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

<table>
<thead>
<tr>
<th>Part 1</th>
<th>General information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Organization details</td>
<td></td>
</tr>
<tr>
<td>Company information</td>
<td></td>
</tr>
<tr>
<td>Name and Address of Clinical Research Site</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>
| Name and Address of Bioanalytical Research Site | Mylan Laboratories Limited, Clinical Research Centre (A Viatris Company) - CRC
 Saradhi Chambers, A-4, Rukminipuri
 Near Poulomi Hospital, Main Road, Dr. A.S. Rao Nagar
 Hyderabad 500 062
 India
 Tel: +91-40-30492900
 Fax: +91-40-27138562 |
| Name and address Statistical Site           | Not applicable      |
| Corporate address of Organization           | Mylan corporate office (India)
 Mylan Laboratories Limited (Viatris)
 Plot no 564/A/22, road no. 92, Jubilee Hills
 Hyderabad – 500096, Telangana
 India
 +91 40 30866666
 Mylan.india@viatris.com |
|                                             |                     |
|                                             |                     |

Mylan Laboratories Limited, Clinical Research Centre (VIATRIS), CRO, Hyderabad, India 14-18 March 2022
This inspection report is the property of the WHO
Contact: prequalinspection@who.int

Page 1 of 17
WHO product numbers covered by the inspection/
Product names/ Study numbers/ Study titles

<table>
<thead>
<tr>
<th>WHO application no. HP026</th>
<th>Bioequivalence study of sofosbuvir and velpatasvir 400 mg/100mg film-coated tablets.</th>
</tr>
</thead>
<tbody>
<tr>
<td>WHO application no. HP025</td>
<td>Bioequivalence study of MyHep DVIRTMI (Daclatasvir/Sofosbuvir) 60 mg/400 mg comprimes pellicules (Tablets)</td>
</tr>
</tbody>
</table>

**Inspection details**

<table>
<thead>
<tr>
<th>Dates of inspection</th>
<th>14-18 March 2022</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type of inspection</td>
<td>Routine</td>
</tr>
</tbody>
</table>

**Introduction**

**Summary of the activities**
The primary activities carried out at this facility included bio-analysis, complex molecules analysis and invitro studies of medicinal products developed by Mylan Laboratories Limited.

**General information about the company and site**
Matrix Laboratories were transformed from an API manufacturing facility to Finished Dose Manufacturer in year 2006. An acquisition took place in 2007, and Matrix became a subsidiary of Mylan. June 2011, Mylan announced renaming of Matrix to Mylan, effective from 5 Oct 2011. From January 2012, Matrix was fully transformed as Mylan Laboratories Ltd. In 2020, Mylan Inc. combined with UpJohn and changed the name of the company to Viatris. Clinical research centre of Mylan Laboratories located at Hyderabad; India is now a subsidiary of Viatris.

**History**
A list of inspections performed by various authorities was provided in the CRO Master File. The CRO was previously inspected by WHO on September 2017, July 2016, March 2015, October 2011, May 2010, August 2009, July 2009, and January 2008.

**Brief report of inspection activities undertaken**
Regarding the Analytical operations, coverage was provided to company practices, qualifications of personnel, and procedures utilized during the method validations and analytical testing.

The company’s history, equipment calibration, validation of computerized systems, employee training, computer controls were investigated. A tour of the facility took place.
A review of the analytical method validation, and analytical study data was conducted, along with comparison of the source data to the study reports.

### Scope and limitations

| Out of scope | Not applicable |

### Abbreviations

<table>
<thead>
<tr>
<th>ADR</th>
<th>adverse drug reaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>AE</td>
<td>adverse event</td>
</tr>
<tr>
<td>ALCOA</td>
<td>attributable, legible, contemporaneous, original and accurate</td>
</tr>
<tr>
<td>BE</td>
<td>bioequivalence</td>
</tr>
<tr>
<td>BDL</td>
<td>below detection limit</td>
</tr>
<tr>
<td>CAPA</td>
<td>corrective actions and preventive actions</td>
</tr>
<tr>
<td>CC</td>
<td>calibration curve</td>
</tr>
<tr>
<td>CPU</td>
<td>clinical pharmacology unit</td>
</tr>
<tr>
<td>CRA</td>
<td>clinical research associate(e)</td>
</tr>
<tr>
<td>CRF</td>
<td>(electronic) case report form</td>
</tr>
<tr>
<td>CRO</td>
<td>contract research organization</td>
</tr>
<tr>
<td>CTM</td>
<td>clinical trial manager</td>
</tr>
<tr>
<td>CoA</td>
<td>certificate of analysis</td>
</tr>
<tr>
<td>CSR</td>
<td>clinical study report</td>
</tr>
<tr>
<td>DQ</td>
<td>design qualification</td>
</tr>
<tr>
<td>ECG</td>
<td>electrocardiogram</td>
</tr>
<tr>
<td>GAMP</td>
<td>good automated manufacturing practice</td>
</tr>
<tr>
<td>GCP</td>
<td>good clinical practice</td>
</tr>
<tr>
<td>GLP</td>
<td>good laboratory practice</td>
</tr>
<tr>
<td>GMP</td>
<td>good manufacturing practice</td>
</tr>
<tr>
<td>HPLC</td>
<td>high-performance liquid chromatograph</td>
</tr>
<tr>
<td>LC-MS/MS</td>
<td>liquid chromatography–mass spectrometry</td>
</tr>
<tr>
<td>IB</td>
<td>investigator’s brochure</td>
</tr>
<tr>
<td>ICF</td>
<td>informed consent form</td>
</tr>
<tr>
<td>ICH</td>
<td>International Conference on Harmonization</td>
</tr>
<tr>
<td>(I)EC</td>
<td>(Independent) Ethics Committee</td>
</tr>
<tr>
<td>IMP</td>
<td>investigational medicinal product</td>
</tr>
<tr>
<td>IQ</td>
<td>installation qualification</td>
</tr>
<tr>
<td>LIMS</td>
<td>laboratory information management system</td>
</tr>
<tr>
<td>LLOQ</td>
<td>lowest limit of quantification</td>
</tr>
<tr>
<td>LOD</td>
<td>limit of detection</td>
</tr>
<tr>
<td>MS</td>
<td>mass spectrophotometer</td>
</tr>
</tbody>
</table>
Part 2  Summary of the findings and comments

General section

1. Organization and management
A presentation was provided explaining the activities of the organization in detail.

A registration certificate under the provisions of New Drugs and clinical trial rules was
issued by CDSCO on 15 Sep 2021 with a validity of 5 years.

The CRC had an organization chart depicting key positions and the names of responsible
persons. The organization was led by Dr Ramakrishna Bangaru who was reporting to Head
Global Clinical Pharmacology, Dr Russ Rackley.

There was a job-description for all personnel, including a description of their
responsibilities. Every job description was signed and dated by the staff member to whom
it applied and kept in the respective training folder. Several folders of staff involved in the
studies in the scope of inspection, was selected and verified.

A list of authorized personnel performing tasks during each study, with their signatures was
available.

Global conflicts of interest disclosure form and secrecy, together with a confidentiality
agreement based on the CRO’s policy and conflicts of interest job aid were required to be
completed and signed by each employee.
The working hours were from 9am to 6pm on weekdays. However, the organization had different rotational arrangement during Pandemic state.

2. **Computer systems**

A list of software and computerized systems used in the studies was available.

The computerized systems were required to be qualified and validated in accordance with SOP for Validation of computerized systems and other applicable SOPs. The validation was risk-assessed, planned, designed, performed and the respective tests were recorded to demonstrate that the system could perform as intended.

The qualification and validation of the temperature monitoring system was verified. The off-the-shelf software system was validated on site by means of IQ, OQ and PQ. The associated computer had enough capacity and memory for the intended use. The software system was access controlled, and a list of personnel incl. their access rights was maintained. Operation, calibration and maintenance of the monitoring system was described in the applicable SOP.

The document management system, and training software system were introduced to the inspectors. The operation of the systems, including data flows, user access concepts, import and export options, generation of reports, availability of audit trails, as well as data storage procedures were discussed.

Analyst® software system linked to the randomly selected instruments was upgraded in the beginning of 2019. The respective documentation, together with a list of validation deliverables were available and reviewed. The validation documentation was extensively provided.

Computerised System’s access was restricted to authorised users and required entry of separate account (user ID and password), in addition to that required by the operating system. Unique logins were used to access the system and use of generic user logins were not allowed. User Management role was restricted and was available to System Administrator. System administrator access was restricted to minimum number of users. User levels were created and assigned to individuals based on their roles and authority. Audit trail setting of bioanalytical computerized systems was reviewed and verified.

The chromatography software systems were not networked, due to technical problems.
The SOP for Backup and archival of data was established to define the data backup procedure, verification of backup performance and data archival on network drive/locking in the CRC. A backup register was available with information about instrument ID, instrument name and files copied from, on a template linked to SOP. All data generated by software systems were backed up on the servers which were located in a remote location in the corporate office and administered by the respective designated team.

Only if a system complexity was considered as high, a disaster recovery plan would apply and prepared. Analyst software system was considered with a medium complexity. Hence, a disaster recovery did not apply to this system in accordance with SOP for GxP risk assessment of CS. The justification for system complexity and system impact was documented.

It was sufficiently ensured that the data collected by the software systems remained fully readable in accordance with the applicable SOP. A request for restoration was required to be raised every quarter to verify a full data backup / archival check. The restoration documentation of Feb 2022, and Oct 2021 was available and reviewed.

A document for Operational Qualification of Analyst 1.7 was provided, including testing the backup and restoration.

During the installation of Symantec on the computer stations, the system was challenged and tested, and the respective documentation dated 19 Feb 2019 was available.

There were SOPs in place for usage of each software program that were used to perform activities of a BE study.

Validation of Excel sheet took place in accordance with SOP for Validation and management of GxP spreadsheet. All cells including calculations were locked so that formulas could not accidentally overwritten. Free access was only given to cells to be filled in with data. Calculation algorithms were tested by the respective department. The sheets were made available in a secured directory.

Observations made with relation to the Computerized systems were adequately addressed in the respective CAPA plan.
3. **Quality management**

The CRO’s Quality Management System consisted of:

- Quality Manual
- Global Policies
- SOPs, Protocols, Site Master File
- Work Instructions, Equipment Manual
- Quality Records, Source Documents, Raw Data Sheets,

Through their Quality Policy, the organization was committed to deliver quality research solutions that meet or exceed their internal customers’ requirements.

The Head of Quality Assurance, under the direction of the Head of Clinical & Bioanalytical Quality was responsible for establishing and maintaining the Quality Assurance systems. The Head of Quality Assurance was required to ensure that all CRC personnel understood the Quality Assurance system and the company's commitment to quality.

QA-Head was directly reporting to Mr Charles Mueller, i.e., the global Head of clinical and Bioanalytical quality. Dr Ramakrishna Bangaru was the Head CRC supervising all other activities and reporting to Head Global Clinical pharmacology.

The main Quality Assurance Unit responsibilities were:

- Control of necessary documentation for the Quality System i.e. Document control
- Review of Standard Operating Procedures
- Preparation & Review of Quality Manual, Site Master File
- Review of instrument/equipment qualification/requalification documentation
- Review of Master Schedule and Study/Validation Protocols
- Responsibility of training programmes with other departments
- Change control management and CAPA management
- Deviation management, vendor audits
- Conduct of Study/Project Specific audits and system audits
- Review of data integrity for Computerised systems
- Review of pest control documentation
- Archival and retrieval of data

A full list of SOPs, together with a copy of SOPs were provided on a pen drive, at the time of inspection. A list of qualified suppliers was also provided.
The change request form for software installation ( Analyst 1.7.0 ) was available with a unique number on the issued template. The change was categorized and described, and the purpose for change was available. Risk assessment was carried out. Implementation of plan was verified and elaborated, and a summary of implemented changes and results obtained was noted. Risk mitigation actions/controls were established. The change was completed and verified by QA.

Quality control activities were verified during sample processing at the time of inspection. All forms and templates used for documentation of raw data were issued by QA to support data integrity of studies. A consecutive number which were generated and recorded in the respective logbooks, was assigned to each form. All forms were signed and dated by QA. Reconciliation of the forms/templates of selected studies were verified during the inspection.

Disaster recovery plans were implemented through various procedures, e.g. SOP for Disaster management and recovery procedure for deep freezers and Mylan onsite emergency plan, approved on 31 Jan 2020. Training, mock drill and evaluation of plan was also a part of documentation.

Observation made in relation to QMS was adequately addressed in the respective CAPA plan.

4. Archive facilities
The CRO had two archive facilities. One facility on the second floor of the main office and the second one was located in another building with walking distance to the main office. The main office facility was visited during the inspection.

The CRO had sufficient and appropriately secure storage space, which was fireproof, relative humidity-controlled and pest-controlled, for archiving of the trial-related documentation. Fire detectors and fire extinguishers were properly installed in the facility. The visit of Pest -control service provider was documented in the respective entry/exit logbook. An agreement was made with an external archive facility to outsource the archiving activities of older documentation. The initial agreement was made on 1 May 2018 which was available and reviewed.
SOP for Retention, control and retrieval procedure of documents in archives was established. Access to archive storage areas was controlled and restricted to the authorized personnel. A list of authorized personnel was displayed at the entrance of the facility. Records of document access and return were maintained. Electronic reports (Bio Analytical reports / Comprehensive reports) were required to be retained for 25 years with exception to Validation Reports as they would be retained permanently.

5. Premises

During the inspection, a tour of facility was conducted.

The facility consisted of five floors, including Ground floor and Cellar. The dimensions and the amenities were depicted in the floor plans and provided as ‘Appendix -1’ of the CROMF. A copy was provided during the inspection.

The building included:
• ICP-MS Room
• Instrumentation Room
• N2 Air dryer room
• Sample Processing area
• Balance room
• Refrigerator and Working Standard Area
• Archival area
• Server room
• Biological Sample storage area
• Invitro Analytical Lab
• Drug products Storage area
• Chemical Storage room

Entry to the restricted facilities was controlled, using biometrics and individual electronic keys.

The CRO had sufficient space to accommodate the personnel and activities required to perform the studies. The bioanalytical laboratory was organized in order to carry out the activities in a logical order and to avoid sample mix-ups.

The facilities had adequate lighting, ventilation and environmental control by proper disposal of waste. Floors, walls and working bench surfaces were easy to clean and to decontaminate.
Laboratory premises were designed to provide adequate protection to all employees, by ensuring their safety while handling or working in the presence of chemicals and biological samples. Safety showers and eye-wash systems were installed in the laboratory. Safety measures such as availability of first aid materials, goggles and spillage kits were implemented.

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

The temperature of the facilities was controlled by digital thermometer or hygro-thermometers, depending on the facilities’ target.

The facility was equipped with a permanently installed automatic standby generator and UPS system to emergency power to a load when the input power source or main power failed.

Observations made with relation to the Premises were adequately addressed in the respective CAPA plan.

6. Personnel
There were a sufficient number of staff. Their appropriate qualifications, training and experience to support the study related activities were verified through the employees’ CV and training documentation. Training curriculum was available as per the applicable SOP. The training program consisted of interactive training, online training using a software system, and Instructor Lead training. Other SOPs were also available for specific trainings such as SOP for Training of operator and data reviewer in bioanalytical laboratory.

7. Investigational medicinal products and comparator products
The clinical pharmacology department was an integral part of the Clinical Research Centre. The department was responsible for Investigational medicinal products receipt, storage and shipment to the CROs. Mylan did not perform any clinical activities.

The Clinical pharmacology personnel receive the adequate quantity of drug products from the formulation group/manufacturing site along with the respective CoAs. Details of innovator and test samples on receipt were entered in a log named as Investigational Products (IPs) Log. Drug products were stored in the Walk-in chamber by the authorized persons as per product label storage instructions.
Entry into the Investigational Products storage area was controlled and restricted. The access was provided only to the designated personnel. The investigational products were shipped to the clinical facility (CRO) as per the study schedule received from the CRO.

**Bioanalytical section**

The inspection included audit of method development process, source documentation and raw data for validation of bioanalytical methods, and analysis of subject plasma samples as well as review of the electronic data audit trails for electronic data capture. Results of calibration standards, quality control samples (QCs), subject plasma samples in analytical runs were inspected along with the chromatograms generated from analytical runs.

QA-personnel & project managers assisting the inspection team with review of study-documents were knowledgeable, transparent and helpful.

8. **Method development, Method validation & Analysis of study samples**

   The laboratory had detailed provisions for development and validation of analytical methods. The selection of isotope-labelled internal standard and regression parameters was justified and documented. The experiments were adequately recorded. An analytical method was issued prior to validation of method. The analytical method, and the established characteristics were described in a validation protocol.

   Method validation was carried out in accordance with the applicable guidelines. The method validation was ensured with a run that was comparable in length to the study sample runs.

   Validation documentation, incl. paper and electronical raw data captured in the acquisition software systems was verified. The documentation was compared with the respective audit trail records to confirm accurate reporting of the results. The preparation of analyte and internal standard stock, intermediate and working solutions, bulk plasma, calibration standards, QCs, and reagents was reviewed.

   Temperature records of the storage facilities, as well as records of samples transfer were verified.

   Validation parameters were evaluated and compared to the reported data. Stability data, as well as number of freeze and thaw cycles supported the stated conditions and period of storage, applied to the study samples.
Preparation of analyte stock solutions, calibration standards, QCs, internal standards, and reagents were reviewed. Each analytical batch and analytical run included a predefined set of calibration standards and quality control samples. All samples collected from a given subject were processed in the same batch and were analysed in the same run. In general, equipment with adequate capacity was used to allow simultaneous sample processing. When samples were split in groups during sample processing, QCs at all concentration levels were included in each batch.

The inspectors reviewed the chromatograms and their integration of sample analytical runs. Absence of signals in blank samples and the absence of any unexplained interruptions in the injected sequences were discussed. The concentration range of the calibration standards and control samples were compared with the concentration range of the study samples. The ratio of the study methods’ LLOQ vs. C\text{max} of the individual subjects was calculated. The acceptance criteria of selected analytical runs, specifically retention time, accuracy of standard and control samples, peak shape and IS peak areas, were verified. The audit trails of applicable software systems were reviewed. The reasons for repeated analyses of selected study samples and instrument failures were discussed. Provisions and documentation for ISR runs were examined. The documentation and justification of reinjection of analytical runs were verified and compared with the applicable SOPs. It was noted that the LIMS software system was able to highlight the samples for repeat. However, there were a few criteria that should be manually handled, such as repetition of runs due to Code G, as per SOP for Re-assay and reinjection of clinical samples and reporting of final concentration.

9. Sample storage and handling of biological material

The CRO was responsible to properly receive and store the biological samples for bioanalytical analyses. Sampling times, volumes and number of samples were described in the respective clinical protocol. Samples were shipped to the CRO under controlled conditions and verified upon arrival. Records of samples shipment, sample receipt, sample verification, sample storage, as well as all sample retrievals and returns were available in the respective logbooks.

Shipment documentation including, datalogger, datalogger calibration, sample documentation from Aizant (incl. missing and haemolytic samples), the LIMS records, samples verification records, courier documentation for Study HP025 was reviewed.
Samples were stored in three different sample rooms either in the main building of the CRO or in an off-site location in the outskirts of Hyderabad. At the time of inspection, the retained samples pertaining to the studies in the scope of the inspection were stored at the off-site sample storage area. Sample request for analytical runs was received through the LIMS software system.

Pooled plasma samples for bioanalytical activities were generally supplied by Valley Biomedical. The aliquots were required to receive an inhouse ID number for internal use. Valley Biomedical products and services INC. was located in Winchester, Virginia, USA.

10. Data processing and documentation
Integration settings were sufficiently justified and consistently applied in accordance with SOP for Development of bioanalytical method and project initiation. The integration settings and iterations were incorporated in the quantitation method, verified during the system suitability runs. Smoothing were kept low enough not to mask possible interferences and changes in peak geometry, and it was restricted to smoothing factor 5. However, use of smoothing factor for more than 5 for the final method required approval from the project manager or designee.

A trend of the internal standard signals was evaluated and a range for acceptable internal standard peak areas was defined. Effected samples were re-assayed.

The audit trail of all computerized systems used for validation sample analyses and evaluation was fully activated. The respective audit trails were reviewed during the inspection. Sample handling, processing and evaluation was documented on controlled forms/templates. Analytical raw data were available and accessible in its original format. Each data point was traceable to a specific sample number and collection time point.

An adequate number of samples were tested as part of incurred samples reanalysis. The difference between initial and the repeated values were evaluated as per the applicable SOP.

Observations made with relation to Data processing were sufficiently addressed in the respective CAPA plan.
11. Good laboratory practices

A total of three groups were working in independent sample processing and instrumentation rooms. These groups shared a room used for cleaning and decontamination of equipment. The laboratory was equipped with an access control system, based on biometric data, which was inactivated due to the Pandemic safety measures. Analytical instruments were kept in a room, separate from the processing area. All rooms where temperature sensitive materials and instruments were stored, processed or analysed were temperature controlled.

The storage systems and areas requiring environmental controls were qualified, calibrated and maintained. The monitoring system was connected to an alarm system that was tested in regular intervals. The records on temperatures and humidity were maintained. Time and appropriate actions were ensured by the procedures.

During requalification, the temperature distribution within the freezers and deep freezers was tested for 72 hours. Remapping was required in case of any significant changes. For requalification, a calibrated multi-channel temperature logger was used. The temperature logger, as well as the probes for the chart recorder and the monitoring system were calibrated. Thresholds for maximum acceptable temperature differences between the individual probes were defined.

Balances and other measuring devices and equipment were periodically calibrated and verified. SOPs for operation, use, calibration, checks and preventive maintenance were in place for various types of equipment. Records were maintained. Equipment used during the study was documented and their qualification state was verified. Pipettes were tested before being used in the study. The performance verification of a selected micropipette was demonstrated. The cause of instrument failure was identified and addressed as per the applicable SOP, during the inspection.

Chemicals, solutions and solvents were found to be adequately labelled. Reference substances were adequately separated from study samples. The quality of water produced by Milli Q water purification system was daily controlled for pH, conductivity and TOC (Total Organic Carbon).

Observations made with relation to Good Laboratory Practices were adequately addressed in the respective CAPA plan.
12. Study report
At the CRO, analytical/Bio Analytical study/Validation Protocol was a document that described the objective(s), design, Analytical methodology, data Management, and special instructions for samples analysis. Study/Validation protocols were prepared by user department, reviewed by scientific reviewer, Quality Assurance auditor and Approved by Analytical Investigator/Study Director.

Completed Method validation reports, Analytical and Bioanalytical study reports were prepared (in D2 Documentum) by designated report author/designee using all relevant documentation necessary for reconstructing the validation or study and maintained in a secure environment of document management system. Once the analytical runs were complete, the project was locked, and the report was sent to the QA for cross verification through an automated process. The final study report was signed out by QA, PK group and the contracted CRO.

<table>
<thead>
<tr>
<th>Miscellaneous</th>
</tr>
</thead>
<tbody>
<tr>
<td>Samples taken</td>
</tr>
<tr>
<td>Assessment of the CRO master file</td>
</tr>
<tr>
<td>Annexes attached</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Part 3</th>
<th>Conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>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 studies were considered to have been conducted at an acceptable level of compliance with WHO GCP guidelines at Mylan Laboratories Limited, Clinical Research Centre (A Viatris Company); located at Saradhi Chambers, A-4, Rukminipuri, Near Poulomi Hospital, Main Road, Dr. A.S. Rao Nagar, Hyderabad 500 062, India.</td>
<td></td>
</tr>
</tbody>
</table>

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, provided that the outcome of any inspection conducted during this period is positive.
Part 4  List of guidelines referenced in the inspection report

   **Short name:** WHO BE guidance or TRS996 Annex 9  
   [http://apps.who.int/iris/bitstream/handle/10665/255338/9789241209960-eng.pdf?sequence=1&isAllowed=y](http://apps.who.int/iris/bitstream/handle/10665/255338/9789241209960-eng.pdf?sequence=1&isAllowed=y)

   **Short name:** WHO GCLP

   **Short name:** WHO GCP Annex 3  
   [https://apps.who.int/iris/bitstream/handle/10665/37340/WHO_TRS_850.pdf?sequence=1&isAllowed=y](https://apps.who.int/iris/bitstream/handle/10665/37340/WHO_TRS_850.pdf?sequence=1&isAllowed=y)

   **Short name:** WHO TRS 1010, Annex 9

   **Short name:** OECD GLP

   **Short name:** WHO Ethics Committee Guidance

   **Short name:** WHO storage and transport guidance or TRS 961 Annex 9

   Short name: WHO CROMF Guidelines or TRS No. 957, Annex 7


   Short name: Glove use information leaflet


    Short name: WHO TRS No. 1033, Annex 4
    https://www.who.int/publications/i/item/55th-report-of-the-who-expert-committee-on-specifications-for-pharmaceutical-preparations

11. Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability

    Republication of Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability, WHO Technical Report Series, No. 992, Annex 7 with a new Appendix 2


    Short name: WHO multisource guidance


    Short name: WHO TRS 1025, Annex 4


   Short name: WHO TRS No. 961, Annex 9


   Short name: Declaration of Helsinki


   Short name: WHO TRS No. 1019, Annex 3