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| **1) GENERAL INFORMATION** |  | **Date:** |  |
| Objective |  | | |
| Company Name |  | | |
| Supplier |  | | |
| Supplier Category - Manufactures / Distributers |  | | |
| Statutory License details |  | | |
| Address |  | | |
| Phone No. |  | | |
| Fax |  | | |
| Email |  | | |
| Total No. of Persons Employed |  | | |
| No. of Shifts |  | | |
| No. of Shifts / Person |  | | |
| Auditor Name |  | | |
| Date of Audit |  | | |

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| **2.MANAGEMENT** | |
|
| Name of the key person Audited |  |
| Position |  |
| Signature |  |
| Type of Products Manufactured |  |
| Details |  |
| Is Supplier Registration done? Is it current? |  |
| Major Customer Details |  |
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| **3. INFRASTRUCTURE** | |
|
| Installed capacity Details |  |
| Plant & Machinery Details |  |

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| **4) MANAGEMENT FOR QUALITY** | **YES** | **NO** | **COMMENTS** |
| Does the company have a documented procedure for their work instructions? |  |  |  |
| Do they follow GMP? |  |  |  |
| Do they have any Policy/Objectives? |  |  |  |
| Define their manufacturing process. |  |  |  |

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| **5) CONTROL OF SPECIFICATIONS** | **YES** | **NO** | **COMMENTS** |
| Is there any system followed to control their drawings/specifications? |  |  |  |
| Do they have our Specifications and Test methods? |  |  |  |
| How do they control the Specifications/Drawings provided by the Customers? |  |  |  |
| Do they have any procedure for customer property handling? |  |  |  |

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| **6) CONTROL OF PROCUREMENT** | **YES** | **NO** | **COMMENTS** |
| What are their raw materials? |  |  |  |
| Who are their Suppliers? |  |  |  |
| Do they have any suppliers list? |  |  |  |
| Is there any raw material rejected for Quality Issues? |  |  |  |
| Is there any Corrective action available for the raw material rejections? |  |  |  |
| Define their Quality Checks? |  |  |  |
| Are the personnel competent for carrying out the work? |  |  |  |
| Do they have adequate resource available for the Testing? |  |  |  |
| Details of the measuring Equipment’s available |  |  |  |
| Do they calibrate the Equipment’s? |  |  |  |
| Is the status of the Equipment been displayed? |  |  |  |
| Is the Equipment’s are identified properly? |  |  |  |
| Do they maintain records for the Calibration? |  |  |  |

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| **7) BATCH CONTROL** | **YES** | **NO** | **COMMENTS** |
| How do they give the batch no for their products? |  |  |  |
| What is their batch coding system? |  |  |  |
| Do they have any adequate traceability? |  |  |  |
| Do they give any certificate of analysis to their customers? |  |  |  |
| How do they control the labelling on the Finished Products? |  |  |  |

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| **8) CONTROL OF PROCESS** | **YES** | **NO** | **COMMENTS** |
| Is it adequate? |  |  |  |
| Is there any Documented Procedure available for the inspections? |  |  |  |
| Do they maintain records for the inspections? |  |  |  |
| How do they control their process? |  |  |  |

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| **9) IDENTIFICATION AND TEST STATUS** | **YES** | **NO** | **COMMENTS** | | | |
| Do they identify the status of the products at each stage of manufacturing? |  |  |  | | | |
| Is it adequate to control the mix-up? |  |  |  |  |  |  |

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| **10) CONTAMINATION CONTROL** | **YES** | **NO** | **COMMENTS** |
| Is there any specific or special condition provided by the customer which will have an adverse effect on the quality of the product? |  |  |  |
| How it is controlled? |  |  |  |

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| **11) CONTROL OF RECORDS** | **YES** | **NO** | **COMMENTS** | | | |
| Do they maintain any records at each stage of their manufacturing? |  |  |  | | | |
| How long they retain the records? |  |  |  |  |  |  |
| Are they easily traceable? |  |  |  |  |  |  |
| Do they maintain adequate Inspection Test Record/Files? |  |  |  |  |  |  |
| Are they up to date? |  |  |  |  |  |  |

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| **12) CONTROL OF FINISHED GOODS** | **YES** | **NO** | **COMMENTS** |
| Do they have any Testing for the Finished Goods? |  |  |  |
| Do they follow any Sampling Plans? |  |  |  |
| Is every batch of Finished Goods are tested as per our specification? |  |  |  |
| Do they retain any Finished Goods samples (Stock Control Samples)? |  |  |  |
| For how many years they retain? |  |  |  |

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| **13) TRAINING** | **YES** | **NO** | **COMMENTS** |
| Are the personnel are trained? |  |  |  |
| Is the training effective? |  |  |  |
| Do they maintain the records? |  |  |  |

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| **14) CONTROL OF NON-CONFORMANCE** | **YES** | **NO** | **COMMENTS** | | | |
| Is there a proper identification for the non-conforming material? |  |  |  | | | |
| Do the carry out any investigation for the non-conforming materials? |  |  |  | | | |
| How do they dispose the non-conforming materials? |  |  |  |  |  |  | |
| Is there any record available? |  |  |  |  |  |  | |

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| **15) CORRECTIVE AND PREVENTIVE ACTIONS** | **YES** | **NO** | **COMMENTS** |
| Is any corrective and preventive action taken for rejections? |  |  |  |
| How do they handle complaints from their customers? |  |  |  |
| Do they maintain any record for the complaints? |  |  |  |
| Is the corrective action taken are effective? |  |  |  |
| How do they communicate the corrective actions to the customers? |  |  |  |
| Is there any feedback system available from their customers? |  |  |  |
| How do they communicate any change in their process or suggestions to the customers? |  |  |  |

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| **16) HANDLING AND STORAGE** | **YES** | **NO** | **COMMENTS** | | | |
| How do they store the Finished Goods? |  |  |  |  |  |  |
| Any special storage condition is followed as per the customer’s specification? |  |  |  | | | |
| Is there any record available for this? |  |  |  |  |  |  |
| Do they assign the shelf life for the materials? |  |  |  |  |  |  |

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| **17) PACKAGING AND SHIPPING** | **YES** | **NO** | **COMMENTS** |
| Is there any legislative requirement required for the products for shipping? |  |  |  |
| What is there mode of shipping? |  |  |  |
| Do they follow any special packaging for the products to avoid damage during transit or as specified by the customer? |  |  |  |
| What control is followed at the time of shipping? |  |  |  |
| Hazardous/ Non-Hazardous |  |  |  |
| **Specific issues / Suggestions:** | | | |
| **Review and Comments of the Auditor: Date:** | | | |

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| **Supplier Authorized**  **Personnel Name** | **Designation** | **Signature** | **Date** |
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| **Name of the Auditor** | **Designation** | **Signature** | **Date** |
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| **Reviewed BY: Approved BY:**  **Purchase Head / QA MR** |