POLICY ON INSPECTION MANAGEMENT

INTRODUCTION:

This document provides a policy for management of inspections conducted by International Regulatory Authorities / Customers.

SCOPE:
This Policy is applicable to all the Inspections conducted by International regulatory authorities/ Customers at ……. and its associated units.

POLICY DETAILS:

- ✧ There shall be written procedure for management of inspections conducted by Regulatory Authorities/ Customer.
- ✧ There shall be appropriate systems in place for communication, co-ordination and confirmation of scheduled inspections within the organization and to the regulatory authorities/ customers.
- ✧ Site Management shall be responsible for managing inspections. Responsible staff shall be present on the scheduled date of inspection.
- ✧ Queries/questions of inspector(s) shall be addressed by concerned personnel.
- ✧ Any information or documents requested by inspector(s) shall be made accessible in time. The Confidentiality of the documents/information shared shall be maintained.
- ✧ Any circumstances constituting delay, denial, or limiting inspection, or refusing to permit entry or inspection shall only be allowed with appropriate justification.
- ✧ Quality Assurance shall ensure that all the requirements during the audit/post audit are complied.
- ✧ The response to non-compliances observed by the Inspector(s) shall be addressed within the stipulated time frame.

AMENDMENT AND WAIVER:

The company reserves the right to amend, alter and/or terminate this policy at any time.

DEFINITION: Not applicable.

ABBREVIATIONS:
USFDA: United States Food and Drug Administration

REFERENCES:
USFDA Guidance for Circumstances that constitute delaying, denying, limiting, or refusing a drug inspection.