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Revision:00

PURCHASING POLICY

1. Purpose

This policy defines the organization's requirements for purchasing to ensure that all materials, equipment, and services used in API manufacturing are procured in a controlled, transparent, and compliant manner to maintain product quality, safety, and regulatory compliance.

2. Scope

This policy applies to the purchase of:

- Raw materials
- Intermediates
- Packaging materials
- Laboratory chemicals and consumables
- · Production equipment and spare parts
- Contract services (testing, calibration, etc.)
- · General items required for operations

3. Vendor Approval Requirement (Strict Enforcement)

- All suppliers shall be approved before any procurement activity.
- Vendor approval is mandatory for procurement of:
 - o APIs
 - Raw materials
 - Solvents
 - Critical items impacting product quality
- Procurement from non-approved vendors is strictly prohibited.
- Any emergency exception shall require prior written approval from Department head and Management.
- Any unauthorized purchase from a non-approved vendor shall be treated as a major policy violation.

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4. Vendor Qualification Criteria

Vendor approval shall be based on:

- Submission of basic credentials (GST, PAN, drug license, as applicable)
- Quality evaluation (Certificate of Analysis review, audits where required)
- Compliance with applicable GMP and regulatory requirements

5. Purchase Indent (PI) Control

- The user department shall raise a Purchase Indent (PI) specifying:
 - Quantity
 - o Material/service specification
 - Urgency
- · The PI must be approved by:
 - Department Head
 - Purchase
 - Management
 - Finance

6. Purchasing Process

- A minimum of 2–3 supplier quotations shall be obtained for competitive evaluation.
- Suppliers shall be evaluated based on:
 - Quality
 - o Price
 - Delivery timelines
 - Past performance
- A formal Purchase Order (PO) shall be issued containing:
 - Material specifications
 - o Quantity
 - o Rate
 - Delivery terms
 - Payment terms

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7. Quality Requirements for Purchased Materials

- All incoming materials must be accompanied by:
 - Certificate of Analysis (CoA)
 - Batch details
 - Regulatory compliance documents, where applicable
- All materials shall undergo Quality Control (QC) testing prior to use.
- Only QA-released materials shall be permitted for manufacturing.

8. Delivery & Inspection

- The Store Department shall verify:
 - o Physical condition of packaging
 - Correct quantity
 - Correct batch numbers
- Any damage, shortage, or deviation shall be immediately reported to:
 - Quality Assurance
 - The concerned supplier

9. Record Keeping

The following records shall be maintained:

- Purchase Indent
- Purchase Orders
- Invoices
- · Certificates of Analysis
- QC test reports
- Vendor approval and audit records

All records shall be traceable, controlled, and readily retrievable for regulatory inspections.

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10. Re-Evaluation of Vendors

- Vendors supplying critical materials shall be reviewed annually based on:
 - Quality performance
 - o On-time delivery performance
 - Complaint history

11. Ethical Procurement & Legal Compliance

- · All procurement activities shall be conducted with:
 - Integrity
 - Transparency
 - Fair competition
- Employees involved in purchasing shall:
 - Avoid conflicts of interest
 - o Not accept bribes, gifts, or inducements
- Any unethical procurement practice shall invite disciplinary action as per company policy.

12. Training & Awareness

- · All personnel involved in:
 - Purchasing
 - o Quality
 - Stores
 - o Finance shall be trained on this Purchasing Policy.
- Refresher training shall be conducted upon:
 - Policy revision
 - Major process changes
- Training records shall be maintained.

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13. Compliance

All purchasing activities shall comply with:

- WHO, GMP guidelines
- · Applicable local regulatory requirements
- Company internal quality policies

14. Policy Review & Revision Control

This policy shall be reviewed:

- o At least once every year, or
- Upon regulatory or business change
- All revisions shall be:
 - Documented
 - Version controlled
 - Approved by Top Management
- Only the current approved version shall be in use.

15. Management Responsibility

Top Management is responsible for ensuring:

- Effective implementation of this policy
- · Availability of required resources
- Ongoing compliance with regulatory and quality requirements

Date: 11/12/2025.

Authorized Signatory (President – Operation)