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Prequalification Team Inspection Services
WHO PUBLIC INSPECTION REPORT
(WHOPIR)
Active Pharmaceutical Ingredient Manufacturer

Part 1	**General information**
Manufacturers details	
Name of manufacturer	**SCL Lifesciences Limited (Formerly Saurav Chemicals Limited)**
Corporate address of manufacturer	SCL Lifesciences Limited Plot No. 370, Industrial Area, Phase-II, Panchkula, Haryana-134109, India, Tel.: +91-172-5054817-18
Name & address of inspected manufacturing site if different from that given above	SCL Lifesciences Limited Derabassi-Barwala Road, Village Bhagwanpura, District Sahibzada Ajit Singh Nagar, Tehsil Derabassi, Punjab 140 507, India
Synthetic unit /Block/ Workshop	Pharma II (synthesis and powder processing area)
Inspection details	
Dates of inspection	16-19 March 2026
Type of inspection	Routine GMP inspection
Introduction	
Brief description of the manufacturing activities	SCL Lifesciences Limited manufactures active pharmaceutical ingredients (non-sterile) and intermediates on-site. According to the site master file, products such as cytotoxic agents, sex hormones, cephalosporins, penicillins, and sterile APIs are not manufactured at the site.
General information about the company and site	SCL Lifesciences Limited was established in 2004 and is engaged in manufacturing active pharmaceutical ingredients and intermediates. In January 2025, the company's name was changed from Saurav Chemical Limited to SCL Lifesciences Limited.
History	The manufacturing site was last inspected on-site by PQ Inspection Services in October 2019.
Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	The following areas were inspected: - Quality management - Premises and equipment - Validation and qualification - Calibration and preventive maintenance - Production and packaging operations - Quality control laboratories
Restrictions	None
Out of scope	The APIs and manufacturing areas other than Diethylcarbamazine (citrate) were out of the scope of this inspection.

WHO APIs covered by the inspection	Diethylcarbamazine Citrate (APIMF216) OR Diethylcarbamazine (citrate) OR Diethylcarbamazine monodihydrogencitrate
Abbreviations	**Meaning**
AHU	Air handling unit
ALCOA	Attributable, legible, contemporaneous, original and accurate
API	Active pharmaceutical ingredient
APR	Annual product review
BMR	Batch manufacturing record
BPR	Batch production record
CC	Change control
CIP	Cleaning in place
CoA	Certificate of analysis
CpK	Process capability
DQ	Design qualification
EDI	Electronic deionization
EM	Environmental monitoring
FMEA	Failure modes and effects analysis
FPP	Finished pharmaceutical product
FTA	Fault tree analysis
GMP	Good manufacturing practices
HEPA	High-efficiency particulate air
HPLC	High-performance liquid chromatography (or high-performance liquid chromatography equipment)
HVAC	Heating, ventilation and air conditioning
IQ	Installation qualification
KF	Karl Fisher
LAF	Laminar air flow
LIMS	Laboratory information management system
MB	Microbiology
MBL	Microbiology laboratory
MR	Management review
NC	Non conformity
NRA	National regulatory agency
OQ	Operational qualification
PHA	Process hazard analysis
PLC	Programmable logic controller
PM	Preventive maintenance
PQ	Performance qualification
PQR	Product quality review
PQS	Pharmaceutical quality system
PW	Purified water
QA	Quality assurance
QC	Quality control
QCL	Quality control laboratory

QMS	Quality management system
QRM	Quality risk management
RA	Risk assessment
RCA	Root cause analysis
RO	Reverse osmosis
SMF	Site master file
SOP	Standard operating procedure
URS	User requirements specifications
UV	Ultraviolet-visible spectrophotometer

Part 2	**Summary of the findings and comments (where applicable)**

1. Quality management

SCL Lifesciences Limited has established a quality management system (QMS) to ensure the safety, efficacy, and quality of its manufactured products. The manufacturer has a quality unit independent of production that fulfilled both QA and QC responsibilities. A list of qualified personnel was identified for the release of batches of finished API and saleable intermediates. The QMS was managed manually, whereas logbooks for various QMS elements, such as change controls, deviations, OOT and OOS ~~laboratory incidents~~, were managed in the ERP.

Product Quality Review (PQR)

The SOP for annual product review was reviewed. It was conducted on a calendar year basis, and critical quality attributes were identified for all APIs and finished intermediates. Minitab was used to calculate process capability and to present the results graphically. A minimum of 10 batches was required to calculate CpK; if fewer than 10 batches were manufactured, batches from the previous year were considered. The areas identified for review were identical to the GMP for APIs. The PQR schedule for 2025 was available, stating a total of 45 APIs and saleable intermediates.

Quality risk management

The SOP for risk assessment and classification of quality-related events applied to change controls, deviations, complaints, recalls, introduction of new products, etc. The SOP listed several tools for risk assessment. The hazard assessment was performed using probability (1, 2, 3), severity (3, 6, 9), and detectability (1, 2, 3).

Nitrosamine impurities

The SOP for the identification, evaluation, and control of nitrosamine impurities in APIs guided the assessment. The risk assessment for Nitrosamine impurities in DCC was reviewed, and it was noted that it included an assessment of the route of synthesis, solvents, reagents, packaging materials, water, and other areas. Three batches were analyzed, and results were reported as ND. The analytical method was LC-MS/MS, and testing was performed on-site.

Management review

The SOP for quality management review was reviewed. The management review was conducted monthly, as described in the SOP. The meeting was led by the quality head, and department heads attended. The agenda was circulated beforehand. The recent meeting minutes were reviewed.

Deviation management

The SOP for handling deviations was discussed. The deviations were defined as unplanned and categorized as critical, major, or minor. The procedure stated that deviations should be logged within 1 working day, and that QA would assign a unique ID. Due to the weekly off, deviations were not always recorded within one working day. The procedure provided a flowchart outlining the steps for performing risk and impact assessments before corrective and preventive actions were taken. The SOP also stated that the ERP module was used for reference and deviation tracking.

Batch release

The SOP for approval, release, and distribution of finished products covered both APIs and saleable intermediates. A flowchart was provided describing how a batch manufacturing and control record (BPCR) was reviewed after batch manufacturing was completed. A batch release form was used. In addition, the SOP for the preparation, review, approval, issuance, filing, verification, receiving, storage, and disposal of batch production control records and equipment cleaning records was reviewed.

The deficiencies raised from this section have been adequately addressed, and the same will be verified during future PQ inspections.

2. Personnel

Mr. Parveen Goyal is the chairman and managing director of the company, and the department heads of VP Quality, Chief Business Officer, Chief Operating Officer, Chief Scientific Officer, Head of HR & Admin, and Director (his son, Mr. Saurav Goyal) report directly to him.

Function	**# of personnels**
Production	286
Quality Control	70
Quality Assurance	34
Warehouse	17
Human Resource/Admin	12
Engineering	70
Finance and Accounts	10
Purchase	6
R&D and ARD	72
Regulatory Affairs	5
Information System Development	4
Projects	12

MSTG / Tech. absorption	13
EHS	19
PPC	1
Operations	2
Planning	2
Project Management	4

Training and development

The SOP for training and development described various types of training, including induction training; GMP training (3 times a year); functional training (on SOPs); EHS & housekeeping (monthly); external training; training for contract staff; and unscheduled training. The training schedule was prepared annually by HR and identified various GMP and safety-related topics.

Hygiene and health

The SOP for personnel hygiene and health was discussed. The medical examination was conducted every 6 months, and a number of tests were administered to the personnel. The procedure required SCL staff members to report any infectious disease before reporting to work.

The deficiencies raised from this section have been adequately addressed, and the same will be verified during future PQ inspections.

3. Buildings and facilities

The manufacturing site has a total land area of 11 acres. There were 3 intermediate blocks, 9 pharma blocks, 1 pressure vessel block, 1 solvent recovery block, an engineering and warehouse block, a separate QA-QC, an R&D building, and an HR Admin Block. A separate solvent storage facility was also provided. A tank farm area with underground tanks for solvent storage was also available. The site has its own drainage system supported by an ETP (Effluent Treatment Plant). The powder processing areas were equipped with HVAC systems to achieve a temperature of NMT 25 °C and a relative humidity of NMT 65%. Powder processing was carried out under positive pressure relative to the atmosphere.

The water source was a borewell. The borewell water was filtered through a sand bed, then treated with carbon, and finally passed through a water softener. The soft water, after gramicid and anti-scalant dosing, pH correction, and SMBS dosing, was stored in the RO-I feed storage tank, then passed through an RO-I system (Chemical Sanitizable Reverse Osmosis system). The water from the RO-I System feeds into the RO-II feed water tank, then passes through the hot water RO-EDI system, a semi-automatic unit for removing dissolved impurities. The RO-EDI water was stored in a 3.5 KL stainless steel storage tank and supplied to user points via a return loop, with UV treatment in the supply line. The DI water was continuously monitored for conductivity and pH. The tanks, RO systems, and distribution loops were sanitized regularly, and records were maintained.

The deficiencies raised from this section have been adequately addressed, and the same will be verified during future PQ inspections.

4. Process equipment

During the visit to the synthesis and powder processing areas, it was noted that the manufacturing site was equipped with various reactors, filters, centrifuges, tray dryers, multi-mill, sifter, rotacone dryers, etc.

The deficiencies raised from this section have been adequately addressed, and the same will be verified during future PQ inspections.

5. Documentation and records

The documents related to the manufacturing of intermediates and APIs were prepared, reviewed, approved, and distributed in accordance with written standard procedures. A hybrid document management system was followed. In a hybrid system, some documents were kept in hard copy, while others were generated electronically via the ERP application.

The deficiencies raised from this section have been adequately addressed, and the same will be verified during future PQ inspections.

6. Materials management

The SOP for vendor qualification was discussed. The materials were categorized into key starting materials, reactants, and general materials. The QA team performed the initial assessment before vendor samples were tested. The results were forwarded to R&D for manufacturing trial batches before the supplier was approved. Key starting materials (KSMs) and primary packaging materials were audited on-site once every 3 years, whereas the rest were ~~audited~~ every 5 years. Vendor qualification of Diethyl Carbamoyl Chloride was performed by QA. The manufacturer was based in Gujarat, India.

7. Production and in-process controls

The inspector visited the manufacturing area, Pharma II, where the WHO prequalified DEC was produced. The manufacturing area was spread over three floors. Dispensed raw materials were transferred to the second floor via elevator/hoist. The second floor housed 4 SS and GLR reactors; the first floor had 3 reactors; and the ground floor had 5 centrifuges, 2 tray dryers, 1 pressure filter, and other equipment. The entrance to Pharma II was shared by staff and visitors, whereas a separate entry was provided for materials. Diethylcarbamazine (citrate) was manufactured using four stages according to the instructions in the BMR. Final purification, crystallization, drying, and packaging were performed in a Class D clean area.

The deficiencies raised from this section have been adequately addressed, and the same will be verified during future PQ inspections.

8. Packaging and identification labelling of APIs and intermediates

The SOP for blending of material (more than one batch) was applied to APIs and intermediates. The definition of blending was provided in the procedure, which described the methodology for performing it. As per the procedure, blending shall be carried out in accordance with the approved BPCR. The procedure stated that OOS batches will not be blended with approved batches.

The deficiencies raised from this section have been adequately addressed, and the same will be verified during future PQ inspections.

9. Storage and distribution

The solid warehouse was briefly visited, and it was noted that incoming materials were stored there, with controlled access. The materials were quarantined before sampling was performed by the quality control laboratory. The RLAF was used to sample polybags. Three dispensing areas were provided for charcoal, primary packaging materials, and other materials. For routine manufacturing, KSM was sampled as per $\sqrt{n}+1$.

The deficiencies raised from this section have been adequately addressed, and the same will be verified during future PQ inspections.

10. Laboratory controls

The inspector visited the QC laboratory, which was equipped with sophisticated instruments such as HPLC, GC, IR Spectrophotometer, UV Spectrophotometer, Polarimeter, Total Organic Carbon Analyzer, Auto-titrator (KF), Analytical Balance, FTIR, Melting Range Apparatus, pH Meter, Malvern Mastersizer, and Conductivity Meter. HPLC & GC instruments were supported by the Empower 3.6.1 server, and all systems were backed up.

Out of specifications (OOS)
The SOP for handling OOS was reviewed. The flow chart was part of the procedure used to conduct an initial investigation to determine whether a laboratory error occurred, and a report was submitted to QA. The QA designee assigned the OOS report number after the initial investigation was completed, not when the OOS was raised.

Laboratory incidents
The SOP for handling laboratory incidents was discussed in relation to two incidents recorded in the 2025 PQR. The incidents were categorized into category A (incident occurred during/after sample testing) and category B (incident occurred before sample testing). The categories were supported with various examples, and incidents were required to be logged within one working day. A checklist was used to investigate the root cause, and quarterly trending was performed.

Microbiology laboratory
The microbiology laboratory was equipped with TOC, HPHV autoclave, LAF, BSC, colony counter, and other equipment and instruments. A double-door autoclave was used for media sterilization, with loading performed in ISO 8 and unloading in ISO 7. LAF was used for microbial limit testing, media preparation, and disinfectant testing. BSC was used for culture preparation, GPT, and pathogens. The media was prepared in-house and subjected to GPT before use. A dynamic passbox was used to receive samples and return media plates to the incubators.

The deficiencies raised from this section have been adequately addressed, and the same will be verified during future PQ inspections.

11. Validation

The validation master plan was reviewed. In general, the VMP included most elements of qualification and validation activities. Requalification was carried out every 5 years for all production equipment. For the quality control equipment and instruments, qualification was a one-time activity, whereas preventive maintenance was performed every 6 months and annually. Similarly, a calibration schedule for the QC equipment and instruments was available, with calibrations performed monthly, quarterly, and half-yearly.

Process validation

The process validation was performed in three stages: stage I was carried out at R&D, and stage II was the process performance qualification, requiring a minimum of 3 batches to validate the process. Stage III was the continued process verification, which was carried out using Minitab software after 30 batches were collected.

Cleaning validation

The SOP for cleaning validation was reviewed. Cleaning methods were divided into batch-to-batch, product changeover, and periodic cleaning. The MACO was calculated based on three criteria as described under product changeover cleaning.

The deficiencies raised from this section have been adequately addressed, and the same will be verified during future PQ inspections.

12. Change control

The SOP for change management provided guidance on implementing changes, conducting assessments, performing risk assessments, and categorizing them. The QA was overall responsible for managing changes, including those related to the document control system. The changes were classified into major, moderate, and minor. There were two types of change: permanent and temporary. The change controls were tracked using the ERP system. The tracking of changes was done using the ERP system.

The deficiencies raised from this section have been adequately addressed, and the same will be verified during future PQ inspections.

13. Rejection and re-use of materials

Reprocessing, reworking, and recovery of finished APIs or intermediates were discussed. Unique numbers were given to reprocessed and reworked batches. For solvent recovery, the procedure is batch-driven. For DEC, although DMF provided a tentative procedure, the manufacturer has not performed any reprocessing. For rework, the manufacturer performed no rework. It was noted that IPA and Acetone were recovered from Stage III and IV, respectively, during the manufacturing of DEC. It was also noted that the manufacturer had submitted a major amendment to the API assessment team to optimize manufacturing and reduce the number of stages from four to three.

The deficiencies raised from this section have been adequately addressed, and the same will be verified during future PQ inspections.

14. Complaints and recalls

A market complaint was received from a customer regarding the drum's lid. The investigation included a review of the batch records and concluded that everything was in order on the manufacturer's end, whereas the logistics provider did not handle the material appropriately. The investigation was further extended using a fish-bone diagram. The SCL decided to replace the container lid to provide better protection.

The deficiencies raised from this section have been adequately addressed, and the same will be verified during future PQ inspections.

15. Contract manufacturers (including laboratories)

The manufacturer confirmed that Diethylcarbamazine (citrate) is manufactured on-site, with no part of it produced outside. The manufacturer used a contract laboratory for performing the XRD test.

The deficiencies raised from this section have been adequately addressed, and the same will be verified during future PQ inspections.

Part 3	**Conclusion – Inspection outcome**

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, ***SCL Lifesciences Limited,*** located at ***Derabassi-Barwala Road, Village Bhagwanpura, District Sahibzada Ajit Singh Nagar, Tehsil Derabassi, Punjab 140 507, India*** was considered to be operating at an acceptable level of compliance with WHO GMP Guidelines for APIs.

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**

1. WHO good manufacturing practices for active pharmaceutical ingredients. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 2. ***Short name: WHO TRS No. 957, Annex 2*** http://www.who.int/medicines/publications/44threport/en/
2. WHO good manufacturing practices for pharmaceutical products: main principles. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-eight Report Geneva, World Health

Organization, 2014 (WHO Technical Report Series, No. 986), Annex 2. ***Short name: WHO TRS No. 986, Annex 2***
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_986/en/

3. WHO guidelines for sampling of pharmaceutical products and related materials. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-ninth Report. Geneva, World Health Organization, 2005 (WHO Technical Report Series, No. 929), Annex 4.
Short name: WHO TRS No. 929, Annex 4
http://whqlibdoc.who.int/trs/WHO_TRS_929_eng.pdf?ua=1
4. Supplementary guidelines on good manufacturing practices: validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fortieth Report. Geneva, World Health Organization, 2006 (WHO Technical Report Series, No. 937), Annex 4.
Short name: WHO TRS No. 937, Annex 4
http://whqlibdoc.who.int/trs/WHO_TRS_937_eng.pdf?ua=1
5. General guidelines for the establishment maintenance and distribution of chemical reference substances. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-First Report Geneva, World Health Organization 2007 (WHO Technical Report Series, No.943) Annex 3. ***Short name: WHO TRS No. 943, Annex 3***
http://whqlibdoc.who.int/trs/WHO_TRS_943_eng.pdf?ua=1
6. WHO Good Practices for Pharmaceutical Quality Control Laboratories. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957, Annex 1.
Short name: WHO TRS No. 957, Annex 1
http://www.who.int/medicines/publications/44threport/en/
7. WHO Good Practices for Pharmaceutical Products Containing Hazardous Substances. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 3.
Short name: WHO TRS No. 957, Annex 3
http://www.who.int/medicines/publications/44threport/en/
8. WHO good manufacturing practices for sterile 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 6.
Short name: WHO TRS No. 961, Annex 6
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9. WHO guidelines on transfer of technology in pharmaceutical manufacturing WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 7.
Short name: WHO TRS No. 961, Annex 7
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1
10. 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://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1
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12. WHO guidelines for drafting a site master file. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 14. ***Short name: WHO TRS No. 961, Annex 14***

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13. WHO guidelines on quality risk management. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Seventh Report Geneva, World Health Organization, 2013 (WHO Technical Report Series, No. 981), Annex 2. ***Short name: WHO TRS No. 981, Annex 2***
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_981/en/
14. WHO guidelines on variation to a prequalified product. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Seventh Report Geneva, World Health Organization, 2013 (WHO Technical Report Series, No. 981), Annex 3. ***Short name: WHO TRS No. 981, Annex 3***
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15. WHO Guidelines on good manufacturing practices: validation, Appendix 7: non-sterile process validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 3. ***Short name: WHO TRS No. 992, Annex 3***
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.pdf
16. WHO General guidance on hold-time studies WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 4. ***Short name: WHO TRS No. 992, Annex 4***
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.pdf
17. WHO Technical supplements to Model Guidance for storage and transport of time – and temperature – sensitive pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 5. ***Short name: WHO TRS No. 992, Annex 5***
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.pdf
18. WHO general guidance on variations to multisource pharmaceutical products. *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifties Report* Geneva, World Health Organization, 2016 (WHO Technical Report Series, No. 996), Annex 10.
Short name: WHO Multisource guidance or ***WHO TRS No. 996, Annex 10***
http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex10.pdf
19. Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty Second Report Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1010), Annex 8. **Short name: WHO TRS No. 1010, Annex 8**
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_1010/en/
20. Stability testing of active pharmaceutical ingredients and finished pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Second Report Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1010), Annex 10.
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21. Production of water for injection by means other than distillation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Forth Report. Geneva, World Health Organization, 2020 (WHO Technical Report Series, No. 1025), Annex 3.
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