet
PQ	performance qualification
QA	quality assurance
QCs	quality control samples
QM	quality manual
QMS	quality management system

RT	retention time
SAE	serious adverse event
SAR	serious adverse reaction
SOP	standard operating procedure
SUSAR	suspected unexpected serious adverse reaction
ULOQ	upper limit of quantification
URS	user requirements specifications
WS	working standard

Part 2	**Summary of the findings and comments**

General section

1. Organization and management

A presentation was provided explaining the activities of the organization at each site in detail.

Clinical Pharmacology Unit Sun Pharmaceutical Industries Ltd located at Tandalja, Vadodara Gujarat was located at the main R&D campus with a total capacity of 107 beds.

The Organizational chart depicting key positions and the names of responsible persons was dated 3 Sep 2018, approved by Head-CPU; Dr Reddy. The interrelationship between human resources and management was explained by the training coordinator who was also responsible for organogram updates in accordance with SOP for Preparation and handling of org chart.

New procedure was implemented to submit the minutes of meeting arranged by local Quality Review Board (QRB) to the top management per the applicable SOP. The information about the review of the trend analysis of the observations was included in the minutes of meeting. The documentation was dated and circulated on 28 Dec 2018 and the amendment was sent on Jan 2019.

The general working hours was considered from 9am to 6pm, with additional shifts depending on the type of activities.

2. Computer systems

A list of software and computer systems used in the studies was provided.

Computerized system inventory and the respective Master validation plan was prepared and organized per applicable SOP for CS periodic validation review which was identical with Hamdard Nagar clinical site.

The connection between the clinical laboratory instruments and CLIS system was recently established. The computerized system validation plan for CLIS was provided. The User Requirement Specification dated 22 Jan 2018 and the respective PQ documentation were reviewed.

The access control was handled by IT using a "User access Manual form" completed by responsible department, upon the employment of staff. In addition, a list of employees, titled as "List of active users of (database)", with information about each individual's access right to the respective database was provided.

All electronic records obtained from computerized systems were backed-up on daily, monthly, weekly and yearly basis. There was also an archival backup process, providing two copies.

Restorage of the data stored on the backup-media was carried out by IT, based on a request form issued by the applicable department. The template was titled as "Electronic data archival and restoration" annexed to the respective SOP. The request form was used for three different activities:

- Data restoration
- Archived data verification
- Periodic verification

The observations made during the inspection were adequately addressed in the respective CAPA plan.

3. Quality management

The CRO's Quality management was investigated to ensure that appropriate and technically valid SOPs were established and followed in a proper manner. The independency of QA unit was ensured by using autonomous reporting route throughout the organization. The QM was a common document shared with New Delhi and Gurgaon sites.

The company's QMS consisted of:

- Quality policy
- Quality manual
- Global standard operating procedures (GSOP)
- Site specific standard operating procedures
- Forms, templates and Logbooks

An adequate CRO Master File was available.

The process for gap assessment and implementation of Global SOPs in the sites' local QMS was described in the global SOP for Global document management. A form B for completion of gap assessment should be completed to assess the compliance of the local SOPs with the applicable global SOPs. Based on this assessment, the site could either use the global SOP as it was or make the required modifications to implement the practice as applicable.

A list of SOPs was available. During the inspection, it was verified whether the reviewed activities were performed in accordance with the organization's SOPs and written protocols.

The independency of the QA-unit was depicted in a separate Organogram. The organogram was provided in accordance with the respective SOP. The communication between SVP & Head-Global Quality & compliance and QA-Unit was confirmed through emails.

CAPA plan process was inspected. The effectiveness review was adequately described in SOP for Handling of Corrective action and preventive action. The procedure was investigated and verified.

A list of selected service providers and an approved vendor audit plan for 2019 were available.

Issuance of templates/forms were performed by the QA-unit, responsible for issuing of the working copies which were paginated, dated and identified with a number. The issuance of forms was logged in another template for "Working copy issuance record" which was controlled by another template-log.

SOP for Change control management was reviewed. The documentation for the most recent change control process handled in Trackwise system was provided. The process was adequately completed.

The observation with relation to the QMS was adequately addressed in the respective CAPA plan.

4. **Archive facilities**

The archive facility was located on the ground floor with the rest of the facility and managed by designated archivists. The facility had sufficient storage space. The storage facility was temperature-, humidity- and pest-controlled. Access to archive storage areas were controlled and restricted to authorized personnel, including Head of Site. Contract valid from 25 March 2015 to 31 March 2016 with Rentokil India Pvt Ltd regarding pest control services was verified.

This storage facility was used for general documentation such as logbooks, laboratory-related data and calibration data. Study-related documentation were transferred to another in-house facility. The process of transfer of study documentation was sufficiently described and all binders were indexed with details. The retrieval and traceability of the archiving process was verified by successful recall of study documentation and supporting records during the conduct of the inspection.

The observation with relation to the Archive facility was adequately addressed.

5. Premises

During the inspection, a tour of facility was provided.

The premises had sufficient space to accommodate the personnel and activities required to perform studies. The facility was clean and had adequate lighting, ventilation, and was easy to clean and decontaminate.

The premises consisted of pharmacy area, CPUs in four wards with a total capacity of 107 beds (4 Clinical Wards with 18 + 26 + 26 + 37 beds), screening facility, separation room, physicians room, CRAs room, Emergency facility, dosing area, cafeteria and clinical pathology laboratory.

The facility was powered by a continuous commercial electricity supply. There was a 500 kVA Diesel Generator (DG) set for power generation with the respective SOP and maintenance logbook available. Additionally, 3 UPS of 30kw, 50 kw and 50kw total of 130 kw were in use at the site.

At the time of conduct of the study in the scope of inspection, the attendance sheet, baggage check and body search were used as documentation for volunteers' visits. There was also a logbook for registration of volunteers' demographic information at the time of screening.

The waste management room was clean and well-ordered, using the back (Emergency) Exit door for evacuation of the waste to the contractor vehicle. The applicable SOP was reviewed. The biomedical waste was categorized in red, blue, white, yellow and hazardous waste. Segregation, packaging and storage of biomedical waste was explained. A Master Service agreement with the Quantum Environment Engineers - Biomedical waste treatment facility was not applicable. The CRO-application was electronically sent to the QEE via their webpage and the payment was recorded in CRO's profile, together with their authorization valid until March 2019.

Synchronized clocks were located throughout the facility to document the exact time study activities occur.

Temperature mapping documentation of deep freezer from July 2015 to July 2016 was adequately provided by Perfect utilities company, based in Ahmedabad on 18 Jul 2015. Temperature records of the deep freezer for duration of the study was verified.

ICU was equipped with all necessary equipment such as defibrillator, suction apparatus, ECG monitor, nebulizer, laryngoscope & Ambu bag, ventilator, oxygen cylinders, stretcher Lift etc. Moreover, the calibration certificates of devices used in the ICU were randomly reviewed and verified.

Pharmacy

The Pharmacy area, located at the second floor was designed to store and dispense the Investigational Products. The facility was well organized, access-controlled by key card and equipped with pharmaceutical refrigerator, racks for storage of IMPs and laminar air flow bench. Investigational products were stored under controlled environmental conditions by regular monitoring of temperature and humidity. IMPs were segregated in separate shelves labelled with Retained IP, Ongoing studies, Controlled IP and Quarantine IPs with shipment defect.

Calibration certificate of the HEPA filter of the LAF hood was provided dated 8 December 2018; providing the following test:

- Particle count test
- Integrity test result (using aerosol photometer)
- Velocity

The observation with relation to the Premises was adequately addressed.

6. Personnel

The CRO had 98 (84 + 14) permanent and contractual employees for timely and proper conduct of the study. A logbook for handling of master signature was available.

Signed and dated job descriptions and CVs of randomly selected personnel were presented and reviewed. A Skill Matrix, where the roles were categorized, and the SOPs were assigned to the applicable roles was available. The matrix was updated once a year. Training was performed per SOP for Training. The categorizations were reflected on the organization charts which were reviewed and verified.

The observation identified relating to Personnel was adequately addressed.

Clinical section

7. Clinical phase

A password protected list of the studies conducted from 2010 was kept in the system on an Excel sheet by the Internal Review QC team of the CPU. Occasionally, studies were performed in two groups in order to reach the adequate number of volunteers. Two studies were performed on the same molecules in the scope of inspection, adequately justified.

The facility was clean, well ordered, easily accessible and appropriate for the intended number of study subjects. Equipment used in clinical sites were calibrated by external service providers at pre-defined intervals and properly labelled. The adequate function and performance of emergency-use equipment was verified prior to the initiation of the study.

The site consisted of one CPU with sufficient space for 107 beds to accommodate the study subjects. The CPUs allowed supervision by the custodians during check-in periods and monitoring of subjects by CCTV. Hence, restriction of the intake of food or medication within the number of hours specified in the protocol was assured.

The facility was equipped with emergency alarms at each bed which were randomly tested both in the CPU and in the showers. Clothing kits were placed in the changing room and lockers for storage of subjects' personal items were provided.

At the time of the study, there were three hospitals to be used in case of emergency. The agreements were renewed.

- The Baroda Heart Institute and Research centre
- Sterling hospital
- The Global Meridian Hospital

Currently, a practice was implemented to inform the hospital about the initiation of the study through an email. However, the receipt of email was not confirmed by the hospital.

An ambulance was readily available owned by the CRO to transfer the subjects to the hospital in case of emergency.

The observations with relation to Clinical phase were adequately addressed.

8. Clinical laboratory An observation was made at the time of inspection which was adequately addressed.

9. Ethics

Study no ABLM_600+300T_4461_15(A) version 00 dated 25 Nov 2015, and amendment 01, ICF v01 25 Nov 2015 were approved by the Vadodara Ethics Committee on 09 December 2015. The Committee's member list was also reviewed. A notification was submitted to the Ethics Committee on 19 February 2016 for amendment 02 of the protocol.

Screening ICF approval from Vadodara EC was also verified.

All signed ICFs were verified.

10. Monitoring

The study in the scope of inspection was not monitored. Preparation of an SOP was in process to implement the monitoring procedure to appoint a monitor during each study. Sun Pharma as sponsor, had a system to perform an audit of all activities of the study. A plan was issued prior to the study no. PKD_15_326, dated 24 Nov 2017.

All applicable steps and activities were scheduled to be audited and the required documentation was provided. Sun Pharma was the sponsor of the clinical studies and the independency of monitoring activities was assured by designating staff that were independent from the clinical activities.

11. Investigators

The investigator's CV and contract were reviewed. Information concerning the investigator's previous experience and qualification was not adequately recorded in his CV. However, the SOP for Planning, Conduct and evaluation of training" revision 04 was updated to amend the content of employees' resume.

Study's delegation log was available.

The observation with relation to the Investigators was adequately addressed.

12. Receiving, storage and handling of investigational drug products

The form for IP information sheet for both Test and Reference and shipment documentation from Sun Pharma Gurgaon were reviewed. The datalogger serial number was recorded on the DHL receipt documentation of the test product, with shipment reference number. The CRO could not provide the temperature record / data during import of the reference product. Nevertheless, the applicable SOP for Receipt, Handling, Dispensing, Accountability, Transfer, Retention, and Archiving of Investigational Product" was revised to record the temperature during transportation.

The check list for IP dispensing and line clearance was completed on 22 February 2016 for period I and 29 February 2016 for period II. A logbook for recording of IP receipt was available. The logbook was used to record the total number of received samples for both test and reference and the consumption of them, being arranged as a source for reconciliation of IMP. The quantity of remaining test drugs used in the study PKD_15_326 (177 tablets) was confirmed. Details of pharmaceutical product used in the study included dosage form and strength, lot number, expiry date were adequately documented. Suitable qualified pharmacists were responsible for storage, delivery, return and keeping records of IMPs.

Generation of consignment randomization and dispensing randomization was performed by site's statistician at the time of inspection. The randomization list for study PKD_15_326 was submitted by Gurgaon site and received at the courier unit of Vadodara site.

Pharmaceutical products were kept under appropriate conditions. Data logger for monitoring of humidity and room temperature of the facility for the period of the study was reviewed. ADI temperature scanner was used for temperature monitoring of the whole facility.

The observation made with relation to the Handling of investigational products was adequately addressed in the CAPA provided by the CRO.

13. Case report forms

Case report forms were randomly reviewed regarding lab-results, ECGs and deviations of blood sample collection times. Standards format was used and adapted for each study protocol in accordance with the requirements for the study. CRFs reflected the actual results obtained during the study, certified by the designated investigator. Copies of clinical laboratory and all ECGs were included in the CRFs for each subject.

14. Volunteers, recruitment methods

The organization maintained a database of volunteers, from which suitable volunteers for studies based on the requirements of the study, were selected. Volunteers were informed by either word of mouth or phone calls and reported to the facility. For registration purposes, volunteers' eligibility was verified using the OVIS database after completing the screening ICF and providing impressions of thumb. Each volunteer thus enrolled into the database was assigned a unique identity number and was issued an identity card for having registered. This served as the proof of identity for that volunteer for all his/her subsequent visits and participations. The registration and screening history of the volunteers were tracked by the database system. Any changes to demographic data should be approved by designated personnel.

Volunteers were informed of the objective and procedures of the study and consent was obtained for their respective screening. Volunteers underwent clinical examination, ECG and screening for various parameters of haematology, biochemistry, urinalysis and serological tests for HIV as defined by the requirements of the protocol or the screening physician.

The OVIS (Online Volunteer Information System) database was linked with several other bioequivalence centres to avoid cross participation by subjects. Volunteers were blocked in the OVIS system prior to the first dose administration in the clinical site according to the list of admission. Blocking would be approved as soon as dose-administration was confirmed.

Those volunteers who qualified with the inclusion and exclusion criteria as described in the study protocol were considered for enrolment and required to complete the screening activities prior to the check-in. The screening activities at the clinical site consisted of OVIS-verification, alcohol breath analysis test, urine test for drug and final physical examination including ECG.

15. Food and fluids

The Contract with catering company was verified.

Contract, CV and job descriptions of dieticians were available.

16. Safety, adverse events, adverse event reporting

Adverse events were adequately documented in the Adverse Event Reporting form according to the applicable SOP for both adverse events occurring during the study and post-study. Adverse event form dated 24 February 2016 and 1 March 2016 regarding Nausea + medication for resolving the issue (Granisetran) was reviewed. Concomitant medication was also captured on the same form.

17. Sample collection, storage and handling of biological material

At the time of study, the actual time of blood sample collection was only documented by the custodian. The process was amended to be supervised by a CRA to verify that the activity was appropriately performed. The documentation for the most recent study was reviewed.

A documentation of the Drug test kit, e.g. photo of the indicator was not provided at the time of the study. The process was revised to provide a robust documentation. The test kit was used to test several substances, e.g. Phencyclidine, amphetamine, morphine, marijuana, cocaine and benzodiazepine.

The calibration information for randomly selected instruments recorded in the logbook for usage of instruments was reviewed. The certificates were available.

18. Data processing and documentation

The general documents included SOPs, Forms, Formats and Log Formats. The SOPs described and standardized all the important study-related and general procedures to be followed across Sun Pharma. The associated Forms, Formats and Log Formats, as well as data-systems mentioned in section 2 were also developed to capture the information/data that was required to be documented.

Study Protocols, Study plans, Informed Consent Documents, Case Report Forms, and other documents that provided guidance in conduct of clinical phases of study were available. All such documents were prepared/generated, reviewed, approved, issued, used, retrieved and retained as necessary after appropriate controlling and distribution. Logbooks were used for chronological recording of activities.

19. Study report

Study reports were provided and used during the inspection to ensure compliance.

Miscellaneous	
Samples taken	Not applicable
Assessment of the CRO master file	CRO Master file, as well as the Quality Manual were provided and reviewed.
Annexes attached	Not applicable

Part 3	Conclusion

Based on the areas inspected, the people met, and the documents reviewed, and considering the findings of the inspection, including the observations listed in the Inspection Report, as well as the corrective actions taken and planned, the study was considered to have been conducted at an acceptable level of compliance with WHO GCP guidelines at **Sun Pharmaceutical Industries Limited** located at:

Clinical site:
Sun Pharmaceutical Industries Limited
Sun Pharma Road, Tandalja
Vadodara - 390 012
Gujarat, India

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

This WHOPIR will remain valid for 3 years. However, on the 2nd of August 2019, Inspection Services; Prequalification Unit (PQT) was notified that the **clinical bioequivalence or bioavailability study activities of Clinical Pharmacology Units (CPU) of Sun Pharma located at Tandalja was ceased and the site was closed.**

Part 4	List of WHO guidelines referenced in the inspection report

1. Guidance for organizations performing in vivo bioequivalence studies. *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifties Report* Geneva, World Health Organization, 2016 (WHO Technical Report Series, No. 996), Annex 9
   Short name: WHO BE guidance
   http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex09.pdf

2. Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability. In: *Expert Committee on Specifications for Pharmaceutical Preparations. Forty-ninth report*. World Health Organization, Geneva. WHO Technical Report Series, No. 992, Annex 7, 2015, pp. 347–390
   Short name: WHO multisource guidance
   http://apps.who.int/prequal/info_general/documents/TRS937/WHO_TRS_937__annex7_eng.pdf

3. Guidelines for good clinical practice for trials on pharmaceutical products. WHO Technical Report Series, No. 850, 1995 (pp. 97–137)
Short name: WHO GCP
http://apps.who.int/medicinedocs/en/d/Js5516e/19.11.html

4. WHO guidance on good data and record management practices. *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifties Report* Geneva, World Health Organization, 2016 (WHO Technical Report Series, No. 996), Annex 5
Short name: WHO TRS No. 996, Annex 5 WHO GDRMP guidance
http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex05.pdf

5. Handbook – Good Laboratory Practice (GLP): quality practices for regulated non-clinical research and development – Annex I: The OECD Principles on GLP, 2nd ed., 2009. This document will be referred to as "GLP".
Short name: WHO GLP
http://www.who.int/tdr/publications/documents/glp-handbook.pdf

6. The Good Automated Manufacturing Practice (GAMP) Guide – A risk-based approach to compliant GxP computerized systems (GAMP5). ISPE – International Society for Pharmaceutical Engineering, December 2009.
http://www.ispe.org/gamp-5

7. Guidelines on Bioanalytical Method Validation EMEA/CHMP/EWP/192217/2009 Rev.1 Corr.* Committee for Medicinal Products for Human Use (CHMP), 1 February 2012.
http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2011/08/WC500109686.pdf

8. WHO Operational guidelines for Ethics Committees that review biomedical research (7). WHO, TDR/PRD/ETHICS/2000.1
http://www.who.int/entity/tdr/publications/documents/ethics.pdf?ua=1

9. Good Practices for Computerised Systems in Regulated "GXP" Environments, PIC/S Guidance, Pharmaceutical Inspection Convention Pharmaceutical Inspection Co-operation Scheme, PI 011–3, 25 September 2007.
http://www.picscheme.org/pdf/27_pi-011-3-recommendation-on-computerised-systems.pdf

10. US FDA Code of Federal Regulations Part 11
http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=11&showFR=1

11. EU guidelines to Good Manufacturing Practice and Medicinal Products for Human and Veterinary Use Annex 11, Computerized systems
http://ec.europa.eu/health/files/eudralex/vol-4/annex11_01-2011_en.pdf

12. Model guidance for the storage and transport of time-and temperature-sensitive pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 9.
Short name: WHO TRS No. 961, Annex 9
http://apps.who.int/prequal/info_general/documents/TRS961/TRS961_Annex9.pdf

13. Guidelines for the preparation of a contract research organization master file, WHO Technical Report Series, No. 957, 2010, Annex 7
Short name: WHO TRS No. 957, Annex 7
http://www.who.int/medicines/publications/TRS957_2010.pdf

14. Glove use information leaflet, Patient Safety, Save lives clean your hands, WHO, revised August 2009
http://www.who.int/gpsc/5may/Glove_Use_Information_Leaflet.pdf

15. WHO Good Clinical Laboratory Practices (GCLP)
http://www.who.int/tdr/publications/documents/gclp-web.pdf