**Prequalification Team Inspection services**
**WHO PUBLIC INSPECTION REPORT**
**of the API manufacturer**

<table>
<thead>
<tr>
<th>Part 1</th>
<th>General information</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Manufacturers Details</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Company information</strong></td>
<td></td>
</tr>
<tr>
<td>Name of manufacturer</td>
<td>Strides Shasun Limited</td>
</tr>
<tr>
<td>Corporate address of manufacturer</td>
<td>‘STRIDES HOUSE’, Bilekahalli, Banneghatta Road, Bangalore - 560 076, INDIA</td>
</tr>
<tr>
<td>Contact:</td>
<td>91-80-67840521 91-80-67840800</td>
</tr>
<tr>
<td><strong>Inspected site</strong></td>
<td></td>
</tr>
<tr>
<td>Address of inspected manufacturing site if different from that given above</td>
<td>Strides Shasun Limited A1/B, SIPCOT Industrial Complex, Kudikadu Village, Cuddalore – 607 005, Tamil Nadu, India.</td>
</tr>
<tr>
<td>Contact:</td>
<td>91-4142-285400 91-4142-239709</td>
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<tr>
<td>GPS coordinates of the site:</td>
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<tr>
<td>Latitude: North 11° 41.104’</td>
<td>Longitude: East 79° 45.308’</td>
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<tr>
<td>D-U-N-S Number</td>
<td>65-056-4045</td>
</tr>
<tr>
<td><strong>Unit / block / workshop number</strong></td>
<td>Production block 4</td>
</tr>
<tr>
<td><strong>Manufacturing license number</strong></td>
<td>License No.: 703 issued by Directorate of Drugs Control, India</td>
</tr>
<tr>
<td>Scope of license:</td>
<td>License to manufacture for sale of drugs for export and domestic sale.</td>
</tr>
</tbody>
</table>

| Inspection details | |
| Dates of inspection | 24-26 October 2016 |
| Type of inspection | Follow-up inspection |

| Introduction | |
| Brief summary of the manufacturing activities | Manufacture including production, quality control and release of non-beta lactam and non-penicillin group: |
|  | • Active Pharmaceutical Ingredients and intermediates |
| General information about the company and site | Shasun Pharmaceuticals Limited was established in the year 1976. The firm set up its plant at Cuddalore, Tamil Nadu, India in the year 1991 to manufacture Active Pharmaceuticals Ingredients and its intermediates. This Cuddalore API site is situated at A1/B, SIPCOT Industrial Complex, in Kudikadu village, |

WHO public inspection report Strides Shasun Limited October 2016

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Cuddalore - 607005, which is about 180 km away from Chennai, the capital of Tamil Nadu state (India). This site is a multiproduct facility manufacturing APIs and its intermediates for different Regulatory markets. The site occupies an area of about of 66000 m². This API site was inspected by various Regulatory Authorities.

On November 19, 2015, pursuant to the strategic decision to combine the two companies Shasun Pharmaceuticals Limited was amalgamated and merged with Strides Arcolab Limited. The name of the new combined business is “Strides Shasun Limited”.

Strides Shasun is having the following manufacturing facilities in India, Italy and Africa:
- Strides Shasun Limited API & FPP Puducherry, India
- Strides Shasun Limited R&D Centre in Chennai, India
- Strides Shasun Limited FPP in Bengaluru, India
- Strides Emerging Markets Private Limited FPP in Bengaluru, India
- Strides Shasun Limited FPP in Palghar, India
- Strides Vital Nig. Ltd FPP in Lagos, Nigeria
- Strides Pharmcare Factory for Human And Veterinary Medicines FPP in Khartoum, Sudan
- Strides Pharma Cameroon FPP in Douala, Cameroon
- Strides Pharma Mozambique Limited FPP in Maputo, Mozambique
- Beltapharm Spa FPP in Milano Italy
- API - R&D Centre in Chennai, India
- Two API manufacturing facilities in Puducherry and Cuddalore, India
- One Formulation facility in Puducherry, India
- One API facility at Dudley, UK, which is involved in CRAMS business

Inspected site has the following manufacturing blocks:
- Production blocks I – V
- Packaging sections I, II, III, V, VII, IX, X, XI, XII, XIII and XIV

History

<table>
<thead>
<tr>
<th>Date of inspection</th>
<th>Authority</th>
<th>Scope of inspection</th>
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<tbody>
<tr>
<td>14- 16 June, 1999</td>
<td>US FDA</td>
<td>GMP inspection</td>
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<tr>
<td>11-15 Nov 2002</td>
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<td>2-3 Oct 2003</td>
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<td>26-30 Mar 2007</td>
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<td>16- 20 Oct 2008</td>
<td>Danish Medicines Agency,</td>
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<tr>
<td>11-16 Oct 2010</td>
<td>US FDA</td>
<td>GMP inspection</td>
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<td>19 – 21 March, 2012</td>
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<td>8 - 9 Nov, 2012</td>
<td>KFDA (MFDS) - Korea</td>
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<td>29 Nov -1 Dec, 2012</td>
<td>WHO – Geneva</td>
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<td>COFEPRIS - Mexico</td>
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<td>9 - 13 June, 2014</td>
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<td>23 - 27 June, 2014</td>
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<tr>
<td>24 - 27 Nov, 2014</td>
<td>EDQM &amp; EMA (HPRA -</td>
<td>EU GMP Inspection</td>
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<tr>
<td>20 - 22 April, 2015</td>
<td>WHO – Geneva</td>
<td>Prequalification Inspection</td>
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<tr>
<td>31 Aug – 4 Sep, 2015</td>
<td>COFEPRIS - Mexico</td>
<td>GMP Inspection</td>
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<tr>
<td>17- 21 Apr 2017</td>
<td>US FDA</td>
<td>GMP Inspection</td>
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**Brief report of inspection activities undertaken**

**Scope and limitations**

**Areas inspected**
- Pharmaceutical Quality System
- Production System
- Facilities and Equipment System
- Laboratory Control System
- Materials System

**Restrictions**
N/A

**Out of scope**
- Packaging and Labeling System and microbiological laboratory

**WHO product numbers covered by the inspection**
- APIMF 177 Cycloserine
- APIMF 236 Tenofovir disoproxil (fumarate)

**Abbreviations**
- AHU: air handling unit
- ALCOA: attributable, legible, contemporaneous, original and accurate
- API: active pharmaceutical ingredient
- APQR: annual product quality review
- BDL: below detection limit
- BMR: batch manufacturing record
- BPR: batch packaging record
- CAPA: corrective actions and preventive actions
- CC: change control
- CFU: colony-forming unit
- CoA: certificate of analysis
- CpK: process capability index
- DQ: design qualification
- EM: environmental monitoring
- FAT: factory acceptance test
- FBD: fluid bed dryer
- FG: finished goods
- FMEA: failure modes and effects analysis
- FPP: finished pharmaceutical product
- FTA: fault tree analysis
- FTIR: Fourier transform infrared spectrometer

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<table>
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<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tr>
<td>GC</td>
<td>gas chromatograph</td>
</tr>
<tr>
<td>GMP</td>
<td>good manufacturing practice</td>
</tr>
<tr>
<td>HACCP</td>
<td>hazard analysis and critical control points</td>
</tr>
<tr>
<td>HPLC</td>
<td>high-performance liquid chromatograph</td>
</tr>
<tr>
<td>HVAC</td>
<td>heating, ventilation and air conditioning</td>
</tr>
<tr>
<td>ID</td>
<td>identity</td>
</tr>
<tr>
<td>IR</td>
<td>infrared spectrophotometer</td>
</tr>
<tr>
<td>IPC</td>
<td>In process control</td>
</tr>
<tr>
<td>IQ</td>
<td>installation qualification</td>
</tr>
<tr>
<td>KF</td>
<td>Karl Fisher</td>
</tr>
<tr>
<td>LAF</td>
<td>laminar air flow</td>
</tr>
<tr>
<td>LIMS</td>
<td>laboratory information management system</td>
</tr>
<tr>
<td>LoD</td>
<td>limit of detection</td>
</tr>
<tr>
<td>LOD</td>
<td>loss on drying</td>
</tr>
<tr>
<td>MB</td>
<td>Microbiology</td>
</tr>
<tr>
<td>MBL</td>
<td>microbiology laboratory</td>
</tr>
<tr>
<td>MF</td>
<td>master formulae</td>
</tr>
<tr>
<td>MR</td>
<td>management review</td>
</tr>
<tr>
<td>NIR</td>
<td>near-infrared spectroscopy</td>
</tr>
<tr>
<td>NRA</td>
<td>nuclear magnetic resonance spectroscopy</td>
</tr>
<tr>
<td>OQ</td>
<td>operational qualification</td>
</tr>
<tr>
<td>PHA</td>
<td>preliminary hazard analysis</td>
</tr>
<tr>
<td>PM</td>
<td>preventive maintenance</td>
</tr>
<tr>
<td>PpK</td>
<td>process performance index</td>
</tr>
<tr>
<td>PQ</td>
<td>performance qualification</td>
</tr>
<tr>
<td>PQR</td>
<td>product quality review</td>
</tr>
<tr>
<td>PQS</td>
<td>pharmaceutical quality system</td>
</tr>
<tr>
<td>QA</td>
<td>quality assurance</td>
</tr>
<tr>
<td>QC</td>
<td>quality control</td>
</tr>
<tr>
<td>QCL</td>
<td>quality control laboratory</td>
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<tr>
<td>QMS</td>
<td>Quality management system</td>
</tr>
<tr>
<td>QRMS</td>
<td>quality risk management</td>
</tr>
<tr>
<td>RA</td>
<td>risk assessment</td>
</tr>
<tr>
<td>RCA</td>
<td>root cause analysis</td>
</tr>
<tr>
<td>RH</td>
<td>relative humidity</td>
</tr>
<tr>
<td>RM</td>
<td>raw materials</td>
</tr>
<tr>
<td>RS</td>
<td>reference standard</td>
</tr>
<tr>
<td>SAP</td>
<td>system applications products for data processing</td>
</tr>
<tr>
<td>SFG</td>
<td>semi-finished goods</td>
</tr>
<tr>
<td>SOP</td>
<td>standard operating procedure</td>
</tr>
<tr>
<td>STP</td>
<td>standard test procedure</td>
</tr>
<tr>
<td>T</td>
<td>temperature</td>
</tr>
<tr>
<td>TAMC</td>
<td>total aerobic microbial count</td>
</tr>
<tr>
<td>TFC</td>
<td>total fungal count</td>
</tr>
<tr>
<td>TLC</td>
<td>thin layer chromatography</td>
</tr>
<tr>
<td>TMC</td>
<td>total microbial count</td>
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</table>
Part 2 | Brief summary of the findings and comments (where applicable)

**Note:** This WHOPIR is based on WHO inspection report (October 24-26, 2016) and desk review of EMA inspection report (January 9-11, 2017), CAPAs and other relevant documents review.

**Brief summary of the findings and comments**

1. **Pharmaceutical quality system**

   In general the system for managing quality encompassed the organizational structure, procedures and processes. There were QA and QC departments that were independent of production. In general deviations from established procedures were documented and explained. Procedure was in place for notifying responsible management of regulatory inspections, serious GMP deficiencies, product defects and related actions.

   **Product Quality review**

   The SOP “Periodic product review” was discussed. PQR was conducted annually and should be reviewed and approved before end of March according to the company SOP.

   PQR for Cycloserine API for 2015 was discussed. There was no reworked/reprocessed/returned batches, no OOS/OOT, no recall. There were two complaints.

   **Management review (MR)**

   The SOP “Quality System Review (QSR)” and log books “Quality system review & attendance 2016” and “Quality system review 2016” were discussed. QSR team was led by the Senior Vice President Quality. QSR team consisted of the heads of all departments. QSR was conducted monthly at unit level and at the corporate level. The following items were subjects of the QSR:
   - Review of action plan as determined in the previous meeting, status of outstanding items/events
   - Market complaints
   - Deviations and change controls
   - Validation summary
   - PQR
   - Audit summary
   - Open CAPA from audits
   - Technology transfer
   - OOS/OOT
   - QC analysis summary
   - Material rejections
   - Rejected batches

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• Microbiology trends
• Training summary
• Recalls, returned goods, field alerts
• Concerns, recommendations and improvements

Quality risk management
The SOP “Quality risk management” and log book “Quality risk assessment” were discussed. The SOP was applicable for API sites and covered all quality system. FMEA was used as a tool.

Deviations
The SOP “Deviations” and flow chart were discussed.
Deviations were classified as:
• Critical
• Major
• Minor

Corrective actions and preventive actions (CAPA)
The SOP “Investigation and CAPA management” was discussed. There were no major deviations and only 1 critical deviation was logged in Trackwise.

Change control (CC)
The SOP “Change management” and CC log book for 2015 were discussed. The changes were initiated by the concerned departments. The substantial decisions during the investigation (in particular the implementation) were made by the QA department. There was no trending of changes and no discussion during MR meeting. The SOP was applicable for:
• Complaint management
• OOS/OOT
• Recalls
• Deviations
• Regulatory inspections
• Process performance trends and PQR
• QRM
• Improvement plans
• QS Review

Root cause investigation was part of the CAPA SOP, the following tools were specified:
• Applicable investigation checklist
• Cause effect diagram
• Brainstorming
• 5-whys
Complaints
The SOP “Complaints” was discussed. Complaints were classified as:
- Manufacturing (quality aspects of product both physical and chemical properties)
- Packaging (quality aspects of packaging)
- Quantity
Complaints log books were product wise as well as trending. According to the SOP trending should be performed quarterly.

Recall
The SOP “Product recall & market withdrawal” was discussed. There were no product recalls in recent years. According to the SOP a mock recall should be performed once in two years for domestic market and every three years for USA/Canada/rest of the world markets.
Recalls were classified as following:
- Class I – should be initiated within 24 hours
- Class II - should be initiated within 48 hours
- Class III - should be initiated within 5 days
- Class IV - should be initiated within 14 days

Supplier qualification
Supplier qualification and management was performed by corporate office.

Returns/rejects
Returned/rejected log books were product based.

Personnel
According to the company presentation, the site employed approximately 778 full time employees:

<table>
<thead>
<tr>
<th>Department</th>
<th>Employees</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturing &amp; Packaging</td>
<td>418</td>
</tr>
<tr>
<td>Quality Control</td>
<td>108</td>
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<tr>
<td>Quality Assurance</td>
<td>38</td>
</tr>
<tr>
<td>Warehouse</td>
<td>21</td>
</tr>
<tr>
<td>Engineering services</td>
<td>101</td>
</tr>
<tr>
<td>Administration &amp; HR</td>
<td>16</td>
</tr>
<tr>
<td>Safety Environment &amp; EHS</td>
<td>33</td>
</tr>
<tr>
<td>Others</td>
<td>43</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>778</strong></td>
</tr>
</tbody>
</table>

Personnel were wearing clothing suitable for the manufacturing activities.
2. Production system

Production block 4 was covered by the inspection. Block 4 was a multiproduct manufacturing facility. Cycloserine API was manufactured in block 4.

Tenofovir disoproxil manufacturing operations in block III were stopped in January 2014. Since that time Tenofovir disoproxil API was not manufactured. According to the planned changes Tenofovir disoproxil manufacturing will be moved to the Production Block 4.

Production operations took place on two floors.

Reactors, including glass lined reactors, were used for Cycloserine production. Centrifuge bags were dedicated for Cycloserine API. Bags were changed after two production batches.

Final processing step was carried out in “clean rooms” (ISO 8).

Production operations were recorded in the step wise BMRs.

3. Facilities and equipment system

In general buildings and facilities had adequate space for the orderly placement of equipment and materials. Mainly closed systems were used for production. Some manual operations were carried out, for example unloading materials from centrifuges.

There were defined areas for the:

- Receipt, identification, sampling, and quarantine of incoming materials, pending release or rejection,
- Quarantine before release or rejection of intermediates and APIs,
- Holding rejected materials before further disposition (e.g. return, reprocessing or destruction),
- Storage of released materials,
- Production operations,
- Laboratory operations.

Laboratory areas and operations were separated from production areas.

Ventilation, air and exhaust systems were provided for “clean rooms”. Permanently installed pipework was appropriately identified. PW was used in the manufacture of APIs and cleaning (final rinsing).

In general equipment used in the manufacture of intermediates and APIs were of appropriate design and adequate size, and suitably located for its intended use, production and permanently installed processing lines used during the production were appropriately identified. Equipment maintenance and calibration was done following written procedures.

VMP for Cuddalore site APIs and facility year 2016 was checked.
The SOP “Cleaning procedure – validation & Routine evaluation” was discussed. There were two types of cleaning used: batch to batch (type I) and product to product (type II).

The SOP “Cleaning of rotary cone vacuum drier cum blender during product change over”, the SOP “Cleaning of centrifuge during product change over”, the SOP “Cleaning of centrifuge” and SOP “Cleaning and checking of RCVD cum blender” were discussed.

The document “Protocol for the cleaning validation of Rebamipide stage-final” was presented to the inspectors. UV analytical method was used. MACO was based on 10 ppm criterion. It was noted that HPLC method was used for Rebamipide assay analysis.

The SOP “Procedure for swabbing” was discussed.

The SOP “Calibration of T indicators and controllers” was discussed. T indicators and controllers calibration was carried out on site. Calibration certificates for selected T indicators were presented to the inspectors.

The SOP “Particulate count test procedure”, “Non-viable particulate count report” and HEPA filter integrity test report were discussed. AHU 1 layout and qualification was discussed. AHU consisted of the following filters cascade: G4→F8→F9→H13→H13. HEPA filters were installed in plenum and in the production rooms. Re-circulated air (10 – 15 %) was mixed with fresh air.

The procedure and records for the spark test of glass reactors and the SOP “Preventive maintenance of reactor” were discussed”. Glass reactors spark tests were carried out every 2 years.

HVAC system serving block 4 “clean rooms” was inspected. Special attention was paid to the AHU No1.

PW system layout was discussed. PW system purification (installed in 2014) and storage tank and distribution system were installed in 2003 were discussed. Sanitization was carried out every week for 2 hours by hot water. Conductivity and pH were monitored on line, on-line TOC meter was under qualification. PQ storage tank had installed hydrophobic 0.2µm filter which was replaced every 3 months. UV lamp intensity and burning hours were specified and monitored. Chemical sanitization of RO membranes was carried out monthly.

VMP for computer system validation was discussed. Document explained validation policy, management of the master plan, validation approach, life cycle approach for computerized systems, and computerized systems retirement.

The SOP “Standalone systems backup tracking register”, effective from 19 October, 2016 and previous SOP “Data back-up procedure” and back-up tracking register were discussed.

Computerized system inventory was presented to the inspectors.
CC record report and document “Impact assessment for XX system” No YY were discussed as well as system release notification for ZZ systems.

4. Laboratory control system
Documented procedures and standard test methods were available. Due to time limits laboratory inspection was limited and attention was paid only to the HPLC No XX and FTIR. FTIR was stand-alone instrument.

All HPLCs and GCs were connected to the Chromeleon software, version 7.2 SR4. There were 5 access levels to the HPLCs:
- Analyst
- Supervisor
- Manager
- Service engineer
- Administrator.

A QC lab signature specimen was presented to the inspectors. In-coming sample registers were product based.

The SOP “Management of Chromeleon 7.2 chromatographic data station” was discussed. It was said that manual integration was not allowed, however this was not reflected in the SOP.

Stability studies HPLC raw data were checked for Cycloserine API batch No XX.

The SOP “Bracketing of standards and general system suitability criteria during analysis was discussed.

5. Materials system
Written procedures describing the receipt, identification, quarantine, storage, handling, sampling, testing and approval or rejection of materials were available.

Suppliers of critical materials and packaging materials, selection, auditing and approval were carried out by corporate office. Lists of approved suppliers for Cycloserine were presented to the inspectors.

Materials management was carried out using SAP system and also paper based system. Upon receipt and before acceptance, containers of materials were examined visually, materials were held under quarantine until they have been sampled, tested and then released for use.

Solvents were store in underground tanks, for daily use solvents were stored in above ground tanks, close to the production blocks.

KSM, other substances and packaging materials were stored in one warehouse in different rooms. Primary packaging materials were stored in locked SS cabinets. Sampling and dispensing operations of solid RM, liquid RM and primary packaging materials were carried out in two
sampling/dispensing rooms located in the warehouse. Sampling and dispensing was carried out under the RLAF.

Containers from which samples were withdrawn were marked to indicate that a sample has been taken.

The SOP “Sampling” was discussed.

**6. Packaging and labelling system**

Cycloserine packaging and labelling operations of finished API was done in the same room as milling and sifting. During inspection packaging and labelling operations were not carried out. It was explained that computer generated, customer specific labels were printed in-house.

**PART 3**

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, a **Strides Shasun Limited** located at A1/B, SIPCOT Industrial Complex, Kudikadu Village, Cuddalore - 607005, Tamil Nadu, India was considered to be operating at an acceptable level of compliance with WHO good manufacturing practices for pharmaceutical products.

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 3 years, provided that the outcome of any inspection conducted during this period is positive.

**PART 4**

**List of GMP guidelines referenced in the inspection report**

   
   **Short name: WHO TRS No. 957, Annex 2**

   
   **Short name: WHO TRS No. 986, Annex 2**
   Short name: WHO TRS No. 970, Annex 2
   http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_970/en/

   Short name: WHO TRS No. 929, Annex 4
   http://whqlibdoc.who.int/trs/WHO_TRS_929_eng.pdf?ua=1

   Short name: WHO TRS No. 961, Annex 5
   http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

   Short name: WHO TRS No. 937, Annex 4
   http://whqlibdoc.who.int/trs/WHO_TRS_937_eng.pdf?ua=1

   Short name: WHO TRS No. 961, 957), Annex 1

   Short name: WHO TRS No. 957, Annex 2

   Short name: WHO TRS No. 961, Annex 6
   http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1
   Short name: WHO TRS No. 961, Annex 7
   http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

   Short name: WHO TRS No. 961, Annex 9
   http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

   Short name: WHO TRS No. 943, Annex 3
   http://whqlibdoc.who.int/trs/WHO_TRS_943_eng.pdf?ua=1

   Short name: WHO TRS No. 961, Annex 2
   http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

   Short name: WHO TRS No. 981, Annex 2
   http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_981/en/

   Short name: WHO TRS No. 981, Annex 3
   http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_981/en/

   Short name: WHO TRS No. 961, Annex 14
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   Short name: WHO TRS No. 992, Annex 3

   Short name: WHO TRS No. 992, Annex 4

   Short name: WHO TRS No. 992, Annex 5

   Short name: WHO TRS No. 992, Annex 6

   Short name: WHO TRS No. 996, Annex 3
   http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex03.pdf

   Short name: WHO TRS No. 996, Annex 5
   http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex05.pdf
   *Short name: WHO TRS No. 996, Annex 10*

   *Short name: WHO TRS No. 996, Annex 3*