Excipient Sourcing

Supplier Verification & Risk Management

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Excipient(s) ??

- Excipients are ingredients used to compound a drug (API) into a drug product.
- Majorly Excipients are Pharmacologically inactive but **Pharmaceutically active**.
- In any Marketed product, Excipient(s) amount will be 0.1% to 99.9% !

"Quality excipient sourcing is crucial in product performance and patient safety."

How to identify appropriate Excipient Supplies ??

- Globally many companies involved in the Mfg of Excipients.
- Depending on the target market, select excipient complying to specific compendium (IP, EP, USP, JP etc).
- Exercise due-diligence in COST Vs QUALITY metric.

"Product Performance Failure (& OR) Patient Death is because of PREFERENTIAL WEIGHTAGE in above metric."

Excipient Supplies – Steps in Verification & Risk Management

1st Step - Contact

- Company Name
- Mfg Address, Headquarter Address
- Phone no & Email.
- Organization Chart
- Workforce no's & Job function
- Quality, Technical & Regulatory Person(s) & Contact Details
- Supply Chain Details & Contacts

Excipient Supplies – Steps in Verification & Risk Management

2nd Step – Regulatory

- Environment, Health & Safety Certification
- National Regulatory Compliance & Certification
- International Regulatory Compliance & Certification
- Quality Policy
- Drug Master Files
- International Organization for Standardization Certification
- Up-to-Date Regulatory Audit(s) & Outcome

Excipient Supplies – Steps in Verification & Risk Management

3rd Step – Quality

- Quality Management System
- Quality Risk Assessment System
- Quality Risk Management System
- How Batch Quality Determined (Specification & STP)
- Batch Numbering System
- Record for Mfg & Testing
- Sampling & Retentions
- Shelf Life & Expiry Dating Policy

Excipient Supplies – Steps in Verification & Risk Management

4th Step – Incoming Goods

- List of Approved Suppliers
- Documentation procedure for Approved Suppliers
- Auditing of Suppliers
- Supply chain of Incoming goods
- Supplier Monitoring / Review System
- Sampling, Inspection, Testing & Methods
- Sampling & Testing – Plan and Frequency
- Purchase Specifications

Excipient Supplies – Steps in Verification & Risk Management

5th Step – Inventory / Storing Practices

- Storage facility – Owned / Contracted
- Material Management System
- Material Status Controls (Approved, Under Test, Sampled, Rejected)
- Sampling Area Availability
- Container Identification System
- WH Work Principle – FIFO or FEFO
- Shelf-life / Expiration dating & Ageing stock identification
- Is WH is temperature controlled & monitored

Excipient Supplies – Steps in Verification & Risk Management

6th Step – Production

- Production process in how many sites
- Procedure for review of batch records, yield limit & reprocessing steps??
- System for non-conformity & deviation control
- Critical process validation, in-process monitoring system
- Process instruction, Cleaning instruction & record, Area Clearance
- Cleaning process validation
- Shelf-life / Expiration dating & Ageing stock identification
- Calibration & Validation of Instrument & Equipment

Excipient Supplies – Steps in Verification & Risk Management

7th Step – Packing

- Production operation segregated from Mfg
- Area labeled with product being packed
- Re-usable container usage
- Cleaning procedure in-place
- Label reconciliation & Label disposable procedure
- Cleaning process validation
- Pack integrity testing
- Calibration & Validation of Instrument & Equipment

Excipient Supplies – Steps in Verification & Risk Management

8th Step – Computerized System

- Validation Master Plan & Software enablement
- Quality system coverage for computer & software
- System in-place for Recovery, Restoration & Archival of data
- Security levels in-place for computer & software
- Validation programme for computer & software
- Anti-virus protection for computer & software
- Change control procedure for computer & software

Excipient Supplies – Steps in Verification & Risk Management

9th Step – Lab Procedures & System

- Equipment & Instrument Usage Log
- All instruments & equipments qualified (IQ, OQ & PQ)
- Preventive Maintenance Programme
- Sampling plan, method, testing, control, investigation etc
- Review system in-place
- Stability testing procedures, protocol & summary
- Annual product review procedure

Excipient Supplies – Steps in Verification & Risk Management

10th Step – Post-Marketing / Distribution Practices

- Client notification on significant change before implementation
- Market complaint procedure
- Market recall procedure
- Handling of complaints & recalls.
- Reprocessing strategy for recalled and complaints
- Document retention period & strategy
- Internal audit programme

Excipient Supplies – Steps in Verification & Risk Management

11th Step – Social Responsibility

- Conflict of interest if any in operation
- Grievances with Govt norms
- Labour law compliance

12th Step – Facilities & House Keeping

- Health & Hygiene practices in-place
- Access restriction in-place
- Containment Zones
- Waste Disposal System in-place

Excipient Supplies – Steps in Verification & Risk Management

13th Step – Training

- Training Matrix & Frequency
- On-Job training evaluation procedures
- Maintenance of training records of employees

14th Step – Compliance Standards

- Certificate of Analysis
- Open Part of Drug Master File for Review
- Pharmacopoeia Compliance
- Specification, Method of Analysis

Excipient Supplies – Steps in Verification & Risk Management

14th Step – Compliance Standards Cont'd

- Material Safety Data Sheets
- TSE / BSE Compliance
- Residual Solvent Compliance (ICH Q3C)
- Elemental Impurity Statement (ICH Q3D)
- Nitrosamine Statement
- Ethylene Oxide / Propylene Oxide in Product
- Gamma irradiated ?
- Biocide Usage / Presence
- Preservatives Usage
- Phthalate Statement
- Carcinogen / Mutagen / Toxic for reproduction (SVHC Statement)

Excipient Supplies – Steps in Verification & Risk Management

14th Step – Compliance Standards Cont'd

- Suitability for Vegetarian, Lacto-Ovo-Vegetarian, Lacto-Vegetarian, Vegan, Diabetics, Coeilacs.
- Kosher certificate
- Halal certificate
- Absence of Nanomaterial (Nanotechnology-Absence)
- Absence of Latex (CIS-1,4-Poly Isoprene)
- Absence of Melamine (MilK & Rice derivation & no RM's from China)
- GMO Statement (No genetically modified organism used)
- Statement of material free from minerals of Central Africa
- Absence of Palm oil or its derivatives
- GMP / GDP Certification

Summary

Before sourcing any excipient(s), if due-diligence was followed in collecting all the relevant information listed above – then – as a drug product manufacturer **we can guarantee the quality of drug product as well as we can ensure the patient safety and product efficacy**.

THANKS FOR YOUR TIME & ATTENTION