पश्चिमबंग पश्चिम बंगाल WEST BENGAL AP 291759

QUALITY AGREEMENT

by and between

DEY'S MEDICAL STORES (MANUFACTURING) LTD.

And

AKUMS DRUGS & PHARMACEUTICALS LTD.

for

Products identified in Appendix 1

("Product")

A. **WHEREAS, AKUMS DRUGS & PHARMACEUTICALS LTD.** is well-established and reputed manufacturer engaged in manufacturing of pharmaceutical drug products in India

B. **AND WHEREAS, DEY'S MEDICAL STORES (MANUFACTURING) LTD.** is a reputed pharmaceutical company, inter-alia engaged in the research and development, manufacturing, distribution and marketing of a wide broad range of healthcare and pharmaceutical products in India and abroad.

C. **AND WHEREAS,** Akums Drugs & Pharmaceuticals Ltd. has represented to Dey's Medical Stores (Manufacturing) Ltd. that Akums Drugs & Pharmaceuticals Ltd. owns the manufacturing facilities and has an expertise, experience, facility, qualifications and personnel along with all regulatory licenses, permissions, approvals to manufacture the Products.

D. **AND WHEREAS**, Dey's Medical Stores (Manufacturing) Ltd. based on the representations made by the Akums Drugs & Pharmaceuticals Ltd. had entered into collaboration, vide a License, Supply and Distribution Agreement whereby Manufacturer would manufacture and supply the Products on the terms and conditions contained herein.

Akums Drugs & Pharmaceuticals Ltd. Haridwar (U.K.)

For Dey's Medical Stores (Manufacturing) Ltd

GAUTAM DEY
Managing Director

Akums Drugs & Pharmaceuticals Ltd. (U.K.)

GAUTAM DEY
Managing Director

E. **AND WHEREAS**, Dey's Medical Stores (Manufacturing) Ltd. and Akums Drugs & Pharmaceuticals Ltd. by this Agreement, wish to define the individual responsibilities of the quality aspects of manufacturing, packaging, testing, quality control and supply of Product to ensure compliance with the approved Product application and/or Dey's Medical Stores (Manufacturing) Ltd. requirements.

F. This Quality Agreement details the activities associated with manufacture, package, analysis, release for dispatch/shipment/sale and supply of the Product. Unless otherwise indicated, responsibility for each activity is assigned to either Akums Drugs & Pharmaceuticals Ltd., or Dey's Medical Stores (Manufacturing) Ltd., or is assigned to both Akums Drugs & Pharmaceuticals Ltd. and Dey's Medical Stores (Manufacturing) Ltd.

TABLE OF CONTENTS

Appendices:

Appendix 1: Product

Appendix 2: List of Contacts

Akums Drugs & Pharmaceuticals Ltd. Haridwar (U.K.)

For Dey's Medical Stores (Manufacturing) Ltd

GAUTAM DEY
Managing Director

QUALITY AGREEMENT

-BETWEEN-
DEY'S MEDICAL STORES (MANUFACTURING) LTD.
62, Bondel Road,
Kolkata- 700019, West Bengal.
Hereinafter referred to as **"DEY'S MEDICAL"**

-AND-
AKUMS DRUGS & PHARMACEUTICALS LTD.
at 305 Mohan Place, LSC, Block C,
Saraswati Vihar, Delhi- 1100034.
Hereinafter referred to as **"MANUFACTURER"**

Both collectively referred to as "**Parties**"

This Quality Agreement ("**Agreement**") is executed between **DEY'S MEDICAL STORES (MANUFACTURING) LTD.** and **AKUMS DRUGS & PHARMACEUTICALS LTD.** whereby MANUFACTURER has agreed to manufacture, package, test and supply to Dey's Medical Stores (Manufacturing) Ltd., the products specified in **Appendix 1** (hereinafter referred to as "**Product**").

The quality agreement shall be revised at any time as necessary after mutually agreed by parties or once in a 2 years whichever is earlier based on terms and responsibilities.

1. PURPOSE

a. This document constitutes the Quality (technical) Agreement required under Current Good Manufacturing Practices (cGMP) to cover contract manufacturing.

b. It defines the responsibilities and assures Drugs Product Quality, Safety and Efficacy. In particular, it assigns the responsibilities under cGMP, into all aspects of manufacturing and includes inter-alia-processing, packing, holding, labelling operations, testing, and operations of the Quality Unit. It also specifies the way in which the responsibility to procure inputs, manufacture and release batches for sale ensures that they comply with the Marketing Authorisation requirements.

2. SCOPE

a. This Quality Agreement defines the expectations and responsibilities relating in any way to the quality of the Product, and includes without limitation, any process of and/or ancillary/incidental to, manufacturing, packaging, labelling, testing, inspection, storage, delivery, shipping, disposal, and document management system including change control, complaint, and recall processes, policies, and procedures.

b. MANUFACTURER will comply with all applicable Sop's, ordinances, rules, orders of public authorities or regulatory agency of the India, and/or any other applicable jurisdiction of any State or locality thereof, relating in any manner to the Product and includes without limitation, any process of and/or any process ancillary/incidental to manufacturing, packaging, labelling, testing, inspection, storage, delivery, shipping, disposal, and document management system including change control, transfer and disposal of Product, and product complaint and recall processes, policies, and procedures, inter-alia including current Good Manufacturing Practices ("cGMP") and any successor provisions (all of the above hereinafter collectively referred to as "Good Manufacturing Practices").

Akums Drugs & Pharmaceuticals Ltd. Haridwar (U.K.)

For Dey's Medical Stores (Manufacturing) Ltd

GAUTAM DEY
Managing Director

c. MANUFACTURER will perform its obligations in accordance with all applicable Good Manufacturing Practices, Good Laboratory Practices etc.

d. MANUFACTURER will be responsible for providing information that may be used in or referenced by any submission filed with the regulatory agency.

3. COMMUNICATION/SITE CONTACTS

A list of contacts (see Appendix 2) will be provided by Dey's Medical and Manufacturer to facilitate communications between the Parties. Each Party shall revise its contact list and communicate to the other Party in writing or by email, as necessary to keep it current and such revision shall not require amendment of this Quality Agreement.

4. MANUFACTURING:

a. MANUFACTURER agrees that the Product shall be manufactured in the product wise specified facility approved by Dey's Medical and that the Manufacturer owns all the necessary rights and have all approvals (including but not limited to dossier), licenses, permissions, authorizations, necessary for the manufacture of the Product, at its facilities (hereinafter "Facilities").

b. The manufacture of the Products by MANUFACTURER, shall be in accordance with the all the specifications and cannot be modified without prior approval from Dey's Medical. Manufacturer will be in compliance with Good Manufacturing Practices.

c. No modification/change manufacturing process and/or manufacturing controls (like testing, procurement of inputs) shall be done by the Manufacturer for the Product unless intimated to Dey's Medical in advance. The Manufacturer shall continue supplying to the Dey's Medical, the Product/s manufactured as per the earlier approved process, until the mutual agreement of both parties on changes.

d. MANUFACTURER agrees to manufacture and deliver the Products to Dey's Medical and shall ensure that the Products shall be of good marketable quality as prescribed under Drug & Cosmetics Act, 1940 and in accordance with (a) the Specifications. The relevant samples of the Products and packaging approved by Dey's Medical as amended from time to time. The applicable Regulatory approvals shall be taken if required.

e. MANUFACTURER warrants non handling of Penicillin's, Cephalosporin, Beta lactams and Hormones and or any other product which is not allowed by Regulatory Authorities to manufacture in same facility / building unless formally approved by "Dey's Medical" based on a risk based approach to evaluate the potential impact that the handling of such activities might have on the product(s).

f. MANUFACTURER shall maintain the vendor management system for all the input materials like API, Packaging Material, Excipient, etc. MANUFACTURER will perform audits at define interval and make available such documents to Dey's Medical, if required.

g. MANUFACTURER will conduct an investigation of any deviation or failure that could impact the quality of the Product. Such investigations will be performed and completed, in order for the MANUFACTURER to issue a Certificate of Conformance for the Product. All investigations must be **closed** and documented by MANUFACTURER prior to issuance of a Certificate of Conformance / COA.

h. All Products provided by MANUFACTURER to Dey's Medical, will comply and conform with the information shown on the Certificate of Analysis and Certificate of Conformance previously provided for the particular batch/lot of Product. In the event the MANUFACTURER determines that any Product (or any associated/incidental services) were not manufactured in accordance with Good Manufacturing Practices, MANUFACTURER shall notify Dey's Medical promptly, in writing. Such notice may be

Akums Drugs & Pharmaceuticals Ltd Haridwar (U.K.)

For Dey's Medical Stores (Manufacturing) Ltd

GAUTAM DEY
Managing Director

accompanied by samples of the non-conforming Product and written details identifying the non-conformance.

i. MANUFACTURER shall ensure that the finished Products do not contain any foreign matter, and shall ensure that all the finished Products and semi-finished Products are in strict compliance with the Specifications and none of the Product provided by MANUFACTURER to Dey's Medical under this Agreement will be adulterated and/or misbranded and/or not of standard quality within the meaning of the Good Manufacturing Practice whilst in its possession and under its control.

j. Upon request from Dey's Medical, MANUFACTURER will provide respective specification and Standard test procedure for Dey's Medical's products manufactured at subjected manufacturer's end.

5. ANNUAL PRODUCT QUALITY REVIEW

MANUFACTURER will be responsible for preparing Annual Product Review ("APR") as required by Good Manufacturing Practices & same shall be shared with Dey's Medical on demand.

6. DOCUMENTATION MANAGEMENT

a. MANUFACTURER will be responsible for reviewing and approving Product related documentation (e.g., specification, **STP**, manufacturing and packaging masters, labeling masters, etc.) prior to use. MANUFACTURER shall prepare and maintain all documentation and records concerning the Product, including, but not limited to documentation regarding manufacturing, packaging, labeling, inspection, testing, storage, and shipping, in accordance with current Good Manufacturing Practices.

i. MANUFACTURER undertakes, to store in its archives accurate data/records of all activities carried out in connection with the manufacture of the Product, copies of all the documents (or any such documents that the Dey's Medical may prescribe) for a period as defined in document retention policy at site, but not less than beyond 1 year of product expiry. Copies of all such records will be available for review to Dey's Medical Stores (Manufacturing) Ltd. upon request.

ii. MANUFACTURER will provide to Dey's Medical a Certificate of Analysis and a Certificate of Conformance for each batch or lot of Product manufactured, packaged, and tested by MANUFACTURER. "Certificate of Conformance" means a certificate which states: (a) the batch or lot of Product has been manufactured and tested in accordance with Good Manufacturing Practices or current Good Manufacturing Practices for Finished Pharmaceuticals. written manufacturing and control standard operating procedures and written testing procedures; (b) the starting materials used in the manufacture of the batch or lot of Product have been tested for the required quality control and comply with the specifications; (c) no deviations or investigations during manufacturing and testing remain unresolved, and all reconciliations and accountability have been satisfactorily completed; (d) the Product complies with the specifications and (e) the Product related information such as identification, Product name and strength, Product code, batch/lot number, manufacturing date, QC reference number, date of release, and quantity or batch/lot size.

7. QUALITY ASSURANCE

a. MANUFACTURER agrees that, it shall at all times during the term of this Agreement, maintain a quality assurance system for its manufacturing process, and control of material quality, processing, assembly, testing, packaging and shipping in accordance with the Specifications and in accordance with the best industry standards, Good Manufacturing

Ayush Drugs & Pharmaceuticals Ltd. Haridwar (U.K.)

For Dey's Medical Stores (Manufacturing) Ltd

GAUTAM DEY
Managing Director

Practices, and shall ensure that the quality management system is in accordance with applicable standards or any succeeding standard in the current version.

b. MANUFACTURER shall at all times maintain suitable premises, sufficient manufacturing capacity and technical expertise to develop and manufacture the Products as per the Specifications in compliance with the provisions of this Agreement and according to the best professional care and best industry standards expected in the sector. MANUFACTURER shall comply with Good Manufacturing Practices and all applicable law, including without limitation, environmental laws, labor laws, laws dealing with hazardous wastes and materials, hazardous materials transportation, occupational safety and health related laws, including process safety management standards.

c. MANUFACTURER agrees to carry out its manufacturing activities at controlled conditions, in order to ensure the implementation of process parameters conducive to the production of Products with the required characteristics, as set out in the Specifications.

d. MANUFACTURER undertakes to implement appropriate process control procedures in accordance with the best industry standards, good manufacturing practices and shall disclose these procedures to the Dey's Medical.

e. MANUFACTURER agrees that any change in, the process control procedures, API, raw and packaging material used in manufacturing the Product, manufacturing process, or the Products themselves, shall not be carried out without the prior written consent of the Dey's Medical.

f. MANUFACTURER agrees not to effect any changes to the Test parameter / Specifications Limit/Testing method without the prior written consent of the Dey's Medical Subject to the mutual consent of the Parties, the Manufacturer shall implement the changes to the Specifications mandated/required by Good Manufacturing Practice.

g. MANUFACTURER agrees that the measurement and testing equipment and instruments used by the manufacturer to control the conformity of, the process, and of the raw materials, components and products, shall be regularly calibrated against national or international standards or against reference instruments with calibration traceable to national or international standards.

h. MANUFACTURER further undertakes such measurement and testing equipment, and instruments will be periodically subjected to functional controls.

i. MANUFACTURER agree that the testing laboratories which may be engaged for any external control deemed necessary to ensure the conformity to the requirements specified in this Agreement shall be selected from NABL/GLP certified testing laboratories.

j. MANUFACTURER undertakes to implement and to disclose to the Dey's Medical appropriate end-product and material/component control procedures and to make available to Dey's Medical suitable analytical evidence of end product conformity to the requirements set out in the Specifications, along with the delivery of each shipment of the Product.

k. MANUFACTURER undertakes to implement and shall duly inform the Dey's Medical of such suitable measures and procedures in order to ensure the unique identification and traceability of API, raw materials, end products, relevant records and test results. The Manufacturer further undertakes to implement, and disclose to Dey's Medical adequate documentation evidencing compliance.

l. MANUFACTURER undertakes to store the Products so as to preserve their characteristics, relevant to the Product and to the satisfaction of Dey's Medical whilst in its possession and under its control. If the Manufacturer has no suitable storage places of its

Akums Drugs & Pharmaceuticals Ltd. Haridwar (U.K.)

For Dey's Medical Stores (Manufacturing) Ltd

GAUTAM DEY
Managing Director

own, the Manufacturer shall obtain the prior written consent of the Dey's Medical before storing the Products at any other location not owned and controlled by the Manufacturer.

m. MANUFACTURER undertakes to inform the Dey's Medical of any test and control results, including those carried out by Regulatory Authority, competent organizations and public bodies.

8. SAMPLE RETENTION

MANUFACTURER will retain and store under conditions consistent with Product labeling, appropriately identified reserve samples that are representative of each batch or lot of Product in an amount sufficient to perform two (2) complete repetitions of full analytical testing, except those for sterility and pyrogens for a period of not less than one (1) year beyond the expiration date.

The reserve samples shall be stored in the same immediate container-closure system in which the Product is marketed. The reserve samples from representative sample lots or batches selected by acceptable statistical Dey's Medical shall be examined visually at least once a year for evidence of deterioration unless visual examination would affect the integrity of the reserve sample. Any evidence of reserve sample deterioration shall be investigated, recorded and maintained with other stability data of the Product.

9. NON-CONFORMANCES

In the event that MANUFACTURER prior to determines that any Services were not performed in accordance with current Good Manufacturing Practices, SOP, Manufacturer shall notify Dey's Medical promptly, in writing. Such notice may be accompanied by samples of the non-conforming Product and written details identifying the non-conformance.

10. DEVIATIONS AND FAILURE INVESTIGATIONS

a. MANUFACTURER will conduct an investigation of any deviation or failure that could impact the quality of the Services, or the Product. Such investigations will be performed and completed in order for MANUFACTURER to issue a Certificate of Conformance for the Product prior to dispatch of the batch...

b. Except for deviations or occurrences identified subsequent to issuance of a Certificate of Conformance, all investigations must be completed, documented, and approved by Dey's Medical prior to issuance of a Certificate of Conformance.

c. All significant quality decisions that will negatively impact the quality of the Product for commercial distribution by Dey's Medical, as a result of deviations, failure investigations, complaints, or otherwise will be made by MANUFACTURER shall be informed to Dey's Medical prior to distribution of product.

11. COMPLAINTS HANDLING

a. Product quality complaints for the Product will be processed and response shall be shared with Dey's Medical within 30 days from receipt of complaint, however critical compliant shall be responded along with investigation within 10 days of receipt of complaint.

b. MANUFACTURER will investigate all complaints including those forwarded by Dey's Medical Stores (Manufacturing) Ltd., as per established procedures.

c. MANUFACTURER shall inform to Dey's Medical immediately within 2 working days of any Product Complaint that is significant enough to have impact on Product batch supplied to Dey's Medical MANUFACTURER shall provide a copy of the preliminary investigation report to Dey's Medical within 07 working days of receipt of such complaint.

Akums Drugs & Pharmaceuticals Ltd. Haridwar (U.K.)

For Dey's Medical Stores (Manufacturing) Ltd

GAUTAM DEY
Managing Director

d. MANUFACTURER shall use commercially reasonable efforts to provide a written report of the investigation to Dey's Medical Quality Complaint Operations within thirty (30) days of the forwarded complaint.

e. Dey's Medical, in consultation with MANUFACTURER, shall respond directly to its complainants.

12. CHANGE CONTROL

a. Changes or proposed changes that impact, directly or indirectly, on the quality of Product will be reviewed and approved by Dey's Medical. Such changes include, but are not limited to, changes to: (a) manufacturing/packaging masters, manufacturing/packaging batch records, applicable test methods, specifications; (b) facility, equipment, site, or testing laboratory, inspection, document retention, or complaint and recall processes, policies or procedures; (c) the manufacturing, packaging, labeling, storage, delivery, transfer, or disposal or other disposition of Product; (d) raw material specifications, and components used in the Manufacture of the Product.

b. Dey's Medical and MANUFACTURER will maintain this Quality Agreement in a current state, and will formally amend it to reflect any change described in subsection. Any proposed amendment to this Quality Agreement must be submitted to the other party in writing with a statement of the reason for the proposed amendment. All changes must be approved and agreed upon by both Parties in writing, prior to implementation.

c. In the event of any changes to Good Manufacturing Practices, MANUFACTURER will review and assess all such changes potentially applicable to Product, and propose any changes to this Quality Agreement that would be necessary to reflect such changes.

13. REGULATORY CONTACTS / INSPECTIONS / GMP COMPLIANCE

a. MANUFACTURER will coordinate for all contacts and communications with any national or local regulatory body or other government authority (collectively "Regulatory Agency") with respect to all matters relating to Product. Unless required by law or a Regulatory Agency, Dey's Medical will have no contacts or communication with any Regulatory Agency regarding the Product without the consent of MANUFACTURER.

b. MANUFACTURER will notify Dey's Medical of any inquiry, contact, or communication received from Regulatory Agency of the territory that relates to the Product. Manufacturer will furnish Dey's Medical with copies of all related written reports, comments, and communications from such Regulatory Agency.

c. MANUFACTURER will furnish to Dey's Medical prior to the communication, copies of all communications to be made by Manufacturer to Regulatory Agency of the territory concerning the Product.

d. Prior to making a commitment to a Regulatory Agency regarding the Product, MANUFACTURER will request Dey's Medical's comments, which shall not be unreasonably withheld or delayed. MANUFACTURER will comply with all reasonable requests and comments by Dey's Medical with respect to all contacts and communications with a Regulatory Agency relating to the Product.

e. MANUFACTURER will immediately notify Dey's Medical if any Regulatory Agency schedules, or without scheduling, begins an inspection of a facility that relates to the Product. Manufacturer will provide Dey's Medical with copies of any correspondence within three days, to or from such Regulatory Agencies, the subject of which could impact

Akums Drugs & Pharmaceuticals Ltd. Haridwar (U.K.)

For Dey's Medical Stores (Manufacturing) Ltd

GAUTAM DEY
Managing Director

the ability of Manufacturer to continue performing its obligations under this Quality Agreement.

f. MANUFACTURER shall immediately notify to Dey's Medical if critical / major issues identified during inspection, which can have impact on approval status of facility including warning letter state regulatory agency or any other regulatory agency. In such cases, Manufacturer shall also send the impact assessment of these issues.

g. MANUFACTURER will make available its facilities and records for audit by Dey's Medical Stores (Manufacturing) Ltd.'s representative to assess and ensure ongoing compliance with the requirements of this Quality Agreement. Audits will be scheduled through the Manufacturer contact identified in Appendix 2 (List of Contacts). During any such audit, Dey's Medical may inspect the relevant documents that Manufacturer is obliged to maintain and any of the facilities of Manufacturer used in the manufacture, testing, packaging or storage of the Product or raw materials and packaging components for the supply of the Product to Dey's Medical. The audit will be conducted at mutually agreeable and reasonable times upon reasonable prior notice provided. Dey's Medical retains the right to conduct "for cause" audits as necessary. Dey's Medical representative may visit at manufacturer site to verify the product/process any time.

h. Dey's Medical reasonably believes that Products fail to comply with Good Manufacturing Practices; Dey's Medical will give notice thereof to MANUFACTURER of the non-conformity for investigation.

i. Notwithstanding any of the foregoing in this Article, this Article shall be subject to the applicable provisions in the Supply Agreement between Dey's Medical and MANUFACTURER. In the event of a conflict between the provisions of this Quality Agreement and the applicable terms of the Supply Agreement, the Supply Agreement shall govern and control in all matters, other than those related to Quality. In matters of Quality, this Quality Agreement shall prevail.

14. DISPOSITION OF MATERIALS

MANUFACTURER will perform the applicable tests to materials associated with Products according to approved test methods and specifications using qualified and calibrated equipment. All test methods shall comply with compendial requirements or be validated, if not from the Pharmacopeia. MANUFACTURER will receive, sample, test, release, hold, and store any material or component obtained for the Products in accordance with current Good Manufacturing Practices. MANUFACTURER shall maintain calibration and preventive maintenance procedures and schedules for equipment/instruments used in the manufacture, packaging, testing, and validation/qualification of the Product. MANUFACTURER shall document and review (including calibration performed by any subcontractor) manufacturing, packaging and laboratory equipment/instrumentation calibration data.

15. LABELS AND OTHER PRINTED MATERIAL

a. MANUFACTURER shall be responsible for packaging and labeling the Products in compliance with the Specifications and the Good Manufacturing Practices.

b. On termination of this Agreement, Dey's Medical shall have the right but not the obligation to require the MANUFACTURER to sell to Dey's Medical all unused packing materials in MANUFACTURER's possession or control.

16. VALIDATION/QUALIFICATION

Dey's Medical and MANUFACTURER agree to the following Validation/Qualification approach:

Akums Drugs & Pharmaceuticals Ltd. Haridwar (U.K.)

For Dey's Medical Stores (Manufacturing) Ltd

GAUTAM DEY
Managing Director

a. MANUFACTURER will perform qualification and/or validation for process, packaging, cleaning, analytical methods, and computerized systems, including qualification/validation of facilities, equipment, and utilities as applicable. MANUFACTURER records and reports of the qualification and validations shall be available for review during audits.

b. MANUFACTURER will notify Dey's Medical of planned changes to a validated manufacturing and packaging process or associated manufacturing and packaging instructions. Any such changes will be made only in accordance with Section 12 of this Quality Agreement.

c. MANUFACTURER will evaluate protocol deviations encountered during validation/qualification to determine any impact on validation/qualification studies, including the need to conduct repeat studies.

d. MANUFACTURER will evaluate validated/qualified systems and processes periodically to verify that they are still operating in compliance.

e. Manufacturer will notify to Dey's Medical in case of any deviation affecting the quality of the Product or any deviation which is related to facility catering to manufacturing of Dey's Medical product.

17. SUB-CONTRACTORS / CONSULTANTS

a. MANUFACTURER will not use subcontracted service providers / consultants for any activity relating to Product without prior approval of Dey's Medical If Manufacturer subcontracts any activity to a subcontractor / consultant, such subcontractor(s) / consultant(s) shall operate in compliance with Good Manufacturing or Good Laboratory Practices, compendia requirements and any other applicable regulations.

b. MANUFACTURER shall maintain a list of all subcontractor(s) / consultant(s) as qualified following approved procedures according to a schedule.

18. QUALIFICATIONS AND TRAINING

a. MANUFACTURER will use appropriately qualified personnel, having the appropriate levels of education, experience and/or skill, and properly documented training to fulfill its obligations under this Quality Agreement.

b. All training records will be appropriately maintained and kept on file and MANUFACTURER shall supply adequate evidence of such training activities and instructions to the Dey's Medical, within seven (7) days of communication of such request to provide adequate evidence.

c. MANUFACTURER undertakes to provide adequate training and instruction to all personnel involved in activities directly impacting product quality to fulfil their obligations and will ensure that the training is regularly conducted, assessed, and documented by qualified individuals.

19. IDENTIFICATION & TRACEABILITY

MANUFACTURER will maintain a system to assure the proper acceptance and identification of any components, packaging materials, in-process materials, and finished product throughout the packaging process and warehousing of Product. MANUFACTURER will maintain records to allow for the traceability of the specific batches/lots of packaging materials used in a particular batch/lot of Product.

Akums Drugs & Pharmaceuticals Ltd. Haridwar (U.K.)

For Dey's Medical Stores (Manufacturing) Ltd

GAUTAM DEY
Managing Director

20. TRANSPORTATION / STORAGE

a. MANUFACTURER will validate/qualify and maintain storage facilities appropriate for conditions specified on the Product label and will maintain records of critical storage parameters.

b. MANUFACTURER will ensure that during manufacturing, packaging, processing, and storage of the Product there is no possibility of deterioration, contamination or mixing with any other materials and will comply with all applicable GMP requirements in relation to required temperatures and conditions for storage whilst in its possession and under its control.

c. MANUFACTURER will ensure Products are stored in appropriately safe and secure areas, that adequate precautions are taken against spillage, breakage or theft and that Products are not subjected to unacceptable levels of heat, cold, light, moisture, attack by microorganisms or pests or other adverse influence whilst in its possession and under its control.

d. MANUFACTURER will establish and maintain an environmental monitoring program including trending activities to assure adherence to specified Product, raw materials, packaging materials and component storage conditions.

e. MANUFACTURER will have validated/qualified systems for controlling quarantined, rejected or recalled materials and segregation of rejected or recalled materials.

f. MANUFACTURER will transport and store Product in a manner that will have no adverse effect on its potency, purity, and physical characteristics whilst in its possession and under its control.

g. MANUFACTURER will package, label, and ship all Product in accordance with the approved specifications, instructions, and with applicable government/regulatory requirements.

21. RECALLS / WITHDRAWALS

a. MANUFACTURER will notify Dey's Medical immediately of any information that potentially could result in the need for a recall / withdrawal of Product in the official mail of the Contact persons mentioned herein below at the earliest.

b. Dey's Medical may take any action relating to the recall / withdrawal that it is required to take by law.

c. Dey's Medical will maintain records of Product distributed to market including lot numbers and distribution information, in order that the Product can be easily traced in case of a recall / withdrawal.

d. Product recalls / withdrawals will be handled as per Dey's Medical procedures.

22. STABILITY

MANUFACTURER shall ensure that a stability program a written testing program designed to assess the stability characteristics of Products, is maintained in accordance with stability protocol. Any confirmed OOS (Out of specification) results obtained during stability testing must be reported to Dey's Medical within 07 working days. In the event that this Quality Agreement is terminated between the Parties supplier will continue to generate stability data to support the acceptability of the Product until all Product distributed by Dey's Medical has reached the end of its shelf–life.

Akums Drugs & Pharmaceuticals Ltd. Haridwar (U.K.)

For Dey's Medical Stores (Manufacturing) Ltd

GAUTAM DEY
Managing Director

23. PROCESS AND PRODUCT WARRANTY

MANUFACTURER warrants and represents that:

a. All Products manufactured by MANUFACTURER to Dey's Medical will comply and conform with the information shown on the Certificate of Analysis and/or Certificate of Conformance previously provided for the particular batch/lot of Product.

b. None of the Products provided by MANUFACTURER to Dey's Medical will cause Product to be adulterated or misbranded within the meaning of Drug and Cosmetic Act, as amended and in effect at the time of shipment, provided that Dey's Medical shall have no responsibility for misbranding caused directly by MANUFACTURER as a result of labels or package texts provided by MANUFACTURER, unless those labels or package texts were approved before use by Dey's Medical Stores (Manufacturing) Ltd.

24. ASSIGNMENT

MANUFACTURER shall not assign any or all of its rights or obligations without Dey's Medical prior written intimation. Dey's Medical shall have the right to assign any or all of its rights or obligations without the prior intimation of MANUFACTURER. In the event of an Assignment Transaction, Dey's Medical shall provide written notice to MANUFACTURER to the appropriate contact person indicated in Appendix 2. In the event of an assignment, the assigned party shall continue to be bound by all pre-existing obligations including all obligations of confidentiality and non-disclosure.

25. RESOLUTION OF QUALITY ISSUES

Quality related disagreements between MANUFACTURER and Dey's Medical that are not resolved in the normal course of business shall be brought to the attention of the appropriate contact person for notices at the MANUFACTURER and Dey's Medical Stores (Manufacturing) Ltd., in writing, as listed in **Appendix 2** (Contacts and Responsibilities).

If the quality issue is not resolved within a reasonable time both the Parties may nominate, by mutual agreement, an independent laboratory who shall examine the quality issue in question; and whose decision shall be binding upon both Parties. All costs arising from such an inspection shall be borne by the Party in error.

26. Miscellaneous

a. Dispute Resolution

The Parties agree that they shall in good faith work towards implementation of this Agreement and any dispute arising out of or in relation to this Agreement shall be first attempted to be resolved amicably by mutual negotiations, failing which such dispute shall be referred to Arbitration to be conducted in accordance with the Indian Arbitration and Conciliation Act, 1996 and the rules framed thereunder as amended from time to time. The arbitration shall be held in Delhi, India and shall be conducted in English by the sole arbitrator mutually appointed in accordance with said Rules. The decision of such arbitrator shall be final, binding and conclusive on the Parties.

b. Governing Law, Jurisdiction

This Agreement and any dispute or claim arising out of or in connection with it or its subject matter or formation shall be governed by and construed in accordance with the law of India. Each Party irrevocably agrees that the courts of Delhi, India shall have exclusive jurisdiction in relation to the dispute between the Parties.

Akums Drugs & Pharmaceuticals Ltd. Haridwar (U.K.)

For Dey's Medical Stores (Manufacturing) Ltd

GAUTAM DEY
Managing Director

c. **Inconsistency:**

This Quality Agreement contains the understanding between Dey's Medical and Akums Drugs & Pharmaceuticals Ltd. hereto with regards to the subject matter hereof. In the event of inconsistency between the Quality Agreement and License, Supply and Distribution Agreement, the provisions of this Quality Agreement shall prevail to the extent that the inconsistency relates to quality related issues. Otherwise, the provisions of the License, Supply and Distribution Agreement shall prevail.

27. **Term:**

This Quality Agreement shall become effective **from the date mentioned (final sign in approval section)** and will remain in effect until the License, Supply and Distribution Agreement is terminated or expired.
Notwithstanding expiry or termination of this Agreement, the responsibilities and obligations of the Parties set out in this Agreement shall survive expiry or termination until the first anniversary of the shelf life expiry date of the last Product supplied by Akums Drugs & Pharmaceuticals Ltd. to Dey's Medical under this Agreement. Dey's Medical and Akums Drugs & Pharmaceuticals Ltd. may agree in writing to transfer the responsibilities with regards to stability studies, and document and samples retention to a Third Party.

28. **QUALITY RESPONSIBILITIES TABLE**

Legends:
B= Dey's Medical Stores (Manufacturing) Ltd., M= Akums Drugs & Pharmaceuticals Ltd.

S. No.	Responsibilities	B	M
1.	**General Compliance**		
1.01	Follow applicable regulations and current Good Manufacturing Practices, as well as local statutory imposed requirements.	Yes	Yes
1.02	Manufacture, package, test, store and ship the Product and materials in an environment meeting the applicable GMP regulations. Permits the effective cleaning of all surfaces and prevents the contamination of the Product.		Yes
1.03	Product quality updating of specifications, methods, expiration date.		Yes
1.04	Manufacture and test the Product in adherence to approved procedures and methods.		Yes
1.05	Notify process or Product changes prior to implementation in accordance with Section 12 of this Quality Agreement.		Yes
1.06	Operate in compliance with applicable environmental, occupational health and safety laws and regulations.		Yes
1.07	Refrain from activity that could adversely affect quality of the Product.	Yes	Yes
1.08	Notify Dey's Medical within three (2) business day of requests for information, notices of violations or other communication from a government agency relating to environmental, occupational health and safety compliance that impact the Product and /or services.		Yes
1.09	Have management controls in place to track and trending of investigations and commitments.		Yes

Akums Drugs & Pharmaceuticals Ltd. Haridwar (U.K.)

For Dey's Medical Stores (Manufacturing) Ltd

GAUTAM DEY
Managing Director

S. No.	Responsibilities	B	M
1.10	Maintain a quality unit that is independent of production that fulfils both quality assurance and quality control responsibilities.		Yes
1.11	Disposition of Product by quality unit.		Yes
1.12	Involve the quality unit in all Good Manufacturing Practices related matters.		Yes
1.13	Maintain internal Good Manufacturing Practices audit program.		Yes
1.14	Maintain a valid manufacturing license and GMP certificate issued by the local health authority and all relevant authorities.		Yes
1.15	Manufacturing activity shall not be sub-contracted without prior consent from Dey's Medical Stores (Manufacturing) Ltd.		Yes
2.	**Right to Audit**		
2.01	Have the right to audit Manufacturer's facilities and systems, as they relate to the manufacturing, packaging and testing of the Bulk finish product and Product, at mutually agreed upon times. Dey's Medical retains the right to conduct "for cause" audits as necessary.	Yes	
2.02	Schedule visits and/or requests for Product specific documents for review to assure continued adherence to the agreed upon manufacturing process, applicable current Good Manufacturing Practices and other applicable requirements.	Yes	
2.03	Issue Manufacturer a confidential audit report summarizing audit observations.	Yes	
2.04	Issue responses to all observations in writing to Dey's Medical within thirty (30) calendar days of receipt. Responses are to include timelines and plans for closure of all commitments.		Yes
3	**Regulatory Inspections and Exchanges**		
3.01	Coordinate the activities necessary to ensure readiness prior to regulatory agency and maintain inspection readiness for all inspections subjected to Dey's Medical Product.	Yes	Yes
3.02	Notify Dey's Medical within three (3) business day of any announced or ongoing regulatory authority inspection or communication related to their Product. In the event that the inspection is specific only to Product.		Yes
3.03	Notify Manufacturer of any regulatory compliance observation received by Dey's Medical that pertains to operations performed by the Manufacturer.	Yes	
3.04	Provide any requested information to Dey's Medical within three (2) business days of notification or as required to meet regulatory obligations.		Yes
3.05	Provide Manufacturer with advance written notification of new or supplemental regulatory submission/application that impact the operations performed by the Manufacturer.	Yes	
4.	**Regulatory Documentation**		
4.01	Maintain the FDA Registration, as applicable, in accordance with the regulations of the applicable regulatory authority.		Yes
4.02	Notify Dey's Medical for any FDA Registration change as applicable before submitting the change to authority and prior to implementation.		Yes
4.03	Manufacturer will notify Dey's Medical within one (1) business day of incidences which require action in market/product Recall.		Yes
5.	**Sub-Contracting and Testing**		

Akums Drugs & Pharmaceuticals Ltd Haridwar (U.K.)

For Dey's Medical Stores (Manufacturing) Ltd

GAUTAM DEY
Managing Director

S. No.	Responsibilities	B	M
5.01	If Manufacturer sub-contracts any laboratory testing or manufacturing work (or like) to a third-party contract laboratory or third-party manufacturer (or the like) (a "Sub-Contractor"), Manufacturer shall require that such Sub-Contractor shall operate in compliance with current Good Manufacturing Practices, compendia requirements and any other applicable regulations.		Yes
5.02	Not engage any Sub-Contractor without the prior written consent of Dey's Medical Stores (Manufacturing) Ltd.		Yes
5.03	Maintain Sub-Contactor as qualified following approved procedures according to a schedule.		Yes
5.04	If Manufacturer engages a Sub-Contractor, Manufacturer shall cause Sub-Contractor to grant access to Dey's Medical and/or any applicable regulatory authority for purposes of any Dey's Medical and/or regulatory authority audits on the same terms and conditions as such access is granted to Dey's Medical and/or any applicable regulatory authority by Manufacturer under the terms of this Quality Agreement and/or the terms and conditions of any other applicable agreement between Manufacturer and Dey's Medical Stores (Manufacturing) Ltd.		Yes
6.	**Change Control**		
6.01	Have approved written procedures for control of changes impacting the Product including but not limited to the manufacturing, packaging process, packaging materials, labeling, computer hardware/software, Product specifications, and test methods. Include in written procedures the process and criteria for customer notification and approval, follow up and closure of changes.		Yes
6.02	Notify Dey's Medical of all changes to facility, process, test methods, quality systems and specifications that impact Product identity, strength, safety, potency, purity, stability, regulatory status or validation/qualification. Allow time for Dey's Medical to comment and approve or reject changes prior to implementation.		Yes
6.03	Provide copies of change control documentation such as supporting data, validation/qualification reports and change control forms for changes impacting Product as requested by Dey's Medical Stores (Manufacturing) Ltd.		Yes
6.04	Have changes reviewed and approved by the Manufacturer's quality unit.		Yes
6.05	Manufacturer shall establish a strategy to secure regulatory approvals as necessary, and shall mutually agree on an implementation timeline. Manufacturer may make minor changes that do not have regulatory impact, such as, amending typographical errors without obtaining customer approval.		Yes
7.	**Validation/Qualification**		
7.01	Have an appropriate written validation/qualification plan for the facilities, equipment/instruments, packaging process, cleaning procedures, analytical procedures, in process control tests and computerized systems approved by the quality unit.		Yes
7.02	Prepare and maintain validation/qualification documentation approved by the quality unit, including protocols, reports and associated documentation. Provide such documents to Dey's Medical upon request.		Yes

Akums Drugs & Pharmaceuticals Ltd. Haridwar (U.K.)

For Dey's Medical Stores (Manufacturing) Ltd

GAUTAM DEY
Managing Director

S. No.	Responsibilities	B	M
7.03	Validate/qualify as necessary all critical systems, utilities and equipment/instruments used for the packaging and control of Product (Installation Qualification (IQ), Operational Qualification (OQ), and/or Performance Qualification (PQ), Process Validation (PV)).		Yes
7.04	Develop and execute a plan for process and method validation/qualification including definition of roles and responsibilities between Manufacturer and Dey's Medical for performing technology transfers.		Yes
8.	**Investigations**		
8.01	Have appropriate procedures for the identification, investigation, reporting, tracking, trending and closure of deviations. Deviations include but are not limited to known lab errors, atypical results and Out-of-Specification results that occur during the packaging and testing of the Product, including stability testing (as applicable) This applies to Critical Defects or any deviation that results in the failure of a lot.		Yes
8.02	Document and notify Dey's Medical of any deviation affecting the quality of the Product or any deviation outside of Product registration prior to release of product, if applicable.		Yes
8.03	Notify Dey's Medical within one (1) business day of first knowledge of all confirmed Out-of-Specification results generated during stability testing of Product.		Yes
8.04	Complete corrective action commitments resulting from investigation closure within the planned timeframe.		Yes
9.	**Documentation and Records**		
9.01	Document all required process and testing steps at the time such process or testing step is executed.		Yes
9.02	Manufacturer's quality unit must review and approve all Good Manufacturing Practices records.		Yes
9.03	Retain, archive and destroy all Good Manufacturing Practices documents and data pertaining to Services performed for Dey's Medical in accordance with regulatory requirements.		Yes
9.04	Have all executed batch related records reviewed and approved by Manufacturer's quality Assurance prior to batch release.		Yes

Akums Drugs & Pharmaceuticals Ltd. Haridwar (U.K.)

For Dey's Medical Stores (Manufacturing) Ltd

GAUTAM DEY
Managing Director

S. No.	Responsibilities	B	M
9.05	Determine/approve the package Lot Number and Expiration Date and forward to Dey's Medical Stores (Manufacturing) Ltd.		Yes
9.06	Assure packaging records have a unique identification number.		Yes
9.07	For laboratory control records, include complete data derived from all tests conducted to ensure compliance with specifications. These records will contain the date and the signature of a second qualified person showing review and verification of the records.		Yes
9.08	Provide copies of documents and/ or records of the Product Batch to Dey's Medical Stores (Manufacturing) Ltd and further share the same with Dey's Medical electronically through mail to the Contact persons mentioned herein below.		Yes
9.09	Maintain a document control system for specifications, including: Product labeling, packaging materials and other materials that would likely affect Product quality.		Yes
9.10	Provide a complete Certificate of Analysis and Certificate of Compliance for the Product		Yes
9.11	Provide a document certifying Product was packaged in a current Good Manufacturing Practices compliant facility and was tested in accordance with and meets specifications.		Yes
10.	**Annual Product Quality Reviews**		
10.01	Have procedures to conduct and document annual product quality reviews on a scheduled basis as agreed to by Dey's Medical Stores (Manufacturing) Ltd.		Yes
10.02	Prepare Annual Product Quality Review that includes at a minimum; • Date of review • Signatures/title of the reviewers • Product identification • Review period • Batch records (including reworks) • Applicable change control records • Returned or salvage Product records • Product investigation records • Batch record deviations (holds, exception reports, etc.) • Complaints • Document evaluations or assessments of the information presented Packaged Product review		Yes
10.03	Provide copies of Annual Product Quality Review to Dey's Medical Stores (Manufacturing) Ltd.		Yes
11.	**Production and In Process Controls, Packaging and Labeling**		
11.01	Have approved written procedures in place for qualification (including audits) of suppliers that provide GMP-materials and services.		Yes
11.02	Make no changes in the sourcing of production materials (APIs, raw materials, inactive ingredients, packaging materials) from the approved supplier list without prior written consent from Dey's Medical Stores (Manufacturing) Ltd.		Yes
11.03	Maintain a Manufacturer Qualification Program in order to establish ongoing inspection and testing requirements for packaging materials received at Manufacturer, including reduced testing for certified vendors.		Yes
11.04	Document actual yields for the Product, and evaluate actual yields versus theoretical or in-process yield control limits.		Yes

Akums Drugs & Pharmaceuticals Ltd. Haridwar (U.K.)

For Dey's Medical Stores (Manufacturing) Ltd

GAUTAM DEY
Managing Director

S. No.	Responsibilities	B	M
11.05	Notify Dey's Medical in the event that there is a change in product category manufactured in the same facility and equipment as Product (such as hazardous, deleterious, potent, sensitizing materials,) No penicillin or cephalosporin products are allowed to be packaged in the same facility as products covered by this quality agreement).		Yes
11.06	Develop all labeling in accordance with applicable regulation (including for the country intended for distribution) and Product license.	Yes	Yes
11.07	Have all Product labeling approved by Dey's Medical prior to use.	Yes	Yes
11.08	Include a representative label in the batch record.		Yes
11.09	Establish and maintain a program for environmental monitoring including tracking and trending processes.		Yes
12.	**Process Equipment**		
12.01	Process equipment must be uniquely identified, and managed with an equipment history log or equivalent system. Process lines will be appropriately identified.		Yes
12.02	Use appropriate food grade machine lubricants and oils that contain no animal derived materials for items that are in direct contact with product or primary packaging components.		Yes
12.03	Maintain a current set of "as-built" drawings for equipment and facilities.		Yes
13.	**Laboratory Controls**		
13.01	Have written procedures for sample management, identification, testing, disposition and recording, approval, tracking, storage, retention and disposal of laboratory data.		Yes
13.02	Hold samples and disposes of as required by specifications and procedures.		Yes
13.03	Destroy samples and sample packaging in a secure and legal manner that prevents unauthorized use or diversion in accordance with Manufacturers procedures. Maintain destruction records.		Yes
13.04	Test Product in accordance with qualified or validated methods as appropriate and with specifications using calibrated, qualified equipment.		Yes
13.05	Verify compendia test methods (i.e. USP, Ph. Eur., BP, JP). Supply a certificate of equivalency or verification report to Dey's Medical Stores (Manufacturing) Ltd., if applicable. Follow approved change to test procedures for changing test methods.		Yes
13.06	Whenever required, provide qualified reference and/ or working standard to Dey's Medical Stores (Manufacturing) Ltd.		Yes
13.07	Adequate Facilities, trained personnel, and approved procedures shall be available for sampling, inspecting and testing of raw materials, packaging material, intermediate, bulk and finished substances.		Yes
13.08	Laboratory equipment used to perform cGMP operations should be qualified, calibrated, and maintained in a controlled state.		Yes

Akum Drugs & Pharmaceuticals Ltd. Haridwar (U.K.)

For Dey's Medical Stores (Manufacturing) Ltd

GAUTAM DEY
Managing Director

S. No.	Responsibilities	B	M
14.	**Stability**		
14.01	Maintain a documented, ongoing stability program to monitor the stability of the Product using stability indicating procedures. Execute stability studies per applicable protocol requirements.		Yes
14.02	Store stability samples in market containers in appropriate chambers as per International Conference on Harmonization storage conditions.		Yes
14.03	Upon request, provide approved stability protocols and stability reports to Dey's Medical Stores (Manufacturing) Ltd.		Yes
15.	**Storage and Distribution**		
15.01	Validate/qualify and maintain storage facilities appropriate for conditions specified on the Product label. Maintain records of any critical parameters.		Yes
15.02	In the event of an environmental excursion-affecting Product, notify Dey's Medical within three (3) business days and make subsequent investigation available to Dey's Medical upon request.		Yes
15.03	Have a system in place for assuring unreleased Product is not shipped unless authorized by Dey's Medical quality unit.	Yes	Yes
15.04	Ensure adequate labeling on each pack and pallet as per shared Product Packaging specification/ Artwork by Dey's Medical Stores (Manufacturing) Ltd.		Yes
16.	**Complaints**		
16.01	Have written procedures in place to document, investigate and manage all product quality related complaints and communication of complaints as established.	Yes	Yes
16.02	Dey's Medical shall notify Manufacturer of Product complaints, if received by Dey's Medical	Yes	
16.03	Provide final investigation report to Dey's Medical within 30 calendar days. Complaints related to death, injury, or safety hazard are reviewed within one (1) business day. Medical adverse complaints must be reviewed with three (3) business days.		Yes
17.	**Product Recalls/Withdrawals**		
17.01	Have written procedures in place to document, investigate, recalls and withdrawals.	Yes	Yes
17.02	Dey's Medical shall advise Manufacturer in writing of any defect that Dey's Medical would likely implement recall/withdrawal in the event a single defective unit was found in the field.	Yes	
18.	**Finished Product Release**		
18.01	Identify and ensure deviations from approved instructions are resolved.		Yes
18.02	Issue Certificate of Analysis (COA) and Certificate of Conformance (COC) upon release of product.		Yes
18.03	Release product for distribution.	Yes	

Akums Drugs & Pharmaceuticals Ltd. Haridwar (U.K.)

For Dey's Medical Stores (Manufacturing) Ltd

GAUTAM DEY
Managing Director

S. No.	Responsibilities Drug and Cosmetic Act Compliance Requirement	B	M
19.			
19.01	The Manufacturer should meet the obligation of applicable requirements under Drug and Cosmetic Act.		Yes

APPROVALS

IN WITNESS WHEREOF, the parties hereto have executed this Quality Agreement as of the effective date set forth above by their duly authorized officers.

Acknowledged, Accepted and Agreed to by:

FOR DEY'S MEDICAL STORES (MANUFACTURING) LTD.				
Name: MR. GAUTAM DEY. Designation: Managing Director	Signature:		Date:	01.11.23
FOR AKUMS DRUGS & PHARMACEUTICALS LTD.				
Name: Mr. Rajeswar Devulapalli Designation: President - CQA	Signature:	For: (JUGAL K. RATHMANSHI)	Date:	11.12.23

APPENDIX 1:

(This form shall be amended as new Products are added or removed)

The following Product(s) is (are) are currently or will be processed for Dey's Medical Stores (Manufacturing) Ltd:

BRAND DETAILS				
SR.NO.	Brand Name	Composition	Pack Size	Count/Pack
1	ChloMetrol	Chlorhexidine Gluconate Solution I.P. Eq. to Chlorhexidine Gluconate 1%w/w Metronidazole Benzoate I.P. Eq. to Metronidazole 1%w/w Lignocaine Hydrochloride I.P. 2% w/w In Mentholated gel base	Saleable-30gm Sample-30gm	Tube- Aluminium Tube Board-Duplex, Board Quality-280 GSM ITC safire White Board, Printing-Offsetwith UV coated. Coating: UV with both spot and Matt Varnish Size- L-130mm x W-30mm x H- 35mm

Akums Drugs & Pharmaceuticals Ltd. Haridwar (U.K.)

For Dey's Medical Stores (Manufacturing) Ltd

GAUTAM DEY
Managing Director

2	Tricilone	Triamcinolone Acetonide I.P. 0.1%w/w Oromucosal Paste q.s Preservatives: Methyl Paraben IP 0.09%w/w Propyl Paraben IP 0.01%w/w	Saleable-15gm Sample-5gm	Tube- Lami Tube Board-Duplex, Board Quality-280 GSM ITC safire White Board, Printing-Offsetwith UV coated. Coating: UV with both spot and Matt Varnish. Size-Saleable (15gm)- L-115mm x W-22mm x H-30mm . Sample (5gm) - L-90mm x W- 20mm x H-25mm.
3	Hexide -Plus	Chlorhexidine Gluconate soln. I.P. Diluted to Chlorhexidine Gluconate 0.2%w/v Sodium Fluoride I.P. 0.05%w/v Zinc Chloride I.P. 0.09%w/v In a pleasant flavoured aqueous base Colour: Fast Green FCF	Saleable- 150ml Sample-50ml	Bottle- PET screw cap Dosing mouthwash bottle,(High quality plastic bottle) Label- according to the diameter of the bottle
4	Amovac	Each film coated tablet contains: Amoxycillin Trihydrate I.P. Eq. to Amoxycillin 500mg Potassium Clavulanate Diluted I.P. Eq. to Clavulanic Acid 125mg Colour Titanium Dioxide I.P.	Saleable- 3x10's Sample-2's in monocarton	Board-Duplex,Board Quality-280 GSM ITC safire White Board, Printing-Offsetwith UV coated. Coating: UV with both spot and Matt Varnish
5	NaHL	Sodium Hyaluronate B.P. 0.1%w/v Stabilized Oxychlorocomplex 0.01%w/v (As Preservative) Sterile aqueous buffered Vehicle q.s. With Sodium Carboxy methylcellulose I.P., Glycerine I.P., Boric acid I.P., Calcium chloride I.P., Erythritol USNF., Levocarnitine I.P., Potassium Chloride I.P., Borax B.P. & Sodium Citrate I.P.	Saleable- 10ml Sample-10ml	Bottle-10ml-3 pcs pack (Material LDPE-low-density polyethylene)Teal Green Bottle Carton- Board-Duplex,Board Quality-280 GSM ITC safire White Board, Printing-Offsetwith UV coated. Coating: UV with both spot and Matt Varnish Size: L-40mmX B-30mmXH-80mm Label-As per diameter of the bottle

8/11/23

Akums Drugs & Pharmaceuticals Ltd. Haridwar (U.K.)

For Dey's Medical Stores (Manufacturing) Ltd

GAUTAM DEY
Managing Director

9 6 08/12/23	Moxitone	Each ml contains : Moxifloxacin Hydrochloride I.P. Eq. to Moxifloxacin 0.5%w/v Sterile aqueous vehicle q.s. Product is a self-preserved	Saleable-5ml Sample-5ml	Bottle-5ml-3 pcs pack (Material LDPE-low-density polyethylene)White colour Bottle Carton- Board-Duplex,Board Quality-280 GSM ITC safire White Board, Printing-Offsetwith UV coated. Coating: UV with both spot and Matt Varnish Size: L32mmXB32mmXH70 mm Label-As per diameter of the bottle

APPENDIX 2
(List of Contact Persons)

FUNCTIONAL AREA	DEY'S MEDICAL	AKUMS DRUGS & PHARMACEUTICALS LTD.
Quality Assurance	NAME: SANTANU ROY TITLE: Deputy Manager (QA) PHONE: 9830430983 EMAIL: santanuroy@deysmedical.com	Name: Mr. Rajeswar Devulapalli Title: President - CQA Phone: +91-8859000237 Email: rajeswar.devulapalli@akums.in
Coordinator at Kolkata	Name: UTPAL DUTTA Title: Manager Accounts Phone: 9830466854 Email: utpaldutta@deysmedical.com	Name: Mr. Allen Das Title: GM – Business Development Phone: +91-9560257111 Email: allen.dass@akums.net
Coordinator at Delhi	Name: JYOTIRMOY BHATTACHARYA Title: Assistant General Manager (Corporate Affairs) Phone: 9811381815 Email: jyotirmoybhattacharya@deysmedical.com	Name: Mr. Satya Prakash Title: AVP – Business Assurance Phone: +91-8859004207 Email: satyaprakash@akums.in

Akums Drugs & Pharmaceuticals Ltd. Haridwar (U.K.)

For Dey's Medical Stores (Manufacturing) Ltd

GAUTAM DEY
Managing Director