KANGOPAK

POUCH. Touch. Pause. Engage.

HAZARD ANALYSIS & RISK ASSESSMENT (HARA)

CONTENT PAGE

MULTI-DISCIPLINARY HARA TEAM

Name and Surname	Job title	Signature This signature serves as confirmation that this study has been Verified by the HARA team on line
CE Schlachter	Director	
ME Schlachter *	Operations Manager	
L Schlachter	Administration Manager	
Gabrielle Gant	Commercial Manager	

***HARA Team Leader**

CONTRIBUTIONS AND EXPERTISE EACH TEAM MEMBER BRINGS TO THE RISK TEAM

CE Schlachter	• 37 years in manufacturing environment. • Exposure to Management Systems i.e. ISO 9000, ISO 14000, ISO 18000, TS16949. • Good relation skills • Human Resources background. • HACCP Training received • 10 years' experience in the packaging industry • Formal Root Cause Analysis Training
ME Schlachter*	• Raw material procurements, • Technical aspects relating to the product, • Quality issues that may affect the product • Production Process. • Systematic • Financial background. • Formal HACCP training received • 12 years' experience in the packaging industry • Formal training on BRC Global Standard for Packaging and Packaging Material • Formal Root Cause Analysis Training • Strong hands-on Team in the Factory environment.
L Schlachter	• Very systematic • Detail focus • Computer Literate. • Managing logistic and services agreement • Formal HACCP training received • 12 years' experience in the packaging industry
G Gant	• Qualified Charted Accountant having extensive experience in a financial audit environment and different industry sectors. • Very systematic • Detail focus • Computer Literate • Planning Process • Performs traceability of raw material and finished goods function. • Formal HACCP training received • 7 years' experience in the packaging industry • Formal training on BRC Global Standard for Packaging and Packaging Material • Formal Root Cause Analysis Training

HARA STUDY PRODUCT DESCRIPTION

TERMS OF REFERENCE

Product Name / Study Title:

- Conversion of various flexible films into pouches, namely Stand-Up Pouches, Flat Pouches and Spouted Pouches.
- Slitting & Rewinding of various reels of Film for the eventual conversion into pouches.

Terms of Reference / Scope of Study:

Scope:

The conversion of printed and plain flexible laminates (PET/LLDPE, BO Nylon/LLDPE) and metallised plastic laminates (MET PET/LLDPE) into stand-up (doy-packs), folded gusseted, 3-side seal, quad seal and spout pouches for food, beverage, personal care and industrial applications.

Slitting and rewinding various raw material reels of film for the eventual use as raw material on the Pouch Making Machines as stated above.

Objective:

To ensure a multidisciplinary Hazard Analysis and Risk Assessment team is in place to develop and manage the hazard and risk analysis system and ensure this is fully implemented and evaluated for its effectiveness.

To implement and maintain a formal Hazard Analysis and Risk Assessment system to ensure that all hazards to product safety, quality and legality are identified and appropriate controls established.

Products:

- Stand-up pouches (doy-pouches)
- Flat pouches
- Spout pouches
- Quad seal pouches

Hazards considered:

- Microbiological Hazards
  - Hand Wash Basin at entrance of Factory.
  - Bacterial contamination risk from cooler bars leaking.
  - Water contamination from cooling system is considered as it is a closed cycle and the water may come into contact with the product if leaking due to being broken.
    - Planned Maintenance to prevent potential risk to Product Safety from any leaks at connections/fitting of pipes.
  -
  - Microbiological hazards that may impact product safety of raw materials of finished goods at the Slitting Department

- Foreign Objects;
  - Temporary modifications are considered where product safety and quality is at risk.
  - Foreign Body Contamination that may impact product safety of raw materials at the Slitting Department
  - The workshop is included in the Site Schematic and potential foreign body contamination is controlled by swarf mats and the workshop door being closed at all times. 'Clean as you go Policy in place'. Training given to employees.
  - Potential Risks introduced from the building structure are considered under foreign objects and preventative measures include Site Standard procedure, housekeeping and cleaning procedure as well as the storage procedure.
  - Malfunctioning equipment was considered as a risk however there are checks in place at required frequency during production of the products to ensure that equipment that may pose a risk to product safety and quality if this equipment malfunctions are identified and rectified. Preventive measures include process control, a maintenance procedure & a control of non-conforming procedure.
    - These include:
      Back Gusset Punch punching correctly
      Condition of Teflon.
      Condition of Rubber Draw Rollers
  - Core dust and debris from the core is considered a Foreign Body Hazard. Housekeeping and Cleaning in place. Clean as you go. Trained employees. Covered product in stores.

- Chemical Contamination:
  - Potential for unintended migration of substances from the packaging material into food or other hygiene sensitive products.
  - Chemical contamination risk from chiller bar leaking.
  - Chemical contamination risk that may impact product safety of raw materials of finished goods at the Slitting Department
  - Water contamination from cooling system is considered as it is a closed cycle and the water may come into contact with the product if leaking due to being broken.
    - Planned Maintenance to prevent potential risk to Product Safety from any leaks at connections/fitting of pipes.

- Quality:
  - Defects critical to consumer safety
  - Hazards that may have an impact on the functional integrity and performance of the final product in use.
  - Hazards that may impact quality of raw materials of finished goods of finished goods at the Slitting Department
  - Potential for malicious
  - Potential for fraud (e.g. substitution, adulteration or misrepresentation)
  - Foreseeable misuse by the consumer.
  - Potential for raw material fraud.
  - Bright lights above machinery to ensure proper visuals of products taken place. – Lights are covered.
  - Malfunctioning equipment was considered as a risk however there are checks in place at required frequency during production of the products to ensure that equipment that may pose a risk to product safety and quality if this equipment malfunctions are identified and rectified. Preventive measures include process control, a maintenance procedure & a control of non-conforming procedure.
    - These include:
      - Condition of Sealer Bars
      - Condition of Rubber Silicon Pads
      - Condition of Teflon.

- **Other Hazards and Information** :

  - Potential problems arising from the use of with recycled materials content are not considered as recycled materials are not used.
  - Legal criteria and Historical Hazards are addressed in the hazard categories depicted above.
  - The allergens that were only considered is allergens that may be present in the machine maintenance lubricants & cleaning products however no allergen is present as stated in declaration from Suppliers.
  - No Printing is done on site.
  - Based on the Hazard Analysis and Risk assessment (HARA) performed below, no in-line testing and measuring equipment was deemed necessary for the manufacture of products, as manual quality checks are performed off line mitigating the quality and product safety risks.
  - Subcontracting processes are not considered as there are no subcontracted processes.

Starting point:

- Supplier Approval

End Point:

- Customer Returns
-

Process Control

To ensure awareness of the potential for any aspect of the process to go out of control, and to have mitigating measures in place the following hazards are considered:

- Product quality defect
- Defects that may have an impact on the functional integrity and performance of the final product in use.
- Defects which result in the production of products which are outside customer-specified quality parameters.

PRODUCTS DESCRIPTIONS AND THEIR INTENDED USE.

End Product Characteristics:

- Sealed laminated PET film to LLDPE and/or laminated BO Nylon film to LLDPE varying in gauge pouches.
- Safe for the use in Food & Beverage, Industrial, Personal Care and Pharmaceutical industries.
- Utilised for liquid and dry products that may be sensitive to UV exposure.
- Re-sealable.
- Spout fitment.

Reasonably intended use of product:

- Packaging of liquid and dry products.
- Safe for the use in use in Food & Beverage, Industrial, Personal Care Pharmaceutical & Pet Care applications.

Defined restrictions on use:

- Product packed under high heat or steam conditions should be done so with caution.
- Product cannot be used to hold food during cooking.
- Product with high acidity should be monitored after packing.
- Products with MET PET construction is best suited for dry goods.
- Unprinted products should be utilized within one (1) year of receipt.
- Printed products should be utilized within six (6) months of receipt.
- Resealable Zipper cannot be used ultimately for sealing the product during distribution and retail phase. Heat seal must be applied above zipper.

Any unintended but reasonably expected mishandling and misuse of end product:

Misuse	Consequential Hazard / Quality/Process Defect	Preventive Measure
Incorrect storage	Permeability, Visual, Moisture vapour transfer rate, Integrity Functionality. Contaminated Product: Pest & Foreign Objects	Information included on the Pouch Specification form & COC. Product packed into liner before corrugate to reduce contamination. Palletised with Slip Sheet to ensure wood chips, dirt from ground and/or other foreign objects are not getting into product.
Incorrect application	Delamination, Permeability & Leaking	Information included on the Pouch Specification form & COC
Handling and transportation	Damaged product Contaminated product: Pest & Foreign Objects Leaking Product due to the utilisation of zipper as the final seal once product is packed.	Product packed into liner before corrugate. Palletised with Slip Sheet Pallet Wrapped with shrink Wrap. Vehicle Inspections done with own delivery vehicle & 3rd party transportation companies. (SLA in place) Adequate final seal to ensure no leaking through the zipper or otherwise in the trade.

Target group:

- Food & Beverage Industry
- Pharmaceutical Industry
- Cosmetics Industry
- Industrial Manufactures.
- Pet Industry – Petconomy

Type of Packaging:

- Plastic Liners
- Corrugate
- Self-Adhesive Tape (Buff Tape)
- Self-Adhesive Label
- Slip sheet
- Pallets

- Shrink Wrap
- Angle Board for Pallets, if applicable.

Shelf life, including storage temperature:

- Ideal Storage Conditions: 5 – 35 ºC
- Dry, enclosed environment.
- Unprinted Pouches should be utilized within one (1) year of receipt and printed pouches should be utilised within six (6) months of receipt.
- Printed products should be utilized within six (6) months of receipt.

Where will it be sold: i.e. retailing, further processing etc.

- Further processing
- Wholesaler
- Distributors

Labelling instructions:

- Customer
- Product Code
- Description
- Work Order Number
- Carton Number
- Carton Quantity
- Weight
- Operator/Packer Initial

Blue label – Intermediate Products (WIP)
Orange labels – Non-Standard Quantity
Red labels – Hold for Segregated Non-Conforming Product.

Special distribution control: i.e. Shipping conditions, Methods of Distribution

- Road transport (max. 1 pallet stacking)
- Hygienic
- Dry storage conditions
- Enclosed / protected
- Traceable (labelling)
- SLAs in place with 3rd party transport companies.

Traceability Sequence: Raw Material to finished Goods and vice versa e.g. Purchase Order No Batch No, Date code

- Raw Material Specifications (Material Data Sheets)
- Purchase Order / Slitting Patterns
- Supplier Delivery Note
- Supplier COC
- Supplier Reel Number/s
- Supplier Work Order Number/s
- Supplier Reel Weight
- Slitting Machine Work Order Number
    - Production Log Sheet (Slitting Machine)
    - Finished Reels (Raw Materials) number/s on labels (Slitting Machine)
- Pouch Makers Work Order Number
    - Production log sheet (Short Interval Control) (Pouch Makers)
    - Finished Product or Work in Process Carton number/s on labels.
- Spout Machines Work Order Number
    - Production Log Sheet (Spout inserter Machine)
    - Finished Goods Carton Number/s on Labels
- Return to Stores Labels with above details – Raw Material, WIP & Finished Goods.
- Picking Slips
- Delivery Note
- COC (if applicable to customer requirement)
- Tax Invoice
- Customer Delivery Note

Treatments and Processes Undertaken

Product scope: Laminated plastic pouches (stand-up/flat), with and without resealable zippers; optional spout and cap assembly. Laminate webs are printed by approved external printers (see Artwork/Print control). No post-consumer recycled content is used in finished products.

Process summary (in order).

1. **Artwork/Print approval:** Customer-approved artwork → printer “on-press approval” (OPA) and signed first-offs → printed laminate supplied to site.
2. **Incoming material receipt & ID:** Films, zippers, spouts/caps, carton liners received, labelled, and verified to spec before release.
3. **Slitting (where applicable):** Reels slit to width per Job Card.
4. **Pouch Making:** heat sealing, zipper application/seal, cosmetic features (punches) where specified.
5. **Process Control—short interval control: Pre-start checks, first-off samples each shift, short-interval control, and documented line clearance at startup and** completion.
    1. **Short Interval Controls:** As per Work Instruction for Quality Checks.
6. **Work-in-progress control:** Formed pouches held as WIP in **blue-label** cartons with full traceability.
7. **Spout inserting (MDB):** Spout placement and sealing to pre-formed pouches.
    1. **Short Interval Controls:** As per Work Instruction for Quality Checks
8. **Pack, label, and release:** Quantity Document, finished goods carton labels with WO and carton numbers, quantity, and packer initials; Certificate of Conformance issued where required.
9. **Storage & Distributioon:** Controlled storage; distribution per picking slip/delivery note; records retained.

Key treatments/controls by step.

Step	Treatment / Operation	Typical Controls & Records
Printing (Supplier)	Printed Pouch Checklist	Customer OPA sign-off & 1st-offs filed by printer; internal artwork pack with Job Card.
Slitting	Mechanical cutting to width	Slitting Job Card & Production Log Sheet; visual/measure checks
Pouch Making	Heat sealing (side/bottom), punching (euro slot/tear nick), zipper sealing	Job Card process specs; pre-start checks; **first-off**/retained samples; interval checks; Production Log Sheet
Spout inserting	Thermal sealing of spout fitment.	MDB Job Card & Log Sheet; **first-off**/retained samples; leak checks
Work-in-progress control: Formed pouches held as WIP in **blue-label** cartons with full traceability.	Water/submersion, template, zipper opening force (if specified)	Results on Production Log Sheet: non-conforming product handled per procedure
Line clearance	Physical removal/cleaning and verification at changeovers	Recorded on Production Log Sheet; supervisor sign-off before restart
Identification & traceability	Raw material → WIP (blue label) → finished goods carton labels → NC Product (RED label segregated)	Label controls; WO/carton numbers; Job Cards; Production Log Sheets; COC where applicable

Records used. Customer-approved artwork pack; Job Cards (pouch, MDB, slitting); Production Log Sheets; first-off/retained samples attached to Log Sheets; WIP blue-label cartons; finished goods carton labels; Certificates of Conformance (when required).

Rework. Any rework remains uniquely identifiable and traceable to the original batch and is processed under the same controls as above.

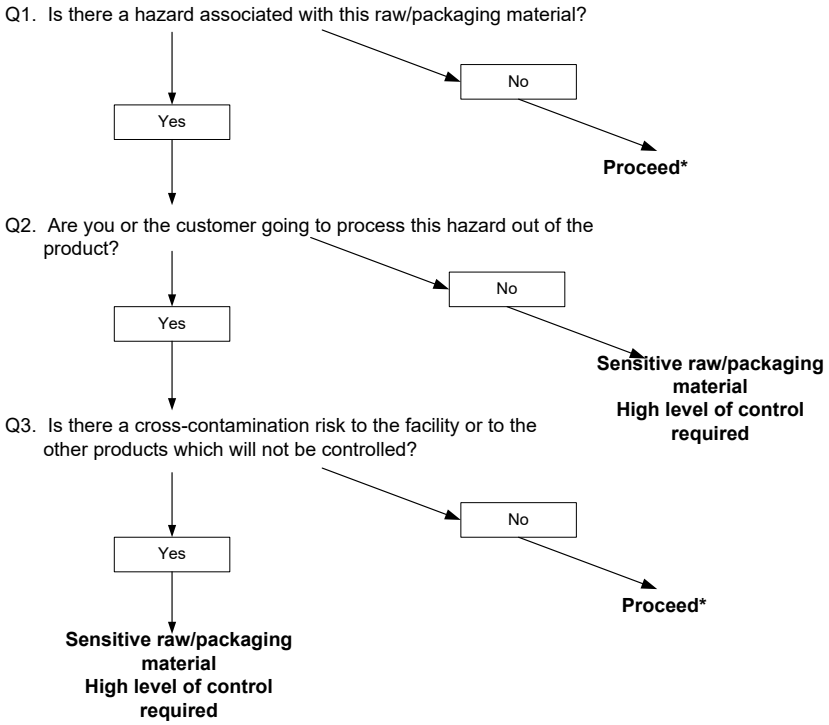
Verification. The HARA flow diagram includes the process flow and is verified during HARA review and internal audits (including annual traceability tests). Line clearance and first-off/interval checks verify that treatment parameters and product dimensions remain within specification.

Functional Properties — Cross-Variant Control (Applies to All SKUs)

Principle: Functional properties for every SKU are controlled by the **approved product specification** and, where applicable, customer-specific requirements. This HARA section defines the **common property set** and the **standard verification methods**. Numeric targets/tolerances are **not duplicated** here; they are taken from the current, approved specification for the variant or customer contract.

Functional property (all variants)	Why it matters (risk)	Acceptance source (per SKU)	Verification & frequency (standard)	Records
Barrier performance (e.g., OTR/WVTR) *(where specified)*	Shelf-life; oxidation/taint	Pouch specifications, supplier CoC/test data, customer spec	At material approval; periodic supplier data review; targeted third-party testing if required	Material approval pack; supplier CoC/test reports; HACCP/spec review notes
Seal integrity (side/bottom seams)	Leakage/contamination	Pouch specifications	First-off each run/shift; in-process interval checks; leak tests where specified	Production Log Sheet; first-off/retained samples; NC/CA records
Zipper function (opening/closing force) *(zipper SKUs only)*	Resealability & adhesion integrity	Pouch specifications	First-off; interval checks	Production Log Sheet; first-off samples
Spout seal integrity & cap fit *(spout SKUs only)*	Leakage; hygiene; safety	Pouch specifications / WI	First-off & interval leak checks; visual/fit/torque checks as specified	MDB Log Sheet; first-off/retained samples
Dimensions & feature positions (H, W, gusset; tear-nicks; euro slot; zipper set-back)	Fill volume, consumer use	Pouch specifications	First-off; interval checks; template/gauges	Production Log Sheet; first-off sample attached
Mechanical robustness *(if specified)*	Transit/handling damage	Pouch specifications or customer spec	As per spec/test plan (per batch/periodic)	Production Log Sheet; test reports
Material suitability/chemical compatibility	Swelling, delamination, taint	Pouch specifications; supplier declarations; legislation refs	Review at approval/change; application checks if needed	Material approval pack; DoC/CoC
Temperature constraints (filling/use/storage)	Seal creep; distortion	Pouch specifications	Pre-dispatch spec confirmation; customer brief	Pouch specifications; order confirmation
Migration/food-contact compliance	Legal compliance	Supplier DoC/CoC; 5.1F1	Doc review at approval and spec review	Compliance file; Pouch specifications
Taint/odour.	Sensory acceptability	Pouch specifications /material DoC	As application/customer requires; complaint trend review	Complaints Register; CAPA
Print/appearance *(printed SKUs)*	Branding; legibility, hidden allergens.	Artwork pack; printer OPA first-offs	Artwork approval; OPA sign-off; incoming visual	Artwork pack; printer 1st-offs
Packout/pallet stability	Damage in distribution	Pack method	Visual check at pack/dispatch	Dispatch checks; picking/dispatch records
Usable life of packaging	Performance over time	Pouch specifications	FIFO/FEFO; condition checks	Warehouse logs; Pouch specifications

SENSITIVE RAW MATERIAL DECISION TREE



*** Proceed to your next raw/packaging material**
**** This raw/packaging material should be managed as a SRM**

SENSITIVE RAW MATERIAL ANALYSIS

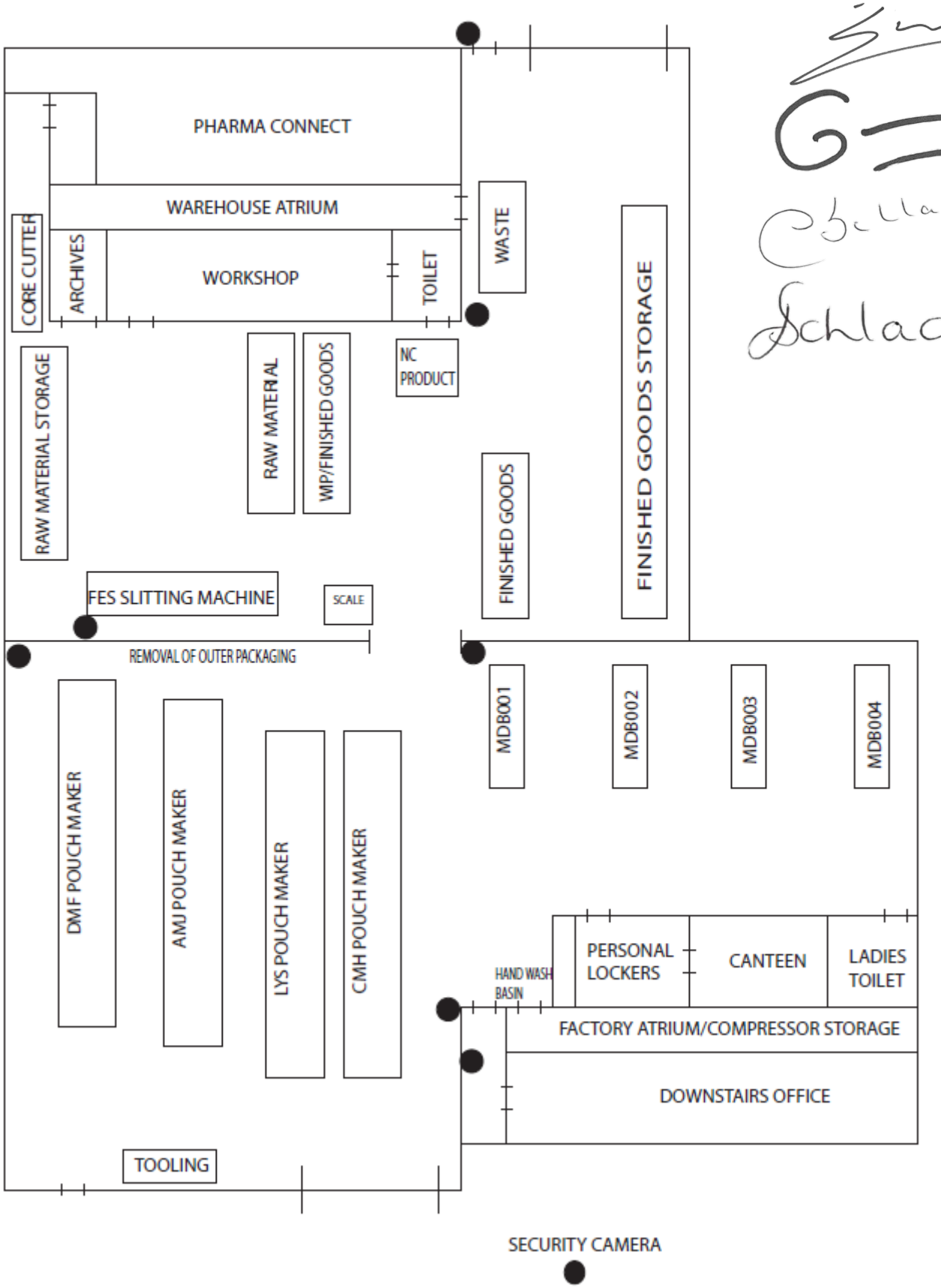
Raw Material / Packaging Material Description	**How is it packaged on arrival**	**Where does it come from**	**Key Specification requirements**	**Hazards / quality defects** that may be present in this raw material	**List Hazards** that may be present in this raw material	**Special storage conditions**	**Does this material contain any allergens?**	**Will the material deteriorate if not stored correctly?**	**Is the Material susceptible to Mycotoxins?**	**Is the Material susceptible to pathogens?**	**Q1**	**Q2**	**Q3**	**SRM (Sensitive Raw Material)**	**Remarks**
Film: Non-Trademarked Reel Stock. Film: Printed Trade Marked Reel Stock (See Raw Material Specification Register)	Shrink wrap / wrapped in clear poly and palletized, and cord strap with Slip Sheets	Refer to Supplier Risk Assessment.	Refer to Raw Material Data Sheets.	Microbiological	None	Slip Sheets utilised for storage & transportation of material. Poly Plank Pallets on site. Materials Stored in separate area, Raw Materials stores inside factory.	No	Yes	No	No	No	-	-	No	Supplier BRC/FDA certificated. Personnel hygiene policy in place at Supplier.
				Foreign Objects	Pests; wood chips from damaged pallets during transportation. Insects/Pests present in the material from production process of supplier. Loose blades/cutters from suppliers.						Yes	Yes	No	No	Supplier BRC/FDA certificated. Incoming Raw Material Inspection completed. Vehicle inspection taken place at raw material supplier.
				Chemical	Non- Food grade Inks for Printed Reel Stock Potential for unintended migration of substances into food or other hygiene sensitive product.						Yes	Yes	No	No	Supplier BRC/FDA certificated. Declaration from Supplier. Vehicle Inspection taken place at raw material supplier as seen on copy of supplier delivery note. Chemical contaminations not possible as chemicals are secure & isolated on site. Analysis of film & migration report from Supplier.

															Limitations of use on both Pouch Spec. Form and CoC
				Quality	Incorrect Specifications Trademark Infringements Hidden Allergens, Misleading Labels Ink Splash Delamination Clarity of Material Creases in material.						Yes	Yes	No	No	Supplier BRC/FDA certificated. CoC verification with delivery note & specifications. Customer signed Pouch Spec Form before placement of order for Raw Material. Customer signs off artwork proof before plates are made for printing. NCAs raised on Suppliers and for continuous improvements. Based on disposition on NCA will determined if NC Product is returned to Supplier.
Zipper	Liners & corrugated carton together with batch number and opening strength label	Refer to approved suppliers list	Refer to Raw Material specification register	Microbiological	None	No	No	No	No	No	No	-	-	-	None
				Foreign Objects	Splicing tape from zipper join may be present in box. Insects/Pests present in the material from production process of supplier.						Yes	Yes	No	No	Splicing tape used is coloured so that it can be noticed by operator at short interval control. Cartons are glued as staples are not permitted in factory.
				Chemical	None						No	-	-	-	No chemicals used in the manufacture of this product.
				Quality	Incorrect specification: Incorrect size & opening force supplied.						Yes	Yes	No	No	On placement of order size and strength is stated. Colour markings on cartons by supplier make easy identification for issue to production. COC received. NCAs raised on Suppliers and for continuous improvements. Based on disposition on NCA will determined if

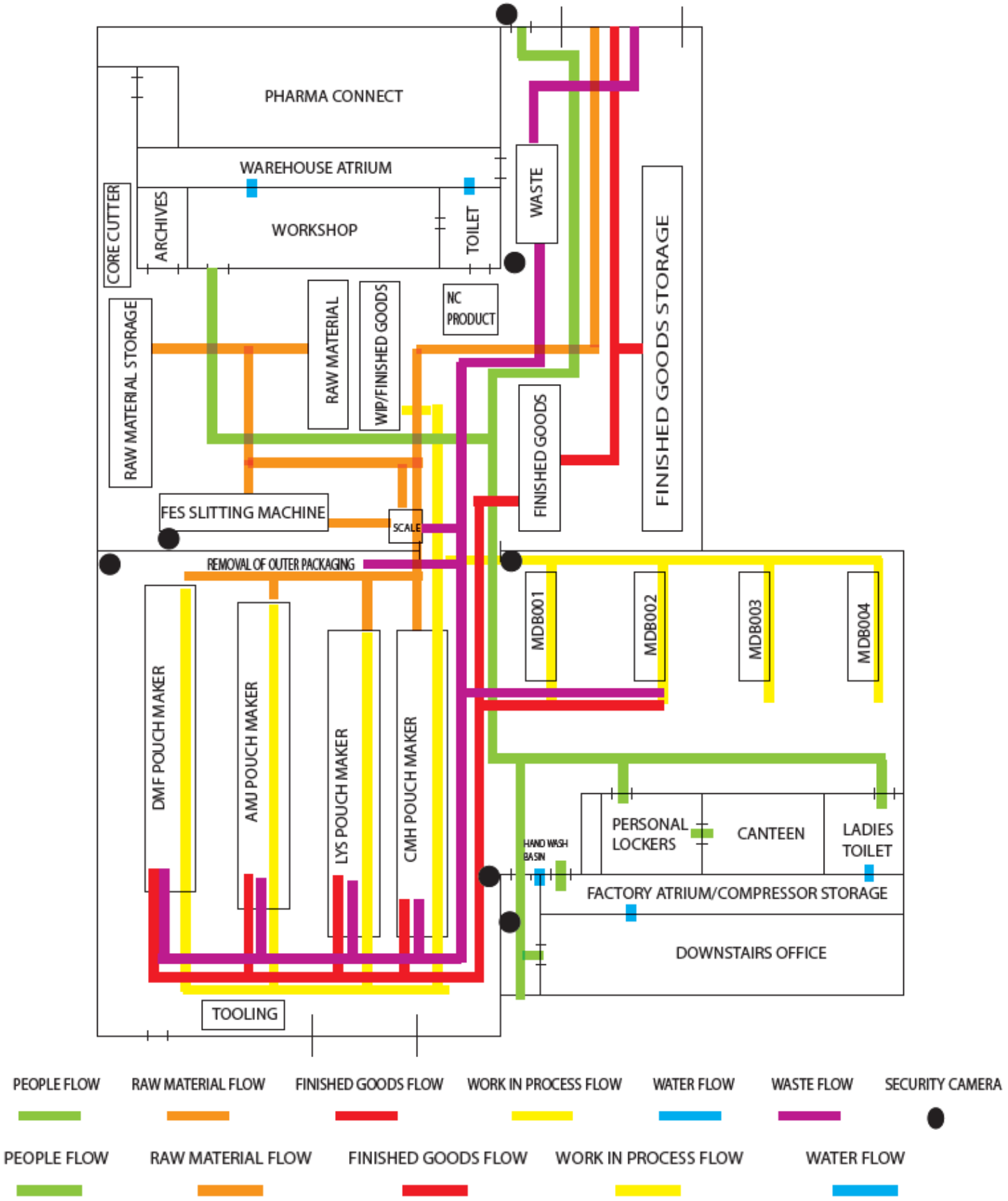
															NC Product is returned to Supplier
Spout & Cap	Liners & corrugated carton together with batch number	Refer to approved suppliers list	Refer to Raw Material specification register	Microbiological	None	No	No	No	No	No	No	-	-	-	None
				Foreign Objects	Pests; wood chips from damaged pallets during transportation. Insects/Pests present in the material from production process of supplier. Loose blades/cutters from suppliers.						Yes	Yes	No	No	Incoming Raw Material Inspection completed. Supplier certification.
				Chemical	None						No	-	-	-	
				Quality	Incorrect specification						Yes	Yes	No	No	Supplier certified. Product Specs in place. COC with each delivery Incoming inspection on each delivery, NCAs raised on Suppliers and for continuous improvements. Based on disposition on NCA will determined if NC Product is returned to Supplier
Virgin Blue Plastic liners	Wrapped in Poly with quantity label.	Refer to approved suppliers list	Refer to Raw Material specification register	Microbiological	None	No	No	No	No	No	No	-	-	No	None
				Foreign Objects	None						No	-	-	No	Visual Inspection at utilization of liner.
				Chemical	None						No	-	-	No	No Chemicals are used in production of liners.
				Quality	None						No	-	-	No	Declaration form Supplier. NCAs raised on Suppliers and for continuous improvements. Based on disposition on NCA will determined if NC Product is returned to Supplier

Splicing tape	Corrugated & shrink sealed	Refer to approved suppliers list	Refer to Raw Material specification register	Microbiological	None	No	No	No	No	No	No	-	-	No	Visual Inspections Non-Traceable Item
				Foreign Objects	None						No	-	-	No	
				Chemical	None						No	-	-	No	
				Quality	None						No	-	-	No	
Corrugated cartons	Palletized with cord strap.	Refer to approved suppliers list	Refer to Raw Material specification register	Microbiological	None	No	No	No	No	No	No	-	-	No	Visual Inspections Non-Traceable Item
				Foreign Objects	None						No	-	-	No	
				Chemical	None						No	-	-	No	
				Quality	None						No	-	-	No	
Pallet Wrap	Poly liners	Refer to approved suppliers list	Refer to Raw Material specification register	Microbiological	None	No	No	No	No	No	No	-	-	No	Visual Inspections Non-Traceable Item
				Foreign Objects	None						No	-	-	No	
				Chemical	None						No	-	-	No	
				Quality	None						No	-	-	No	

DOWNSTAIRS SITE SCHEMATIC



DOWNSTAIRS FLOW DIAGRAM



PEOPLE FLOW RAW MATERIAL FLOW FINISHED GOODS FLOW WORK IN PROCESS FLOW WATER FLOW

CONCLUSION:

Raw Material Flow: The raw material is stored in the warehouse, labelled, and covered with outer packaging. Slip sheets are used to prevent foreign bodies from contaminating the product. When practical, plastic pallets are utilised as much as possible. Raw Material that is “returned to stores” is covered with a blue liner, labelled with relevant traceability details, and stored back with other raw materials in the warehouse.

Drainage / Water Flow: There are no drains in the factory, only from ablutions to the outside. Any water that may spill onto the factory floor is cleaned up immediately as per the “Clean as you Go” Policy.

Water chiller units and water flow are closed systems. Maintenance is planned to prevent potential product safety risks from leaks at pipes, fittings, or connections.

Air Flow: The factory has no positive airflow, as all doors and windows are kept closed. However, “Whirly Birds” are situated on top of the roof for ventilation.

Finished Product Flow: When finished goods are packed from the production line into cartons, they are packed onto plastic pallets with slip sheets. Blue liners are utilised in the finished goods cartons to prevent contamination from chemicals, gas fumes from transport, pests, and/or dust. All finished goods are packed onto the finished goods shelving or palletised in the warehouse, ready for dispatch or storage.

WIP Flow: All WIP is palletised, covered where applicable, and stored in the warehouse. It is issued to production as and when needed. This WIP is identified with blue labels for easy segregation to prevent cross-contamination with finished goods.

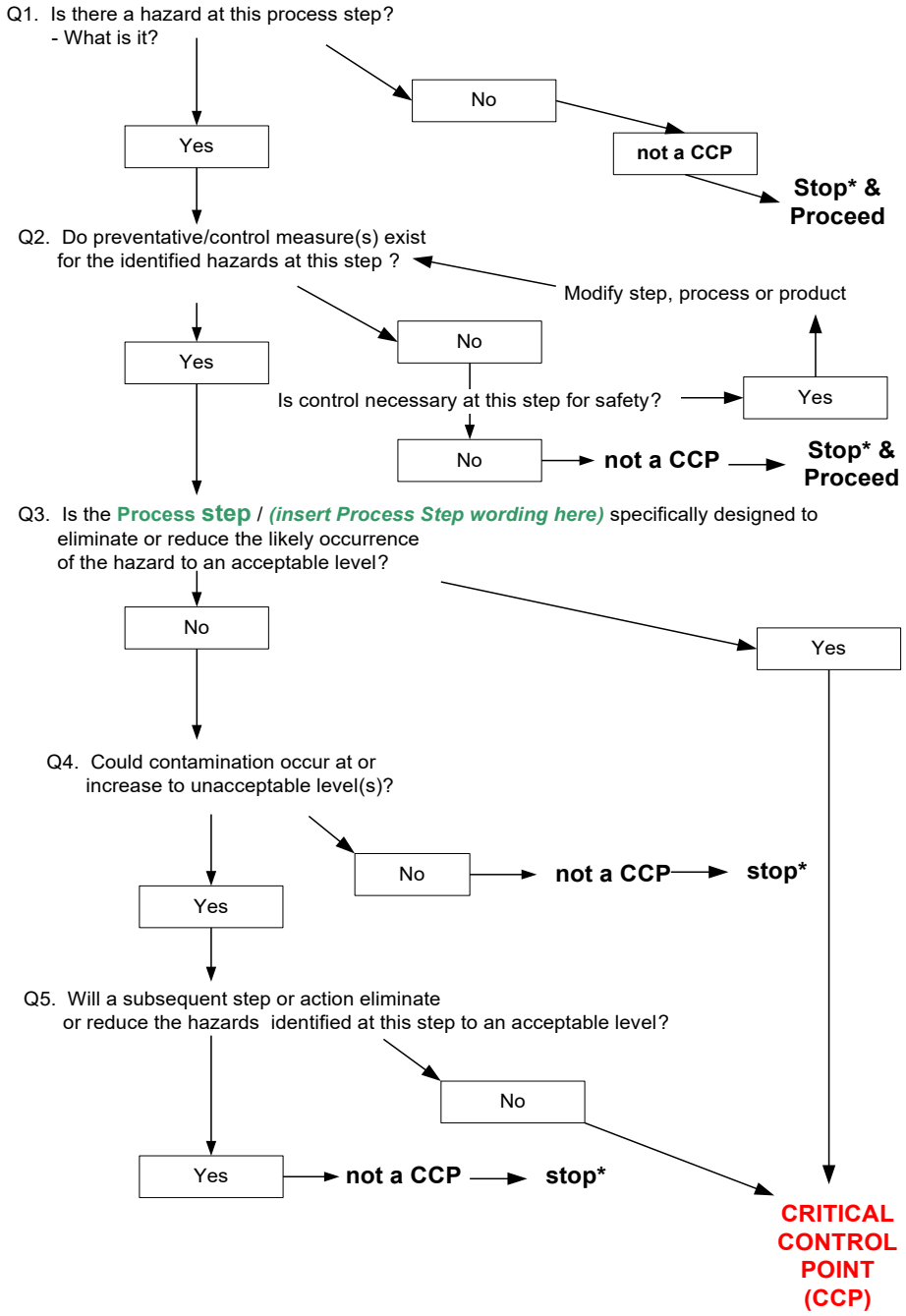
People flow: People must stay in demarcated areas identified by yellow markings on the factory floor. Unauthorised access is restricted.
Employees entering the factory for the start and end of their shifts must sanitise, keep on the walkway, and go straight up to change rooms to change into their PPE. Contractors and visitors are handled by a responsible person, who issues PPE after reporting to reception.

Waste Flow: Set-up production waste is cleared from machines before start-up, weighed, recorded on Production Log Sheets, and segregated for destruction and disposal.

Trademark waste is weighed and documented on the **Trademarked Waste Destruction & Disposal Record**. The weight is recorded once the waste is destroyed, and the destroyed waste is disposed of. This disposal is then logged in the **Trademarked Waste Destruction & Disposal Record**. The baling process is adhered to.

Punch-outs (including Back Gusset Punches, Euro Slots, Tear Nicks, and Cropped Round Corners) are stored in designated blue bins on the factory floor to minimise the number of trips to the skip and reduce the risk of environmental pollution.

CRITICAL CONTROL POINT DECISION TREE



*** Stop and proceed with the next hazard at the current step or the next step in the described process**

Step #	Process Activity - FLOW DIAGRAM	Process Variable	Product Attribute	Any Outsourced / subcontracted work	Raw Material Input	Rework Input	Waste Output
1	Supplier Approval	Price Quality Quantity	Product Specification (Prod. Spec.)	Supply of Material	N/A	N/A	N/A
2	Artwork Approval	Quality Delivery Date	Prod. Spec.	Printing of Material	N/A	N/A	N/A
3	Specification approval	Product Specification (Prod. Spec.) Price	Prod. Spec.	None	N/A	N/A	N/A
4	Order placement	Quantity Delivery date Price	Prod. Spec.	None	N/A	N/A	N/A
5	Material receipt	Certificate of Conformance (CoC) Delivery note Incoming Inspection	Raw Materials Specification (RM Spec.)	None	Raw Material / Consumables	N/A	N/A
6	Raw Material Storage	Gauge demarcation	RM Spec: Good condition Width Weight	None	Raw Material / Consumables	N/A	Pallet wrapping
7	Planning / Allocation of Raw Material (RM)	Width Weight Raw Materials (RM) Availability Description	Prod. Spec.	None	N/A	N/A	N/A
8	Job card generation (Slitting Machine)	Prod. Spec. Job Card number	Prod. Spec.	None	N/A	N/A	N/A
9	Material Issue as per Job card (Slitting Machine)	Job Card – Description	RM Spec: Width Weight Type	None	Relevant Raw Material	N/A	Poly wrap
10	Cutting of Core – Core Cutter	Job card – Width Specification as per Job Card	76'' Core	None	Repurposed Cores from Pouch Makers	N/A	Core Off Cuts

11	Manual Stacker arrives at Line (Slitting Machine)	Job card – Material Specification Works Order (WO) Number	Single sheeting film. Clear, silver or printed. Weight Construction Width Gauge	None	Relevant Raw Material	N/A	Cores from previous Job
12	Removal of outer packaging & load and Splice material. (Slitting Machine)	Exposed raw material Position on air shaft Unwind direction Inflation of air shaft.	RM Spec.	None	Relevant Raw Material	N/A	Cores from previous Job
13	Set empty cores on rewind unit (Slitting Machine)	Job Card – Width Specification Positioned on Air Shaft at rewind unit.	Empty 76'' Core	None	Core	N/A	N/A
14	Set blades (Slitting Machine)	Sharpness of blade Correct blade positioning	Film slit as per Specifications	None	None	N/A	N/A
15	Unloaded and Weighed (Slitting Machine)	Meters of Reel Weight Traceability Details	Finished Reels slit as per Specifications on Job Card	None	Unused Labels Cello tape Trim	N/A	Unwind Unit empty Core
16	Checked for defects (Slitting Machine)	Quality	Short Interval Control	None	None	N/A	N/A
17	Storage and Processing of waste: Waste (Machine Waste, set-up, running, trim, cores) removed and stored for removal (Slitting Machine). Baling Process	Weight of Waste	Waste packed into tubing	None	Plastic Tubing	N/A	Waste
18	Return Raw Material to Stores (Slitting Machine)	Label Weight	Supplier WO Reel Number Previous WO Weight Description Returned By	None	Label Pallet Wrapped	N/A	N/A
19	Finished Slit Product strapped with clear tape and then covered with Blue liner and packed in Raw Materials/WIP Stores (Slitting Machine)	Weight Meters Material Description Reel Number	Label on reels Reels palletised and pallet wrapped.	None	None	N/A	N/A

		Work Order Number (WO) Actual Width Number of joins Operators Name Gauge Clear Tape Liner					
20	Job card generation (Pouch Makers -DMF, AMJ, LYS & CMH)	Prod. Spec. Job Card number	Prod. Spec.	None	N/A	N/A	N/A
21	Material Issue as per Job card from warehouse raw material stores (Pouch Makers -DMF, AMJ, LYS & CMH)	Job Card – Description	RM Spec: Width Weight	None	Relevant Raw Material	N/A	Poly wrap
22	Manual Stacker arrives at Line (Pouch Makers -DMF, AMJ, LYS & CMH)	Job card – Material Specification Works Order (WO) Number	Single sheeting film. Clear, silver or printed. Weight Construction Width Gauge	None	Relevant Raw Material	N/A	Cores from previous Job
23	Removal of outer packaging & load, and Splice body and gusset material. (Pouch Makers -DMF, AMJ, LYS & CMH)	Exposed raw material Position on the air shaft Unwind direction Inflation of the air shaft.	RM Spec.	None	Relevant Raw Material	N/A	Cores from previous Job
24	Set blade on vertical bar (Pouch Makers -DMF, AMJ, LYS & CMH)	Positioning of the bar Sharpness of the blade Correct blade positioning	Film slit in Half	None	None	N/A	N/A
25	Check gusset punch tooling (Pouch Makers -DMF, AMJ, LYS & CMH)	Size of the punch hole diameter	As per Job card	None	None	N/A	N/A
26	Key in pouch width (Pouch Makers -DMF, AMJ, LYS & CMH)	Width of pouch Punch positioning.	As per Job card	None	None	N/A	N/A
27	Gusset insertion & Punch Out (Pouch Makers -DMF, AMJ, LYS & CMH)	Gusset material unwinding Direction	Gusset material film folded in half.	None	None	N/A	N/A
28	Zipper insertion, hot seal and cooler bar (Pouch Makers -DMF, AMJ, LYS & CMH)	Zipper Direction (Customer/product side). Size of Zipper. Temperature of heat seal & chill bar. Dwell Pressure (TDP). Teflon.	Zipper sealed to body film.	None	Relevant Zipper	N/A	N/A
29	Cross seal – Gusset & Straight Seals & Cooler Bars (Pouch Makers -DMF, AMJ, LYS & CMH)	Position of heat seal bar and cooler bar. TDP. Teflon	Gusset sealed to body film or Centre seal is sealed to body film.	None	None	N/A	N/A

30	Trim (Pouch Makers -DMF, AMJ, LYS & CMH)	Winding unit switch. Blade positioning. Size of gusset	Smooth Edges. Correct gusset height.	None	None	N/A	Trimmings
31	Zipper Crusher Seal (Pouch Makers -DMF, AMJ, LYS & CMH)	TDP. Position & appearance.	Zipper crushes on side seal.	None	None	N/A	N/A
32	3-point Seal (Pouch Makers -DMF, AMJ, LYS & CMH)	Positioning of the sealer. Films are meeting correctly. TDP	3-point seal crush on gusset and body film.	None	None	N/A	N/A
33	Side seal & Cooler Bars (Pouch Makers -DMF, AMJ, LYS & CMH)	TDP. Positioning of the sealer. Appearance. Teflon durability. Punch hole position	Side seal is sealed on body and gusset and zipper crush, 3-point seal and centre of punch hole	None	None	N/A	N/A
34	Features (tear nick; Euro slot, rounded corners) (Pouch Makers -DMF, AMJ, LYS & CMH)	Position Sharpness of the blade	Cosmetics as per Job card	None	None	N/A	Off-cuts
35	Straight middle cut at end (Pouch Makers -DMF, AMJ, LYS & CMH)	Sharpness of blade. Position of the blade.	Two pouches are slit into individual pouches.	None	None	N/A	N/A
36	Final cut into a pouch. (Pouch Makers -DMF, AMJ, LYS & CMH)	Width of side seals. Edge appearance. Timeliness of the blade.	Product is formed.	None	None	N/A	Off-cuts
37	Checked for defects (Pouch Makers -DMF, AMJ, LYS & CMH)	Quality	Short Interval Control	None	None	N/A	N/A
38	Liners are placed into cartons to pack finished goods. Cartons sealed with clear tape for storage and distribution. (Pouch Makers)	Carton liners Counting of pouches. Number of Cartons. Label generation.	Product in box as per packing instructions	None	Cartons; plastic liners	N/A	N/A
39	Storage and Processing of waste: Waste (Machine Waste, set-up, running and off-cut) removed and stored for removal (Pouch Maker). Baling Process	Weight of Waste	Waste packed into tubing	None	Plastic Tubing	N/A	Waste
40	Return Raw Material to Stores (Pouch Makers)	Label Weight	Supplier WO Reel Number Previous WO Weight Description Returned By	None	Virgin Poly Liner Label	N/A	N/A
41	Finished Cartons or WiP Packed into cartons are stored in the warehouse in the Finished Goods Store (Pouch Makers)	Quantity Description Carton Number Work Order Number (WO)	Label on Carton. Cartons taped together with buff tape.	None	None	N/A	N/A

42	Job Card Generation (Spout Inserter Machines)	Prod. Spec. Job Card No.	Product Specifications.	None	None	N/A	N/A
43	Caps counted & packed into liners	Quality	Cap, liner and carton	None	Caps	N/A	Soiled caps
44	Raw Material and WiP are issued to the Spout Inserter from the warehouse in the Finished Goods Store (Spout Inserter Machines) as per the Job card.	Job Card - Description	RM/ Work in Progress (WiP) Specification: Description Width Dimensions	None	Relevant RM and WiP	N/A	Cartons, liners
45	WiP Pouches loaded into Spout Machine (Spout Inserter Machines)	Positioning of magazine.	Work in Progress (WiP) Specification: Description Dimensions	None	None	N/A	N/A
46	Spouts fitments loaded into vibration bowl (Spout Inserter Machines)	Spout size.	RM Specification: Description Dimensions	None	None	N/A	N/A
47	Set PLC specifications (Spout Inserter Machines)	Vibration setting Pre-heat setting	As per Job Card	None	None	N/A	N/A
48	Pouch Pick (Spout Inserter Machines)	Position of vacuum sucker	Pouch Picked, no change in product.	None	None	N/A	N/A
49	Angle Cut (Spout Inserter Machines)	Positioning of Blade Position of spout fitment	Pouch cropped as per product specification.	None	None	N/A	Off-cuts
50	Spout Pick (Spout Inserter Machines)	Positioning of picking arm.	Spout picked, no change in product.	None	None	None	None
51	Pouch Open (Spout Inserter Machines)	Position of vacuum sucker	Pouch sucked open at cropped opening.	None	None	None	None
52	First sealing, 1 & 2 (Spout Inserter Machines)	Temperature Dwell Pressure	Sealed spout to pouch	None	None	None	None
53	Hot seal 1 & 2 (Spout Inserter Machines)	Temperature Dwell Pressure	Sealed spout to pouch	None	None	None	None
54	Hot seal 3 & 4 (Spout Inserter Machines)	Temperature Dwell Pressure	Sealed spout to pouch	None	None	None	None
55	Cold Seal 1 & 2 (Spout Inserter Machines)	Temperature Dwell Pressure	Sealed spout to pouch	None	None	None	None
56	Checked for defects (Spout Inserter Machines)	Quality	Short Interval Control (Production log sheet)	None	None	None	Rejected pouches

57	Liners are placed into cartons to pack finished goods. Cartons sealed with clear tape for storage and distribution. (Spout Inserter Machines)	Carton liners Counting of pouches. No. of Cartons. Label generation.	Product in box as per packing instruction on job card.	None	Cartons; plastic liners, Self-adhesive tape	None	None
58	Storage and Processing of waste: Waste (Machine Waste, set-up, running and off-cut) removed and stored for removal (Sout Inserter). Baling Process	Number of pouches	Tubing utilised.	None	Plastic Tubing (Consumable)	None	Waste
59	Palletise / shrink wrap	Pallet configuration Correct label	Aa per packing instruction. Completely wrapped Delivery Labels.	None	Shrink wrap	N/A	Core
60	Storage & Distribution	Quantity Description Job No. Carton No. Customer details	Completely wrapped	None	None	N/A	N/A
61	**Returns:** **Customer Returns:** Complaint Handling procedure/Control of Non-Conforming Product Procedure. **Supplier Returns**: Control of Non-Conforming Product Procedure.	Quantity Description Job No. Carton No. Customer details NCA	Label on Carton and Reels HOLD Sticker	None	None	Yes	None

RISK ASSESSMENT MATRIX

(L) Likelihood ▲▲ / ▼▼	(S) Severity ▶▶ Low (L)	Minor (Mi)	Moderate (Mo)	Major (Ma)	Extreme (E)
Almost Certain (AC)	High Risk (H)	H	Extreme Risk (E)	E	E
Likely (L)	Medium Risk (M)	H	H	E	E
Possible (P)	Low Risk (L)	M	H	E	E
Unlikely (U)	L	L	M	H	E
Rare (R)	L	L	M	H	H

Likelihood (L) X Severity (S) = Risk Rating/Control Required

Significant Risk:

Yes (Y): High / Extreme Risk Rating
No (N): Low / Medium Risk Rating

Hazard Source	
P = Present	**G** = Grow
I = Introduced at this step	**S** = Survive

HAZARD ANALYSIS

Step #	Process Activity	Potential Product Safety Hazard or Quality defect	List Hazards for each Process Step	Hazard Source	Acceptable level of Hazard	Preventive measures for each hazard	Likelihood	Severity	Rating	Significant Risk	Q1	Q2	Q3	Q4	Q5	CCP	Remarks / additional preventive measures
1	Supplier Approval	Quality	Non-Conforming Raw Material.	P	As per specifications	Supplier Approval & Performance Monitoring Procedure in place.	U	Mi	L	N	-	-	-	-	-	-	Supplier Risk assessment BRC/FDA Approved Supplier/s
		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-	-	No product received on site at this point in time
		Foreign Objects	None	-	-	-	-	-	-	-	-	-	-	-	-	-	No product received on site at this point in time
		Microbiological	None	-	-	-	-	-	-	-	-	-	-	-	-	-	No product received on site at this point in time
2	Artwork Approval	Quality	Misleading Labels: Incorrect Allergens/Safety information. Fraudulent use of Artwork	P	As per specifications	Specifications Procedure in place. Graphic Design & Artwork Control Procedure in place Security Procedure in place	R	L	L	N	-	-	-	-	-	-	No Printing on site Artwork approved by customer
		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		Foreign Objects	None	-	-	-	-	-	-	-	-	-	-	-	-	-	No product received on site at this point in time
		Microbiological	None	-	-	-	-	-	-	-	-	-	-	-	-	-	No product received on site at this point in time
3	Specification approval	Quality	Non-Conforming Raw Material/Finished Goods.	P	-	Specifications Procedure in place.	U	Mi	L	N	-	-	-	-	-	-	BRC/FDA Approved Supplier/s Raw Material Specifications Register Declaration of Compliance from Supplier Pouch Specification Forms Artwork Approval
		Chemical	Non-food Grade Inks. Potential for unintended migration of substances into food or other hygiene sensitive product.	P	-	Specifications Procedure in place Chemical and biological control procedure in place	R	Mo	M	N	-	-	-	-	-	-	No product received on site at this point in time Raw Material Specifications Register BRC/FDA Approved Supplier/s

HAZARD ANALYSIS

Step #	Process Activity	Potential Product Safety Hazard or Quality defect	List Hazards for each Process Step	Hazard Source	Acceptable level of Hazard	Preventive measures for each hazard	Likelihood	Severity	Rating	Significant Risk	Q1	Q2	Q3	Q4	Q5	CCP	Remarks / additional preventive measures
																	Declaration of Compliance from Supplier Analysis of film & migration report from Supplier. Limitations of use on both Pouch Spec. Form and CoC
		Foreign Objects	None	-	-	-	-	-	-	-	-	-	-	-	-	-	No product received on site at this point in time
		Microbiological	None	-	-	-	-	-	-	-	-	-	-	-	-	-	No product received on site at this point in time
4	Order placement	Quality	None	-	-	-	-	-	-	-	-	-	-	-	-	-	Raw material specification available. No product received on site at this point in time
		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-	-	No product received on site at this point in time
		Foreign Objects	None	-	-	-	-	-	-	-	-	-	-	-	-	-	No product received on site at this point in time
		Microbiological	None	-	-	-	-	-	-	-	-	-	-	-	-	-	No product received on site at this point in time
5	Material receipt	Quality	Damaged. Telescoping etc. Incorrect Specifications Trademark Infringements Product damaged in transit or during offloading. Misprint. Fraudulent Raw Materials.	P	As per specifications	Supplier Approval Procedure in place. Transport, Storage & Distribution Procedure in place Specifications Procedure in place Product Authenticity Procedure (Food Fraud)	P	Mi	M	N	-	-	-	-	-	-	Incoming Inspection in place. Trained operators CoC verification with delivery note & specifications. Customer signs off artwork proof before plates are made for printing. Customer signed Pouch Spec Form before placement of order for Raw Material. Supplier BRC/FDA certificated. Inspection later in the process. Trained forklift operators

HAZARD ANALYSIS

Step #	Process Activity	Potential Product Safety Hazard or Quality defect	List Hazards for each Process Step	Hazard Source	Acceptable level of Hazard	Preventive measures for each hazard	Likelihood	Severity	Rating	Significant Risk	Q1	Q2	Q3	Q4	Q5	CCP	Remarks / additional preventive measures
																	Copy of signed artwork provided to Operators for visual inspection
		Chemical	No Food Grade Chemicals transported with Raw Materials increasing risk of contamination	P	None	Supplier Approval Procedure in place. Transport, Storage & Distribution Procedure in place	R	Ma	H	Y	Y	Y	N	N	-	-	Incoming material inspection. Chemicals not transported on same transport as raw or packaging material. Supplier BRC/FDA certificated. Vehicle Inspection taken place at raw material supplier as seen on copy of supplier delivery note.
		Foreign Objects	Pests; wood chips from damaged pallets during transportation or offloading. Insects/Pests present in the material from production. Glass/Brittle plastic from Forklift	p	None	Supplier Approval Procedure in place. Transport, Storage & Distribution procedure in place. Glass and brittle plastic procedure in place.	U	Mo	M	N	-	-	-	-	-	-	Incoming material inspection Supplier BRC/FDA Approved. Slip Sheets utilised for transportation of material Product protection Inspection with short interval control (PLS) later in process. Vehicle Inspection taken place at raw material supplier as seen on copy of supplier delivery note. Trained forklift operators
		Microbiological	None	-	-	-	-	-	-	-	-	-	-	-	-	-	Product protected at delivery Product undergoes no physical change
6	Raw Material Storage	Quality	Damaged Product. Malicious Intervention.	I	None	Transport, Storage & Distribution procedure in place. Security Procedure in place.	U	Mi	L	N	-	-	-	-	-	-	Good storage conditions maintained. Raw materials are stored in segregated storage area. Visual inspection of product prior use. Product protected, slip sheets used. Product undergoes no physical change

HAZARD ANALYSIS

Step #	Process Activity	Potential Product Safety Hazard or Quality defect	List Hazards for each Process Step	Hazard Source	Acceptable level of Hazard	Preventive measures for each hazard	Likelihood	Severity	Rating	Significant Risk	Q1	Q2	Q3	Q4	Q5	CCP	Remarks / additional preventive measures
																	Trained forklift operators
		Chemical	Contamination from non-food grade chemicals/Malicious Intervention	I	None	Transport, Storage & Distribution procedure in place. Security Procedure in place	R	Mo	M	N	-	-	-	-	-	-	Chemicals stored in locked room away from product. Food Grade Lubricants & Cleaning agents only used. Material Safety Data available. Product protected. Raw Materials stored in separate area: Raw Materials stores Product undergoes no physical change
		Foreign Objects	Damaged pallets cause wood chips, pests, paint chips floors, Glass/Brittle plastic from Forklift Foreign objects from damage to building structure	I	None	Transport, Storage & Distribution procedure in place. Pest Control Procedure in place. Cleaning Procedure in place Foreign Body Contamination Control Procedure Site standard procedure	U	Mo	M	N	-	-	-	-	-	-	Internal Self Audit. Cleaning programme in place. Product protection, slip sheets used. Product undergoes no physical change All product stored off the floors on pallets or racking and away from walls. Trained forklift operators High Level Cleaning
		Microbiological	Bacteria from product handling (Corona Virus)	I	None	Transport, Storage & Distribution procedure in place. Personnel Hygiene Procedure in place. Chemical & Biological Control Procedure in place	R	Mo	M	N	-	-	-	-	-	-	Product protection. Hand Wash Facilities provided. Trained Personnel. Product undergoes no physical change Based on this risk assessment the water used in the hand washing facilities is tested on an annual basis. Annual validation of hand washing by swab tests

HAZARD ANALYSIS

Step #	Process Activity	Potential Product Safety Hazard or Quality defect	List Hazards for each Process Step	Hazard Source	Acceptable level of Hazard	Preventive measures for each hazard	Likelihood	Severity	Rating	Significant Risk	Q1	Q2	Q3	Q4	Q5	CCP	Remarks / additional preventive measures
7	Planning / Allocation of Raw Material	Quality	Shelf life of Raw Material	P	1 year from receipt of material.	Transport, Storage & Distribution procedure in place.	R	Mi	L	N	-	-	-	-	-	-	FIFO practise. Raw Materials Labelled Product undergoes no physical change
		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-	-	Product undergoes no physical change
		Foreign Objects	None	-	-	-	-	-	-	-	-	-	-	-	-	-	Product undergoes no physical change
		Microbiological	None	-	-	-	-	-	-	-	-	-	-	-	-	-	Product undergoes no physical change
8	Job card generation (Slitting Machine)	Quality	Incorrect specifications on Job Card	I	None	Specifications procedure in place	U	Mo	M	N	-	-	-	-	-	-	Approval of Specifications by customer. Trained personnel generating job card Job Card. Product undergoes no physical change
		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-	-	Product undergoes no physical change
		Foreign Objects	None	-	-	-	-	-	-	-	-	-	-	-	-	-	Product undergoes no physical change
		Microbiological	None	-	-	-	-	-	-	-	-	-	-	-	-	-	Product undergoes no physical change
9	Material Issue as per Job card (Slitting Machine)	Quality	Incorrect material issued.	I	None	In-Process Control in place: Documented Process Checking Traceability procedure in place	P	Mi	M	N	-	-	-	-	-	-	Short Interval Control & Job Card initial. Raw material identifiable. Trained personnel. Labels Job Card Product undergoes no physical change
		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-	-	No chemicals present in this process

HAZARD ANALYSIS

Step #	Process Activity	Potential Product Safety Hazard or Quality defect	List Hazards for each Process Step	Hazard Source	Acceptable level of Hazard	Preventive measures for each hazard	Likelihood	Severity	Rating	Significant Risk	Q1	Q2	Q3	Q4	Q5	CCP	Remarks / additional preventive measures
																	Product undergoes no physical change
		Foreign Objects	Glass, wood splinters from supplier pallets, dust as outer packaging is removed, pests. Foreign objects from damage to building structure	I	None	Glass and brittle plastic procedure in place. Housekeeping & Cleaning procedure in place Incident Reporting procedure in place Pest control procedure in place Site standard procedure	U	Mo	M	N	-	-	-	-	-	-	Product undergoes no physical change Incoming Raw Material Inspection of material packaging and pallets.
		Microbiological	Bacteria from product handling	I	None	Personnel Hygiene Procedure & Standard in place Housekeeping & Cleaning Procedure in place Chemical & Biological Control Procedure in place	R	Mo	M	N	-	-	-	-	-	-	Washing / sanitising of Hands Maintenance Cleaning of equipment. Product undergoes no physical change Trained personnel Based on this risk assessment the water used in the hand washing facilities is tested on an annual basis. Annual validation of hand washing by swab tests
10	Cutting of Core – Core Cutter	Quality	None	-	-	-	-	-	-	-	-	-	-	-	-	-	Product undergoes no physical change
		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-	-	Product undergoes no physical change
		Foreign Objects	Core Dust Broken Blade	I	None	Housekeeping & Cleaning Procedure in Place	R	Mo	M	N	-	-	-	-	-	-	Product undergoes no physical Change Clean as you go Policy Sharps Policy Blade register for issue of blades
		Microbiological	None	-	-	-	-	-	-	-	-	-	-	-	-	-	Product undergoes no physical change

HAZARD ANALYSIS

Step #	Process Activity	Potential Product Safety Hazard or Quality defect	List Hazards for each Process Step	Hazard Source	Acceptable level of Hazard	Preventive measures for each hazard	Likelihood	Severity	Rating	Significant Risk	Q1	Q2	Q3	Q4	Q5	CCP	Remarks / additional preventive measures
11	Manual Stacker arrives at Line (Slitting Machine)	Quality	Incorrect material specification loaded onto machine	I	None	In-Process Control in place: Documented Process Checking.	P	Mi	M	N	-	-	-	-	-	-	Raw material identified Raw material batch number recorded on Process control sheets. Segregation of materials per machine and label check to see matches materials specified on job card. Trained Personnel. Initial Job Card & PLS, SIC Product undergoes no physical change
		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-	-	No chemicals used at this part of the machine Product undergoes no physical change
		Foreign Objects	Glass / brittle plastic. Jewellery, pests, paint chips floors Foreign objects from damage to building structure	I	None	Glass and brittle plastic procedure in place. Housekeeping & Cleaning procedure in place Personal Hygiene Standard in place. Pest control procedure in place. Site standard procedure	R	Mo	M	N	-	-	-	-	-	-	Glass and brittle plastics register Trained operator. Line clearance in place. Incident management Product undergoes no physical change. Product is protected by suitable outer covering. "Tread Plates" installed to protect the flooring and avoid damage
		Microbiological	Bacteria from product handling	I	None	Personnel Hygiene Procedure & Standard in place Housekeeping & Cleaning Procedure in place Chemical & Biological Control Procedure in place	R	Mo	M	N	-	-	-	-	-	-	Washing / sanitising of Hands. Hand Wash Basin. Personnel trained on personal hygiene practices Product undergoes no physical change Trained personnel Based on this risk assessment the water used in the hand washing

HAZARD ANALYSIS

Step #	Process Activity	Potential Product Safety Hazard or Quality defect	List Hazards for each Process Step	Hazard Source	Acceptable level of Hazard	Preventive measures for each hazard	Likelihood	Severity	Rating	Significant Risk	Q1	Q2	Q3	Q4	Q5	CCP	Remarks / additional preventive measures
																	facilities tested on an annual basis. Annual validation of hand washing by swab tests
12	Removal of outer packaging & load and Splice material. (Slitting Machine)	Quality	Incorrect material specification loaded onto machine Telescoping Reels form Supplier	I	None	In-Process Control in place: Documented Process Checking Control of Non-Conforming Procedure.	P	Mi	M	N	-	-	-	-	-	-	Raw material identified Product inspection Raw material batch number recorded on Process control sheets. Segregation of materials per machine and label check to see matches materials specified on job card. Trained Personnel. Initial Job Card & PLS, SIC Bright Lights above machines.
		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-	-	No chemicals used at this part of the machine Product undergoes no physical change
		Foreign Objects	Glass / brittle plastic Jewellery, blades, pests Temporary Modification	I	None	Glass and brittle plastic procedure in place. Housekeeping & Cleaning procedure in place Sharps Policy Personal Hygiene Standard in place. Pest control procedure in place Foreign Body Contamination Procedure.	R	Mo	M	N	-	-	-	-	-	-	Trained operator. Line clearance in place. Incident management Product undergoes no physical change Designated Area for removal of outer packaging Process Control checks (PLS) Bright Lights above machines.
		Microbiological	Bacteria from product handling	I	None	Personnel Hygiene Procedure & Standard in place Housekeeping & Cleaning Procedure in place	R	Mo	M	N	-	-	-	-	-	-	Washing / sanitising of Hands after removal of outer packaging before product handling. Hand Wash Basin.

HAZARD ANALYSIS

Step #	Process Activity	Potential Product Safety Hazard or Quality defect	List Hazards for each Process Step	Hazard Source	Acceptable level of Hazard	Preventive measures for each hazard	Likelihood	Severity	Rating	Significant Risk	Q1	Q2	Q3	Q4	Q5	CCP	Remarks / additional preventive measures
						Chemical & Biological Control Procedure in place											Personnel trained on personal hygiene practices Product undergoes no physical change Designated Area for removal of outer packaging Trained personnel Annual validation of hand washing by swab tests Based on this risk assessment the water used in the hand washing facilities is tested on an annual basis.
13	Set empty cores on rewind unit (Slitting Machine)	Quality	None	-	-	-	-	-	-	-	-	-	-	-	-	-	Product undergoes no physical change
		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-	-	Product undergoes no physical change
		Foreign Objects	Glass / brittle plastic Jewellery, blades, pests Temporary Modification Core Dust	I	None	Glass and brittle plastic procedure in place. Housekeeping & Cleaning procedure in place Sharps Policy Personal Hygiene Standard in place. Pest control procedure in place Foreign Body Contamination Procedure.	R	Mo	M	N	-	-	-	-	-	-	Trained operator. Line clearance in place. Incident management Product undergoes no physical change Bright Lights above machines.
		Microbiological	None	-	-	-	-	-	-	-	-	-	-	-	-	-	Product undergoes no physical change
14	Set blades (Slitting Machine)	Quality	Sharpness of blade	P	None	In-Process Control in place	P	L	L	N	-	-	-	-	-	-	Change Blade when blunt as seen on Blade register Pre-start up blade inspection at each shift
		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-	-	Material safety datasheets available,

HAZARD ANALYSIS

Step #	Process Activity	Potential Product Safety Hazard or Quality defect	List Hazards for each Process Step	Hazard Source	Acceptable level of Hazard	Preventive measures for each hazard	Likelihood	Severity	Rating	Significant Risk	Q1	Q2	Q3	Q4	Q5	CCP	Remarks / additional preventive measures
																	Post maintenance cleaning in place Food grade (NSF) chemicals used during machine maintenance/cleaning
		Foreign Objects	Blade chips/Broken Fragments Temporary Modification	I	None	In-Process Control in place: Documented Process Checking Foreign Body Contamination Procedure	R	Mo	M	N	-	-	-	-	-	-	Blades are checked prior to start up at shift handover – refer to production log sheets Blade register for issue of blades Process Control checks (PLS)
		Microbiological	Bacteria from product handling	I	None	Personnel Hygiene Procedure & Standard in place Housekeeping & Cleaning Procedure in place Chemical & Biological Control Procedure in place	U	Mo	M	N	-	-	-	-	-	-	Washing / sanitising of Hands. Hand Wash Basin. Personnel trained on personal hygiene practices Annual validation of hand washing by swab tests
15	Unloaded and Weighed (Slitting Machine)	Quality	Malicious intervention	I	None	Transport, storage and distribution procedure in place Security procedure in place	R	Mo	M	N	-	-	-	-	-	-	Product labelling Traceability procedure in place Access control Visitors' registers
		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-	-	No chemicals used at this process step
		Foreign Objects	Pests, dirt, glass and brittle plastic, Jewellery	I	None	Personal Hygiene Standard in place Glass and brittle plastic procedure in place. Housekeeping & Cleaning Procedure in place Pest control procedure in place	U	Mo	M	N	-	-	-	-	-	-	Glass and brittle plastics register. Incident management. Bright Lights above Machines.
		Microbiological	Bacteria from product handling	I	None	Personnel Hygiene Procedure & Standard in place Chemical & Biological Control Procedure in place	R	Mo	M	N	-	-	-	-	-	-	Product is handled on outside Carton Liners Glass and brittle plastics register Personnel trained on personal hygiene practices

HAZARD ANALYSIS

Step #	Process Activity	Potential Product Safety Hazard or Quality defect	List Hazards for each Process Step	Hazard Source	Acceptable level of Hazard	Preventive measures for each hazard	Likelihood	Severity	Rating	Significant Risk	Q1	Q2	Q3	Q4	Q5	CCP	Remarks / additional preventive measures
																	Based on this risk assessment the water used in the hand washing facilities is tested on an annual basis. Hand Wash Basin. Annual validation of hand washing by swab tests
16	Checked for defects (Slitting Machine)	Quality	Incorrect Specification	P	None	In-Process Control in place: Documented Process Checking	P	Mi	M	N	-	-	-	-	-	-	Job Card 1st off Sample. Train Personnel Documented product quality checks on PLS Bright Lights above machines.
		Chemical	None	-	-	-	-	-	--	-	-	-	-	-	-	-	No chemicals used at this process step
		Foreign Objects	Glass / brittle plastic, Jewellery, blades, pests Temporary Modification	I	None	In-Process Control in place: Documented Process Checking Glass and brittle plastic procedure in place. Sharps Policy Personal Hygiene Standard in place Pest control procedure in place Foreign Body Contamination Procedure	U	Mo	M	N	-	-	-	-	-	- -	Glass and brittle plastics register. Incident management. Pre-start-up checklist Documented visual product inspection Pouch is sealed at this stage Process Control checks (PLS) Bright Lights above machines.
		Microbiological	Bacteria from product handling	I	None	Personnel Hygiene Procedure & Standard in place Housekeeping & Cleaning Procedure in place Chemical & Biological Control Procedure in place	U	Mo	M	N	-	-	-	-	-	-	Product is handled on outside. Washing / sanitising of Hands Hand Wash Basin. Inspected sample used as retention. Based on this risk assessment the water used in the hand washing facilities is tested on an annual basis.

HAZARD ANALYSIS

Step #	Process Activity	Potential Product Safety Hazard or Quality defect	List Hazards for each Process Step	Hazard Source	Acceptable level of Hazard	Preventive measures for each hazard	Likelihood	Severity	Rating	Significant Risk	Q1	Q2	Q3	Q4	Q5	CCP	Remarks / additional preventive measures
																	Annual validation of hand washing by swab tests
17	Storage and Processing of waste: Waste (Machine Waste, set-up, running, trim, cores) removed and stored for removal (Slitting Machine). Baling Process	Quality	Fraudulent use of trademark waste	I	None	Waste Management Procedure in place	U	Mo	M	N	-	-	-	-	-	-	Trademark waste is rendered unusable through an in-house destruction process.
		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-	-	No chemicals used at this process step
		Foreign Objects	Punch Outs Pieces of Trim.	P	None	In-Process Control in place: Documented Process Checking Waste management procedure in place	P	Mi	M	N	-	-	-	-	-	-	Line Clearance as per PLS Trained Personnel Initials Line Clearance on PLS
		Microbiological	None	-	-	-	-	-	--	-	-	-	-	-	-	-	No product handling at this step
18	Return Raw Material to Stores (Slitting Machine)	Quality	Untraceable product, incorrect labelling Malicious intervention	I	None	Traceability procedure in place Transport, storage and distribution procedure in place Security procedure in place	U	Mo	M	N	-	-	-	-	-	-	Return to store labels Access control Visitors' registers Product is protected covered with blue liner, slip sheets on pallets
		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-	-	Material safety datasheets available, Post maintenance cleaning in place Food grade (NSF) chemicals used during machine maintenance. No Chemicals used at this step.
		Foreign Objects	Damaged pallets cause wood chips, pests. Jewellery,	P	None	Transport, storage and distribution procedure in place Housekeeping & Cleaning Procedure in place Pest Control procedure in place Personal Hygiene Standard in place	U	Mo	M	N	-	-	-	-	-	-	Product protection Product undergoes no physical change
		Microbiological	Bacteria from product handling	I	None	Personnel Hygiene Procedure & Standard in place	U	Mo	M	N	-	-	-	-	-	-	Material handled so that the surface that comes into contact

HAZARD ANALYSIS

Step #	Process Activity	Potential Product Safety Hazard or Quality defect	List Hazards for each Process Step	Hazard Source	Acceptable level of Hazard	Preventive measures for each hazard	Likelihood	Severity	Rating	Significant Risk	Q1	Q2	Q3	Q4	Q5	CCP	Remarks / additional preventive measures
						Housekeeping & Cleaning Procedure in place Chemical & Biological Control Procedure in place											with hands and equipment does not come into contact with food. Hands are sanitised. Based on this risk assessment the water used in the hand washing facilities is tested on an annual basis. Annual validation of hand washing by swab tests
19	Finished Slit Product strapped with clear tape and then covered with blue liner and packed in Raw Materials/WIP Stores (Slitting Machine)	Quality	Malicious intervention	I	None	Transport, storage and distribution procedures in place Security procedure in place	R	Mo	M	N	-	-	-	-	-	-	Product labelling Traceability procedure in place Access control Visitors' registers
		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-	-	Material safety datasheets available, Post maintenance cleaning in place Food grade (NSF) chemicals used during machine maintenance. No Chemicals used at this step.
		Foreign Objects	None	-	-	-	-	-	-	-	-	-	-	-	-	-	Product is stored in designated area. Cleaning in place, Pest control in place Good Storage practices
		Microbiological	None	-	-	-	-	-	-	-	-	-	-	-	-	-	Product Protection
20	Job card generation (Pouch Makers)	Quality	Incorrect specifications on Job Card	I	None	Specifications procedure in place	U	Mo	M	N	-	-	-	-	-	-	Approval of Specifications by customer. Trained personnel generating job card Job Card. Product undergoes no physical change

HAZARD ANALYSIS

Step #	Process Activity	Potential Product Safety Hazard or Quality defect	List Hazards for each Process Step	Hazard Source	Acceptable level of Hazard	Preventive measures for each hazard	Likelihood	Severity	Rating	Significant Risk	Q1	Q2	Q3	Q4	Q5	CCP	Remarks / additional preventive measures
		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-	-	Product undergoes no physical change
		Foreign Objects	None	-	-	-	-	-	-	-	-	-	-	-	-	-	Product undergoes no physical change
		Microbiological	None	-	-	-	-	-	-	-	-	-	-	-	-	-	Product undergoes no physical change
21	Material Issue as per Job Card (Pouch Makers)	Quality	Incorrect material specification issued.	I	None	In-Process Control in place: Documented Process Checking Traceability procedure in place	P	Mi	M	N	-	-	-	-	-	-	Short Interval Control & Job Card initial. Raw material identifiable. Trained personnel. Labels Job Card Product undergoes no physical change
		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-	-	No chemicals present in this process Product undergoes no physical change
		Foreign Objects	Glass, wood splinters from supplier pallets, dust as outer packaging is removed, pests. Foreign objects from damage to building structure	I	None	Glass and brittle plastic procedure in place. Housekeeping & Cleaning procedure in place Incident Reporting procedure in place Pest control procedure in place Site standard procedure	U	Mo	M	N	-	-	-	-	-	-	Product undergoes no physical change Incoming Raw Material Inspection of material packaging and pallets.
		Microbiological	Bacteria from product handling	I	None	Personnel Hygiene Procedure & Standard in place Housekeeping & Cleaning Procedure in place Chemical & Biological Control Procedure in place	R	Mo	M	N	-	-	-	-	-	-	Washing / sanitising of Hands Maintenance Cleaning of equipment. Product undergoes no physical change Trained personnel Based on this risk assessment the water used in the hand washing

HAZARD ANALYSIS

Step #	Process Activity	Potential Product Safety Hazard or Quality defect	List Hazards for each Process Step	Hazard Source	Acceptable level of Hazard	Preventive measures for each hazard	Likelihood	Severity	Rating	Significant Risk	Q1	Q2	Q3	Q4	Q5	CCP	Remarks / additional preventive measures
																	facilities is tested on an annual basis. Annual validation of hand washing by swab tests
22	Manual Stacker arrives at Line (Pouch Makers)	Quality	Incorrect material specification loaded onto machine	I	None	In-Process Control in place: Documented Process Checking.	P	Mi	M	N	-	-	-	-	-	-	Raw material identified Raw material batch number recorded on Process control sheets. Segregation of materials per machine and label check to see matches materials specified on job card. Trained Personnel. Initial Job Card & PLS, SIC Product undergoes no physical change
		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-	-	No chemicals used at this part of the machine Product undergoes no physical change
		Foreign Objects	Glass / brittle plastic. Jewellery, pests, paint chips floors Foreign objects from damage to building structure	I	None	Glass and brittle plastic procedure in place. Housekeeping & Cleaning procedure in place Personal Hygiene Standard in place. Pest control procedure in place. Site standard procedure	R	Mo	M	N	-	-	-	-	-	-	Glass and brittle plastics register Trained operator. Line clearance in place. Incident management Product undergoes no physical change. Product is protected by suitable outer covering. "Tread Plates" installed to protect the flooring and avoid damage
		Microbiological	Bacteria from product handling	I	None	Personnel Hygiene Procedure & Standard in place Housekeeping & Cleaning Procedure in place	R	Mo	M	N	-	-	-	-	-	-	Washing / sanitising of Hands. Hand Wash Basin. Personnel trained on personal hygiene practices

HAZARD ANALYSIS

Step #	Process Activity	Potential Product Safety Hazard or Quality defect	List Hazards for each Process Step	Hazard Source	Acceptable level of Hazard	Preventive measures for each hazard	Likelihood	Severity	Rating	Significant Risk	Q1	Q2	Q3	Q4	Q5	CCP	Remarks / additional preventive measures
						Chemical & Biological Control Procedure in place											Product undergoes no physical change Trained personnel Based on this risk assessment the water used in the hand washing facilities is tested on an annual basis. Annual validation of hand washing by swab tests
23	Removal of outer packaging & load and Splice body and gusset material. (Pouch Makers)	Quality	Incorrect material specification loaded onto machine. Telescoping Reels	I	None	In-Process Control in place: Documented Process Checking Control of Non-Conforming Product Procedure	P	Mi	M	N	-	-	-	-	-	-	Raw material identified Product inspection Raw material batch number recorded on Process control sheets. Segregation of materials per machine and label check to see matches materials specified on job card. Trained Personnel. Initial Job Card & PLS, SIC Bright Lights above machines.
		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-	-	No chemicals used at this part of the machine Product undergoes no physical change
		Foreign Objects	Glass / brittle plastic Jewellery, blades, pests Temporary Modification	I	None	Glass and brittle plastic procedure in place. Housekeeping & Cleaning procedure in place Sharps Policy Personal Hygiene Standard in place. Pest control procedure in place Foreign Body Contamination Procedure.	R	Mo	M	N	-	-	-	-	-	-	Trained operator. Line clearance in place. Incident management Product undergoes no physical change Designated Area for removal of outer packaging Process Control checks (PLS) Bright Lights above machines.

HAZARD ANALYSIS

Step #	Process Activity	Potential Product Safety Hazard or Quality defect	List Hazards for each Process Step	Hazard Source	Acceptable level of Hazard	Preventive measures for each hazard	Likelihood	Severity	Rating	Significant Risk	Q1	Q2	Q3	Q4	Q5	CCP	Remarks / additional preventive measures
		Microbiological	Bacteria from product handling	I	None	Personnel Hygiene Procedure & Standard in place Housekeeping & Cleaning Procedure in place Chemical & Biological Control Procedure in place	R	Mo	M	N	-	-	-	-	-	-	Washing / sanitising of Hands after removal of outer packaging before product handling. Hand Wash Basin. Personnel trained on personal hygiene practices Product undergoes no physical change Designated Area for removal of outer packaging Trained personnel Annual validation of hand washing by swab tests Based on this risk assessment the water used in the hand washing facilities is tested on an annual basis.
24	Set blade on vertical bar (Pouch Makers)	Quality	Sharpness of blade	P	None	In-Process Control in place	P	L	L	N	-	-	-	-	-	-	Change Blade when blunt as seen on Blade register Pre-start up blade inspection at each shift
		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-	-	Material safety datasheets available, Post maintenance cleaning in place Food grade (NSF) chemicals used during machine maintenance/cleaning
		Foreign Objects	Blade chips Temporary Modification	I	None	In-Process Control in place: Documented Process Checking Foreign Body Contamination Procedure	R	Mo	M	N	-	-	-	-	-	-	Blades are checked prior to start up at shift handover – refer to production log sheets Blade register for issue of blades Process Control checks (PLS)

HAZARD ANALYSIS

Step #	Process Activity	Potential Product Safety Hazard or Quality defect	List Hazards for each Process Step	Hazard Source	Acceptable level of Hazard	Preventive measures for each hazard	Likelihood	Severity	Rating	Significant Risk	Q1	Q2	Q3	Q4	Q5	CCP	Remarks / additional preventive measures
		Microbiological	Bacteria from product handling	I	None	Personnel Hygiene Procedure & Standard in place Housekeeping & Cleaning Procedure in place Chemical & Biological Control Procedure in place	U	Mo	M	N	-	-	-	-	-	-	Washing / sanitising of Hands. Hand Wash Basin. Personnel trained on personal hygiene practices Annual validation of hand washing by swab tests
25	Check gusset punch tooling (Pouch Makers)	Quality	Sharpness of Punch.	P	None	In-Process Control in place: Documented Process Checking	P	L	L	N	-	-	-	-	-	-	Documented visual product inspection Documented machine check of equipment
		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-	-	Material safety datasheets available, Post maintenance cleaning in place Food grade (NSF) chemicals used during machine maintenance
		Foreign Objects	Glass / brittle plastic, Gusset Punch out, Jewellery Temporary Modification	I	None	Glass and brittle plastic procedure in place. Housekeeping & Cleaning procedure in place Personal Hygiene Standard in place. In-Process Control in place: Documented Process Checking Foreign Body Contamination Procedure	U	Mo	M	N	-	-	-	-	-	-	Trained operator. Line clearance in place. Incident management Documented visual product inspection Documented machine check of equipment Process Control checks (PLS)
		Microbiological	None	I	None	-	-	-	-	-	-	-	-	-	-		No product handling at this step Product undergoes no physical change
26	Key in pouch width (Pouch Makers)	Quality	Incorrect Pouch Width	I	None	In-Process Control in place: Documented Process Checking	R	Mo	M	N		-	-	-	-	-	Train Personnel, Job Card Product undergoes no physical change Documented product specification checks

HAZARD ANALYSIS

Step #	Process Activity	Potential Product Safety Hazard or Quality defect	List Hazards for each Process Step	Hazard Source	Acceptable level of Hazard	Preventive measures for each hazard	Likelihood	Severity	Rating	Significant Risk	Q1	Q2	Q3	Q4	Q5	CCP	Remarks / additional preventive measures
																	1st off Sample
		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-	-	Product undergoes no physical change
		Foreign Objects	None	-	-	-	-	-	-	-	-	-	-	-	-	-	Product undergoes no physical change
		Microbiological	None	-	-	-	-	-	-	-	-	-	-	-	-	-	Product undergoes no physical change No product handling at this step
27	Gusset insertion & Punch Out (Pouch Makers)	Quality	Incorrect Gusset Tooling	I	None	In-Process Control in place: Documented Process Checking	U	Mo	M	N	-	-	-	-	-	-	1st off Sample Documented product specification checks on PLS Job Card Trained personnel
		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-	-	Material safety datasheets available, Post maintenance cleaning in place Food grade (NSF) chemicals used during machine maintenance
		Foreign Objects	Punch Outs Temporary Modification	I	None	In-Process Control in place: Documented Process Checking Foreign Body Contamination Procedure	U	Mo	M	N	-	-	-	-	-	-	Line clearance in place. Cleaning Trained operators. Documented visual product inspection Documented machine check of equipment Process Control checks (PLS)
		Microbiological	None	-	-	-	-	-	-	-	-	-	-	-	-	-	No product handling at this step
28	Zipper insertion, hot seal and cooler bar (Pouch Makers)	Quality	Weak Seal Strength Incorrect Zipper Utilisation. Incorrect direction of Zipper Inserted	I	None	In-Process Control in place: Documented Process Checking	P	Mi	M	N	-	-	-	-	-	-	1st off Sample Labels Documented product specification quality checks on PLS Job Card

HAZARD ANALYSIS

Step #	Process Activity	Potential Product Safety Hazard or Quality defect	List Hazards for each Process Step	Hazard Source	Acceptable level of Hazard	Preventive measures for each hazard	Likelihood	Severity	Rating	Significant Risk	Q1	Q2	Q3	Q4	Q5	CCP	Remarks / additional preventive measures
			Brittle seal from high heat causing zipper to tear														Trained personnel Process specifications on Job Card
		Chemical	If applicable -Possible leaking of "descale" solution from cooler bars.	I	None	Food Grade "descale" used if applicable. Maintenance: Condition monitoring	R	L	L	N	-	-	-	-	-	-	Material safety datasheets available. Post maintenance cleaning in place. Food grade (NSF) chemicals used during machine maintenance.
		Foreign Objects	Glass / brittle plastic, Splicing Tape, Teflon strands. Temporary Modification	I	None	Maintenance Procedure in place Glass and brittle plastic procedure in place. In-Process Control in place: Documented Process Checking Foreign Body Contamination Procedure	U	Mo	M	N	-	-	-	-	-	-	Glass and brittle plastics register Teflon inspected as per maintenance plan Incident management Documented visual product inspection Process Control checks (PLS)
		Microbiological	Bacteria from product handling Bacteria from water leaking at connections of pipes to cooler bars from chiller unit.	I	None	Personnel Hygiene Procedure & Standard in place Housekeeping & Cleaning Procedure in place Chemical & Biological Control Procedure in place Water is constantly circulating in the unit. Maintenance: Condition monitoring	R	Mo	M	N	-	-	-	-	-	-	Washing / sanitising of Hands. Hand Wash Basin. Personnel trained on personal hygiene practices Based on this risk assessment the water used in the hand washing facilities is tested on an annual basis. Annual validation of hand washing by swab tests Environmental Monitoring Plan.
29	Cross seal – Gusset & Straight Seals & Cooler Bars (Pouch Makers)	Quality	Weak Seal Strength	I	None	In-Process Control in place: Documented Process Checking	U	Mo	M	N	-	-	-	-	-	-	1st off Sample Job Card Documented product specification quality checks on PLS

HAZARD ANALYSIS

Step #	Process Activity	Potential Product Safety Hazard or Quality defect	List Hazards for each Process Step	Hazard Source	Acceptable level of Hazard	Preventive measures for each hazard	Likelihood	Severity	Rating	Significant Risk	Q1	Q2	Q3	Q4	Q5	CCP	Remarks / additional preventive measures
																	Trained personnel Pre-Start Up Checklist as per PLS
		Chemical	If applicable -Possible leaking of "descale" solution from cooler bars.	I	None	Food Grade "descale" used if applicable. Maintenance: Condition monitoring	R	L	L	N	-	-	-	-	-	-	Material safety datasheets available. Post maintenance cleaning in place. Food grade (NSF) chemicals used during machine maintenance.
		Foreign Objects	Glass / brittle plastic Jewellery Temporary Modification	I	None	Maintenance Procedure in place Glass and brittle plastic procedure in place. In-Process Control in place: Documented Process Checking Personal Hygiene Standard in place. Foreign Body Contamination Procedure	R	Mo	M	N	-	-	-	-	-	-	Glass and brittle plastics register Teflon change as per maintenance plan Incident management Documented visual product inspection Process Control checks (PLS)
		Microbiological	Bacteria from water leaking at connections of pipes to cooler bars from chiller unit.	I	None	Water is constantly circulating in the unit. Maintenance: Condition monitoring	R	L	L	N	-	-	-	-	-	-	Environmental Monitoring Plan. Water Testing
30	Trim (Pouch Makers)	Quality	Sharpness of blade	P	None	In-Process Control in place: Documented Process Checking	R	L	L	N	-	-	-	-	-	-	Change Blade when blunt as seen on Blade register Pre-start up blade inspection at each shift handover Documented product quality checks
		Quality	Incorrect Height of Pouch	I	-+1mm	In-Process Control in place: Documented Process Checking	P	L	L	N	-	-	-	-	-	-	Job Card. In process inspection plan 1st off Sample.
		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-	-	Material safety datasheets available, Post maintenance cleaning in place Food grade (NSF) chemicals used during machine maintenance

HAZARD ANALYSIS

Step #	Process Activity	Potential Product Safety Hazard or Quality defect	List Hazards for each Process Step	Hazard Source	Acceptable level of Hazard	Preventive measures for each hazard	Likelihood	Severity	Rating	Significant Risk	Q1	Q2	Q3	Q4	Q5	CCP	Remarks / additional preventive measures
		Foreign Objects	Glass / brittle plastic, blade chips, Jewellery Temporary Modification	I	None	In-Process Control in place: Documented Process Checking Personal Hygiene Standard in place Foreign Body Contamination Procedure	R	Mo	M	N	-	-	-	-	-	-	Set-up checklist Glass and brittle plastics register Planned maintenance Blade & Knife Register Incident management. Documented visual product inspection Process Control checks (PLS)
		Microbiological	None			No product handling at this step	-	-	-	-	-	-	-	-	-	-	No product handling at this step
31	Zipper Crush Seal (Pouch Makers)	Quality	Weak Seal Strength Zipper deformed	I	None	In-Process Control in place: Documented Process Checking	P	Mi	M	N	-	-	-	-	-	-	Water Test. 1st off Sample Documented product quality checks Pre-Start Up Checklist as per PLS
		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-	-	Material safety datasheets available, Post maintenance cleaning in place Food grade (NSF) chemicals used during machine maintenance
		Foreign Objects	Glass / brittle plastic, Jewellery Temporary Modification	I	None	In-Process Control in place: Documented Process Checking Glass and brittle plastic procedure in place. Housekeeping & Cleaning Procedure in place Personal Hygiene Standard in place Foreign Body Contamination Procedure	R	Mo	M	N	-	-	-	-	-	-	Glass and brittle plastics register. Cleaning Incident management. Set-up checklist Documented visual product inspection Process Control checks (PLS)
		Microbiological	None	-	-	-	-	-	-	-	-	-	-	-	-	-	No product handling at this step
32	3-point Seal (Pouch Makers)	Quality	Weak Seal. Strength	I	None	In-Process Control in place: Documented Process Checking	U	Mo	M	N	-	-	-	-	-	-	In process Inspection Plan Water Test. Quality Control. 1st off Sample

HAZARD ANALYSIS

Step #	Process Activity	Potential Product Safety Hazard or Quality defect	List Hazards for each Process Step	Hazard Source	Acceptable level of Hazard	Preventive measures for each hazard	Likelihood	Severity	Rating	Significant Risk	Q1	Q2	Q3	Q4	Q5	CCP	Remarks / additional preventive measures
																	Documented product quality checks Pre-Start Up Checklist as per PLS
		Chemical	None	-	-	-	-	-	--	-	-	-	-	-	-	-	Material safety datasheets available, Post maintenance cleaning in place Food grade (NSF) chemicals used during machine maintenance
		Foreign Objects	Glass / brittle plastic, Jewellery Temporary Modification	I	None	In-Process Control in place: Documented Process Checking Glass and brittle plastic procedure in place. Housekeeping & Cleaning Procedure in place Personal Hygiene Standard in place Foreign Body Contamination Procedure	R	Mo	M	N	-	-	-	-	-	-	Glass and brittle plastics. Incident management. Set-up checklist Documented visual product inspection Process Control checks (PLS)
		Microbiological	None	-	-	-	-	-	-	-	-	-	-	-	-	-	No product handling at this step
33	Side seal & Cooler Bars (Pouch Makers)	Quality	Weak Seal Strength	I	None	In-Process Control in place: Documented Process Checking	U	Mi	M	N	-	-	-	-	-	-	1st off Sample , Documented product quality checks Pre-Start Up Checklist as per PLS
		Chemical	If applicable -Possible leaking of "descale" solution from cooler bars.	I	None	Food Grade "descale" used if applicable. Maintenance: Condition monitoring	R	L	L	N	-	-	-	-	-	-	Material safety datasheets available. Post maintenance cleaning in place. Food grade (NSF) chemicals used during machine maintenance.
		Foreign Objects	Glass / brittle plastic, Jewellery Temporary Modification	I	None	In-Process Control in place: Documented Process Checking Glass and brittle plastic procedure in place. Housekeeping & Cleaning Procedure in place Personal Hygiene Standard in place	R	Mo	M	N	-	-	-	-	-	-	Glass and brittle plastics Register Cleaning Incident management. Documented visual product inspection Process Control checks (PLS)

HAZARD ANALYSIS

Step #	Process Activity	Potential Product Safety Hazard or Quality defect	List Hazards for each Process Step	Hazard Source	Acceptable level of Hazard	Preventive measures for each hazard	Likelihood	Severity	Rating	Significant Risk	Q1	Q2	Q3	Q4	Q5	CCP	Remarks / additional preventive measures
						Foreign Body Contamination Procedure											
		Microbiological	Bacteria from water leaking at connections of pipes to cooler bars from chiller unit.	I	None	Water is constantly circulating in the unit. Maintenance: Condition monitoring	R	L	L	N	-	-	-	-	-	-	Environmental Monitoring Plan. Water Testing
34	Features: Tear nick; Euro slot, rounded corners (Pouch Makers)	Quality	Not as per specification	I	None	In-Process Control in place: Documented Process Checking	U	Mo	M	N	-	-	-	-	-	-	Job Card 1st Off Sample Train Personnel. Documented product specification quality checks on PLS
		Chemical	None	-	-	-	-	-	--	-	-	-	-	-	-	-	Material safety datasheets available, Post maintenance cleaning in place Food grade (NSF) chemicals used during machine maintenance
		Foreign Objects	Glass / brittle plastic, Punch Chips, Jewellery Temporary Modification	I	None	In-Process Control in place: Documented Process Checking Glass and brittle plastic procedure in place. Housekeeping & Cleaning Procedure in place Personal Hygiene Standard in place Foreign Body Contamination Procedure	R	Mo	M	N	-	-	-	-	-	-	Glass and brittle plastics register Incident management Documented visual product inspection Process Control checks (PLS)
		Microbiological	None	-	-	-	-	-	-	-	-	-	-	-	-	-	No product handling at this step
35	Straight middle cut at end (Pouch Makers)	Quality	Incorrect Height	I	+-1mm	In-Process Control in place: Documented Process Checking	P	Mi	M	N	-	-	-	-	-	-	Job Card 1st Off Sample Train Personnel. Documented product specification quality checks on PLS
		Quality	Sharpness of blade	I	None	In-Process Control in place: Documented Process Checking	P	L	L	N	-	-	-	-	-	-	Change Blade when blunt

HAZARD ANALYSIS

Step #	Process Activity	Potential Product Safety Hazard or Quality defect	List Hazards for each Process Step	Hazard Source	Acceptable level of Hazard	Preventive measures for each hazard	Likelihood	Severity	Rating	Significant Risk	Q1	Q2	Q3	Q4	Q5	CCP	Remarks / additional preventive measures
																	Pre-start up inspection of blades at shift handover 1st off Sample. Documented product quality checks
		Chemical	None	-	-	-	-	-	--	-	-	-	-	-	-	-	Material safety datasheets available, Post maintenance cleaning in place Food grade (NSF) chemicals used during machine maintenance
		Foreign Objects	Glass / brittle plastic, blade chips, Jewellery Temporary Modification	I	None	In-Process Control in place: Documented Process Checking Glass and brittle plastic procedure in place. Personal Hygiene Standard in place Foreign Body Contamination Procedure	R	Mo	M	N	-	-	-	-	-	-	Glass and brittle plastics register Incident management. Documented visual product inspection Pre-start up inspection of blades at shift handover Pouch is sealed at this stage Process Control checks (PLS)
		Microbiological	None	-	-	-	-	-	--	-	-	-	-	-	-	-	No product handling at this step
36	Final cut into a pouch (Pouch Makers)	Quality	Size of Seals	I	+-1mm	In-Process Control in place: Documented Process Checking	U	L	L	N	-	-	-	-	-	-	1st off Sample. Job Card Trained Personnel Visual Check Documented product specification quality checks on PLS
		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-	-	Material safety datasheets available, Post maintenance cleaning in place Food grade (NSF) chemicals used during machine maintenance

HAZARD ANALYSIS

Step #	Process Activity	Potential Product Safety Hazard or Quality defect	List Hazards for each Process Step	Hazard Source	Acceptable level of Hazard	Preventive measures for each hazard	Likelihood	Severity	Rating	Significant Risk	Q1	Q2	Q3	Q4	Q5	CCP	Remarks / additional preventive measures
		Foreign Objects	Glass / brittle plastic, blade chips from cutter Jewellery blade. Temporary Modification	I	None	In-Process Control in place: Documented Process Checking Glass and brittle plastic procedure in place. Maintenance procedure in place Personal Hygiene Standard in place Sharps Policy Foreign Body Contamination Procedure	R	Mo	M	N	-	-	-	-	-	-	Glass and brittle plastics register Incident management. Documented visual product inspection Pre-start up inspection of blades at shift handover Pouch is sealed at this stage Process Control checks (PLS)
		Microbiological	None	-	-	-	-	-	-	-	-	-	-	-	-	-	No product handling at this step
37	Product checked for defects (Pouch Makers)	Quality	Incorrect Specification	P	None	In-Process Control in place: Documented Process Checking	P	Mi	M	N	-	-	-	-	-	-	Job Card 1st off Sample. Train Personnel Documented product quality checks on PLS Bright Lights above machines.
		Chemical	None	-	-	-	-	-	--	-	-	-	-	-	-	-	No chemicals used at this process step
		Foreign Objects	Glass / brittle plastic, Jewellery, blades, pests Temporary Modification *Gusset / Side Seal Integrity i.e., @ 3 point. *Gusset Seal Integrity *Misprint Ink Splash - Supplied as such from Supplier *Side Seal Integrity *Non adhesion caused by NC material from Supplier	I	None	In-Process Control in place: Documented Process Checking Glass and brittle plastic procedure in place. Sharps Policy Personal Hygiene Standard in place Pest control procedure in place Foreign Body Contamination Procedure	U	Mo	M	N	-	-	-	-	-	- -	Glass and brittle plastics register. Incident management. Pre-start-up checklist Documented visual product inspection Pouch is sealed at this stage Process Control checks (PLS) Bright Lights above machines.

HAZARD ANALYSIS

Step #	Process Activity	Potential Product Safety Hazard or Quality defect	List Hazards for each Process Step	Hazard Source	Acceptable level of Hazard	Preventive measures for each hazard	Likelihood	Severity	Rating	Significant Risk	Q1	Q2	Q3	Q4	Q5	CCP	Remarks / additional preventive measures
			*Channel Leaker - Zipper Crusher Seal *Clarity of Clear Material *Delamination of Material *Lines / Creases / Scuff Marks *Round corner punch not aligned correctly. *Weak Zipper Strength - Product Side *Gusset Punch not to Register *Zipper not Locking														
		Microbiological	Bacteria from product handling	I	None	Personnel Hygiene Procedure & Standard in place Housekeeping & Cleaning Procedure in place Chemical & Biological Control Procedure in place	U	Mo	M	N	-	-	-	-	-	-	Product is handled on outside. Washing / sanitising of Hands Hand Wash Basin. Inspected sample used as retention. Based on this risk assessment the water used in the hand washing facilities is tested on an annual basis. Annual validation of hand washing by swab tests
38	Liners are placed into cartons to pack finished goods. Cartons sealed with clear tape for storage and distribution. (Pouch Makers)	Quality	Malicious intervention Counting Scales set incorrectly.	I	None	Transport, storage and distribution procedure in place Security procedure in place Calibration Procedure Training	R	Mo	M	N	-	-	-	-	-	-	Product labelling Traceability procedure in place Access control Visitors' registers Product is secure in corrugated box with plastic liner

HAZARD ANALYSIS

Step #	Process Activity	Potential Product Safety Hazard or Quality defect	List Hazards for each Process Step	Hazard Source	Acceptable level of Hazard	Preventive measures for each hazard	Likelihood	Severity	Rating	Significant Risk	Q1	Q2	Q3	Q4	Q5	CCP	Remarks / additional preventive measures
		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-	-	No chemicals used at this process step Verification of accuracy of counting scale Trained Personnel
		Foreign Objects	-Pests, dirt, glass and brittle plastic, Jewellery -Counting Scales Charger Plug Breaks. -Plastic and Sharps from Broken Tape Gun	I	None	Personal Hygiene Standard in place Glass and brittle plastic procedure in place. Housekeeping & Cleaning Procedure in place Pest control procedure in place Incident Reporting	U	Mo	M	N	-	-	-	-	-	-	Glass and brittle plastics register. Incident management. Bright Lights above Machines.
		Microbiological	Bacteria from product handling	I	None	Personnel Hygiene Procedure & Standard in place Chemical & Biological Control Procedure in place	R	Mo	M	N	-	-	-	-	-	-	Product is handled on outside Carton sealed once full Carton Liners Glass and brittle plastics register Personnel trained on personal hygiene practices Based on this risk assessment the water used in the hand washing facilities is tested on an annual basis. Hand Wash Basin. Annual validation of hand washing by swab tests
39	Storage and Processing of waste: Waste (Machine Waste, set-up, running and off-cut) removed and stored for removal (Pouch Maker).	Quality	Fraudulent use of trademark waste	I	None	Waste Management Procedure in place	U	Mo	M	N	-	-	-	-	-	-	Trademark waste is rendered unusable through an in-house destruction process.
		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-	-	No chemicals used at this process step
		Foreign Objects	Punch Outs Pieces of Trim.	P	None	In-Process Control in place: Documented Process Checking Waste management procedure in place	P	Mi	M	N	-	-	-	-	-	-	Line Clearance as per PLS Trained Personnel Initials Line Clearance on PLS

HAZARD ANALYSIS

Step #	Process Activity	Potential Product Safety Hazard or Quality defect	List Hazards for each Process Step	Hazard Source	Acceptable level of Hazard	Preventive measures for each hazard	Likelihood	Severity	Rating	Significant Risk	Q1	Q2	Q3	Q4	Q5	CCP	Remarks / additional preventive measures
	Baling Process	Microbiological	None	-	-	-	-	-	--	-	-	-	-	-	-	-	No product handling at this step
40	Return Raw Material to Stores (Pouch Makers)	Quality	Untraceable product, incorrect labelling Malicious intervention	I	None	Traceability procedure in place Transport, storage and distribution procedure in place Security procedure in place	U	Mo	M	N	-	-	-	-	-	-	Return to store labels Access control Visitors' registers Product is protected covered with blue liner, slip sheets on pallets
		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-	-	Material safety datasheets available, Post maintenance cleaning in place Food grade (NSF) chemicals used during machine maintenance. No Chemicals used at this step.
		Foreign Objects	Damaged pallets cause wood chips, pests. Jewellery,	P	None	Transport, storage and distribution procedure in place Housekeeping & Cleaning Procedure in place Pest Control procedure in place Personal Hygiene Standard in place	U	Mo	M	N	-	-	-	-	-	-	Product protection Product undergoes no physical change
		Microbiological	Bacteria from product handling	I	None	Personnel Hygiene Procedure & Standard in place Housekeeping & Cleaning Procedure in place Chemical & Biological Control Procedure in place	U	Mo	M	N	-	-	-	-	-	-	Material handled so that the surface that comes into contact with hands and equipment does not come into contact with food. Hands are sanitised. Based on this risk assessment the water used in the hand washing facilities is tested on an annual basis. Annual validation of hand washing by swab tests

HAZARD ANALYSIS

Step #	Process Activity	Potential Product Safety Hazard or Quality defect	List Hazards for each Process Step	Hazard Source	Acceptable level of Hazard	Preventive measures for each hazard	Likelihood	Severity	Rating	Significant Risk	Q1	Q2	Q3	Q4	Q5	CCP	Remarks / additional preventive measures
41	Finished Cartons or WiP Packed in Goods Store (Pouch Makers)	Quality	Malicious intervention	I	None	Transport, storage and distribution procedure in place Security procedure in place	R	Mo	M	N	-	-	-	-	-	-	Product labelling Traceability procedure in place Access control Visitors' registers Product is secure in corrugated box with plastic liner
		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-	-	Material safety datasheets available, Post maintenance cleaning in place Food grade (NSF) chemicals used during machine maintenance. No Chemicals used at this step.
		Foreign Objects	None	-	-	-	-	-	-	-	-	-	-	-	-	-	Product is stored in designated area. Cleaning in place, Pest control in place Good Storage practices Product protection with corrugate and liner.
		Microbiological	None	-	-	-	-	-	-	-	-	-	-	-	-	-	Corrugated & Liners used. Product Protection
42	Job Card Generation (Spout Inserter Machines)	Quality	Incorrect specifications	I	None	Specifications procedure in place	U	Mo	M	N	-	-	-	-	-	-	Approval of Specifications by customer. Trained personnel generating job card Job Card. Product undergoes no physical change
		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-	-	Product undergoes no physical change
		Foreign Objects	None	-	-	-	-	-	-	-	-	-	-	-	-	-	Product undergoes no physical change

HAZARD ANALYSIS

Step #	Process Activity	Potential Product Safety Hazard or Quality defect	List Hazards for each Process Step	Hazard Source	Acceptable level of Hazard	Preventive measures for each hazard	Likelihood	Severity	Rating	Significant Risk	Q1	Q2	Q3	Q4	Q5	CCP	Remarks / additional preventive measures
		Microbiological	None	-	-	-	-	-	-	-	-	-	-	-	-	-	Product undergoes no physical change
43	Caps counted & packed into liners	Quality	*Incorrect Caps for Spouts supplied in Cartons of Spouted pouches.	-	-	Trained Personnel	-	-	-	-	-	-	-	-	-	-	-
		Chemical	None	-	-		-	-	-	-	-	-	-	-	-	-	
		Foreign Objects	Glass, wood splinters, dust as outer packaging is removed. Jewellery, pests	I / P	None	WI for spout inserting Glass and brittle plastic procedure in place. Housekeeping & Cleaning procedure in place Pest control procedure in place	U	Mo	M	N	-	-	-	-	-	-	
		Microbiological	Bacteria from product handling	I	None	WI for spout inserting Personnel Hygiene Procedure & Standard in place Housekeeping & Cleaning Procedure in place Chemical & Biological Control Procedure in place	U	Mo	M	N	-	-	-	-	-	-	Washing / sanitising of Hands Hand Wash Basin. Personnel trained on personal hygiene practices. Annual validation of hand washing by swab tests
44	Raw Material and WiP issued to Spout inserter (Spout Inserter Machines) as per Job card	Quality	Incorrect WIP loaded onto machine as per job card and allocation	I	None	In-Process Control in place: Documented Process Checking	R	Mo	M	N	-	-	-	-	-	-	Short Interval Control & Job Card initial. Raw material identifiable. Trained personnel. Labels Job Card Product undergoes no physical change
		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-	-	Material safety datasheets available, Post maintenance cleaning in place Food grade (NSF) chemicals used during machine maintenance.

HAZARD ANALYSIS

Step #	Process Activity	Potential Product Safety Hazard or Quality defect	List Hazards for each Process Step	Hazard Source	Acceptable level of Hazard	Preventive measures for each hazard	Likelihood	Severity	Rating	Significant Risk	Q1	Q2	Q3	Q4	Q5	CCP	Remarks / additional preventive measures
																	No Chemicals used at this step.
		Foreign Objects	Glass, wood splinters, dust as outer packaging is removed. Jewellery, pests	I	None	Glass and brittle plastic procedure in place. Housekeeping & Cleaning procedure in place Pest control procedure in place	R	Mo	M	N	-	-	-	-	-	-	Pallets are inspected and covered with Slip sheets Spouts have liner protecting them in corrugate: Product protection. Product undergoes no physical change
		Microbiological	Bacteria from product handling	I	None	Personnel Hygiene Procedure & Standard in place Housekeeping & Cleaning Procedure in place Chemical & Biological Control Procedure in place	U	Mo	M	N	-	-	-	-	-	-	Washing / sanitising of Hands Hand Wash Basin. Personnel trained on personal hygiene practices. WIP handled so that the surface that comes into contact with hands and equipment does not come into contact with food. Based on this risk assessment the water used in the hand washing facilities is tested on an annual basis. Annual validation of hand washing by swab tests
45	WiP Pouches loaded into Spout Machine (Spout Inserter Machines)	Quality	Incorrect WIP loaded onto machine as per job card and allocation. WIP Pouches loaded in incorrect direction resulting in incomplete top seal	I	None	In-Process Control in place: Documented Process Checking	P	Mi	M	N	-	-	-	-	-	-	Raw material & WIP identifiable 1st off.
		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-	-	Material safety datasheets available,

HAZARD ANALYSIS

Step #	Process Activity	Potential Product Safety Hazard or Quality defect	List Hazards for each Process Step	Hazard Source	Acceptable level of Hazard	Preventive measures for each hazard	Likelihood	Severity	Rating	Significant Risk	Q1	Q2	Q3	Q4	Q5	CCP	Remarks / additional preventive measures
																	Post maintenance cleaning in place Food grade (NSF) chemicals used during machine maintenance. No Chemicals used at this step.
		Foreign Objects	Glass / brittle plastic. Jewellery, Blades Temporary Modification	I	None	Glass and brittle plastic procedure in place. Personal Hygiene Standard in place Sharps Policy Foreign Body Contamination Procedure	R	Mo	M	N	-	-	-	-	-	-	Pouches are sealed when issued. Pouches deemed fit for use from previous process (DMF & AMJ) Process Control checks (PLS)
		Microbiological	Bacteria from product handling	I	None	Personnel Hygiene Procedure & Standard in place Housekeeping & Cleaning Procedure in place Chemical & Biological Control Procedure in place	U	Mo	M	N	-	-	-	-	-	-	Washing / sanitising of Hands Hand Wash Basin. Personnel trained on personal hygiene practices WIP handled so that the surface that comes into contact with hands and equipment does not come into contact with food. Based on this risk assessment the water used in the hand washing facilities is tested on an annual basis. Annual validation of hand washing by swab tests
46	Spouts fitments loaded into vibration bowl (Spout Inserter Machines)	Quality	Incorrect material loaded onto machine as per job card and allocation	I	None	In-Process Control in place: Documented Process Checking	R	Mo	M	N	-	-	-	-	-	-	Raw material identified Only one spouts fitment size being utilised. 1st off Sample Short Interval Control (PLS), later process.
		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-	-	Material safety datasheets available,

HAZARD ANALYSIS

Step #	Process Activity	Potential Product Safety Hazard or Quality defect	List Hazards for each Process Step	Hazard Source	Acceptable level of Hazard	Preventive measures for each hazard	Likelihood	Severity	Rating	Significant Risk	Q1	Q2	Q3	Q4	Q5	CCP	Remarks / additional preventive measures
																	Post maintenance cleaning in place Food grade (NSF) chemicals used during machine maintenance. No Chemicals used at this step.
		Foreign Objects	Glass / brittle plastic. Dust & Hair. Jewellery, blades, pests Temporary Modification	I	None	Glass and brittle plastic procedure in place. Housekeeping & Cleaning Procedure in place Personnel Hygiene Procedure & Standard in place Sharps Policy Pest control procedure in place Foreign Body Contamination Procedure	R	Mo	M	N	-	-	-	-	-	-	Glass and Brittle plastics register. Incident management. Spouts have liner protecting them in corrugate: Product protection Process Control checks (PLS)
		Microbiological	Bacteria from product handling	I	None	Personnel Hygiene Procedure & Standard in place Housekeeping & Cleaning Procedure in place Chemical & Biological Control Procedure in place	U	Mo	M	N	-	-	-	-	-	-	Washing / sanitising of Hands Hand Wash Basin. Personnel trained on personal hygiene practices Based on this risk assessment the water used in the hand washing facilities is tested on an annual basis. Annual validation of hand washing by swab tests
47	Set PLC specifications (Spout Inserter Machines)	Quality	None			-	-	-	-	-	-	-	-	-	-	-	Product undergoes no physical change
		Chemical	None			-	-	-	-	-	-	-	-	-	-	-	Product undergoes no physical change
		Foreign Objects	None			-	-	-	-	-	-	-	-	-	-	-	Product undergoes no physical change
		Microbiological	None			-	-	-	-	-	-	-	-	-	-	-	Product undergoes no physical change

HAZARD ANALYSIS

Step #	Process Activity	Potential Product Safety Hazard or Quality defect	List Hazards for each Process Step	Hazard Source	Acceptable level of Hazard	Preventive measures for each hazard	Likelihood	Severity	Rating	Significant Risk	Q1	Q2	Q3	Q4	Q5	CCP	Remarks / additional preventive measures
48	Pouch Pick (Spout Inserter Machines)	Quality	None			-	-	-	-	-	-	-	-	-	-	-	Product undergoes no physical change
		Chemical	None			-	-	-	-	-	-	-	-	-	-	-	Product undergoes no physical change
		Foreign Objects	None			-	-	-	-	-	-	-	-	-	-	-	Product undergoes no physical change
		Microbiological	None			-	-	-	-	-	-	-	-	-	-	-	Product undergoes no physical change
49	Angle Cut (Spout Inserter Machines)	Quality	Angle of cut incorrect	I	None	In-Process Control in place: Documented Process Checking	U	L	L	N	-	-	-	-	-	-	1st off Sample, Trained Personnel
		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-	-	Material safety datasheets available, Post maintenance cleaning in place Food grade (NSF) chemicals used during machine maintenance. No Chemicals used at this step.
		Foreign Objects	Glass / brittle plastic, blade chips, pouch cut-off Jewellery	I	None	Glass and brittle plastic procedure in place In-Process Control in place: Documented Process Checking Personal Hygiene Standard in place Sharps Policy	R	Mo	M	N	-	-	-	-	-	- -	Incident management. Pre-start-up checklist Cut-off slide
		Microbiological	None	-	-	-	-	-	-	-	-	-	-	-	-	-	No product handling at this step
50	Spout Pick (Spout Inserter Machines)	Quality	None	-	-	-	-	-	-	-	-	-	-	-	-	-	No product handling at this step
		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-	-	No product handling at this step
		Foreign Objects	None	-	-	-	-	-	-	-	-	-	-	-	-	-	No product handling at this step
		Microbiological	None	-	-	-	-	-	-	-	-	-	-	-	-	-	No product handling at this step
51	Pouch Open (Spout Inserter Machines)	Quality	None	-	-	-	-	-	-	-	-	-	-	-	-	-	No product handling at this step
		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-	-	No product handling at this step
		Foreign Objects	None	-	-	-	-	-	-	-	-	-	-	-	-	-	No product handling at this step
		Microbiological	None	-	-	-	-	-	-	-	-	-	-	-	-	-	No product handling at this step
52		Quality	Weak Seal: Product may leak.	I	None	In-Process Control in place: Documented Process Checking	U	Mo	M	N	-	-	-	-	-	-	PLS maintains constant heat.

HAZARD ANALYSIS

Step #	Process Activity	Potential Product Safety Hazard or Quality defect	List Hazards for each Process Step	Hazard Source	Acceptable level of Hazard	Preventive measures for each hazard	Likelihood	Severity	Rating	Significant Risk	Q1	Q2	Q3	Q4	Q5	CCP	Remarks / additional preventive measures
																	Automatically stops machine if variation of heat Water Test. 1st off Sample
	First sealing, 1 & 2 (Spout Inserter Machines)	Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-	-	Material safety datasheets available, Post maintenance cleaning in place Food grade (NSF) chemicals used during machine maintenance. No Chemicals used at this step.
		Foreign Objects	None	-	-	-	-	-	-	-	-	-	-	-	-	-	Product is sealed completely.
		Microbiological	None	-	-	-	-	-	-	-	-	-	-	-	-	-	Product does not come into contact with machine. Only outside of product.
53	Hot seal 1 & 2 (Spout Inserter Machines)	Quality	Weak Seal: Product may leak.	I	None	In-Process Control in place: Documented Process Checking	U	Mo	M	N	-	-	-	-	-	-	PLS maintains constant heat. Automatically stops machine if variation of heat. Water Test. 1st off Sample
		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-	-	Material safety datasheets available, Post maintenance cleaning in place Food grade (NSF) chemicals used during machine maintenance. No Chemicals used at this step.
		Foreign Objects	None	-	-	-	-	-	-	-	-	-	-	-	-	-	Product is sealed completely.
		Microbiological	None	-	-	-	-	-	-	-	-	-	-	-	-	-	Product does not come into contact with machine. Only outside of product. Product is sealed completely.

HAZARD ANALYSIS

Step #	Process Activity	Potential Product Safety Hazard or Quality defect	List Hazards for each Process Step	Hazard Source	Acceptable level of Hazard	Preventive measures for each hazard	Likelihood	Severity	Rating	Significant Risk	Q1	Q2	Q3	Q4	Q5	CCP	Remarks / additional preventive measures
54	Hot seal 3 & 4 (Spout Inserter Machines)	Quality	Weak Seal Strength	I	None	In-Process Control in place: Documented Process Checking	U	Mo	M	N	-	-	-	-	-	-	Water Test. 1st off Sample
		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-	-	Material safety datasheets available, Post maintenance cleaning in place Food grade (NSF) chemicals used during machine maintenance. No Chemicals used at this step.
		Foreign Objects	None	-	-	-	-	-	-	-	-	-	-	-	-	-	Product is sealed completely.
		Microbiological	None	-	-	-	-	-	-	-	-	-	-	-	-	-	Product does not come into contact with machine. Only outside of product. Product is sealed completely.
55	Cold Seal 1 & 2 (Spout Inserter Machines)	Quality	Appearance of Seal.	I	None	In-Process Control in place: Documented Process Checking	U	Mo	M	N	-	-	-	-	-	-	Water Test. 1st off Sample Visual Check.
		Chemical	If applicable -Possible leaking of "descale" solution from cooler bars.	I	None	Food Grade "descale" used if applicable. Maintenance: Condition monitoring	R	L	L	N	-	-	-	-	-	-	Material safety datasheets available. Post maintenance cleaning in place. Food grade (NSF) chemicals used during machine maintenance.
		Foreign Objects	None	-	-	-	-	-	-	-	-	-	-	-	-	-	Product is sealed completely.
		Microbiological	Bacteria from water leaking at connections of pipes to cooler bars from chiller unit.	I	None	Water is constantly circulating in the unit. Maintenance: Condition monitoring	R	L	L	N	-	-	-	-	-	-	Product does not come into contact with machine. Only outside of product. Product is sealed completely. Environmental Monitoring Plan. Water Testing
56	Checked for defects (Spout Inserter Machines)	Quality	Incorrect Specification	P	None	In-Process Control in place: Documented Process Checking	P	Mi	M	N	-	-	-	-	-	-	1st off Sample. Trained Personnel Bright Lights above machines.

HAZARD ANALYSIS

Step #	Process Activity	Potential Product Safety Hazard or Quality defect	List Hazards for each Process Step	Hazard Source	Acceptable level of Hazard	Preventive measures for each hazard	Likelihood	Severity	Rating	Significant Risk	Q1	Q2	Q3	Q4	Q5	CCP	Remarks / additional preventive measures
		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-	-	No chemicals used at this process step
		Foreign Objects	Glass / brittle plastic, Jewellery, pests *Incorrect Dimensions – Height *Pouches of another dimension mixed with others. *Top Seal Integrity - Inadequate Seal Strength *Spout Seal Integrity	I	None	Glass and brittle plastic procedure in place In-Process Control in place: Documented Process Checking Personal Hygiene Standard in place Pest control procedure in place	U	Mo	M	N	-	-	-	-	-	-	Incident management Bright Lights above machines.
		Microbiological	Bacteria from product handling	I	None	Personnel Hygiene Procedure & Standard in place Housekeeping & Cleaning Procedure in place Chemical & Biological Control Procedure in place	U	Mo	M	N	-	-	-	-	-	-	Washing / sanitising of Hands Hand Wash Basin. Based on this risk assessment the water used in the hand washing facilities is tested on an annual basis. Annual validation of hand washing by swab tests
57	Liners are placed into cartons to pack finished goods. Cartons sealed with clear tape for storage and distribution. (Spout Inserter Machines)	Quality	Malicious intervention *Incorrect Caps for Spouts supplied in Cartons of Spouted pouches. *Counting Scales set incorrectly.	I	None	Transport, storage and distribution procedure in place Security procedure in place Training Calibration Procedure	R	Mo	M	N	-	-	-	-	-	-	Product labelling Traceability procedure in place Access control Visitors' registers Product is secure in corrugated box with plastic liner Bright Lights above machines. Trained Personnel Verification for accuracy of scales
		Chemical	None	-	-	-	-	-	--	-	-	-	-	-	-	-	No chemicals used at this process step

HAZARD ANALYSIS

Step #	Process Activity	Potential Product Safety Hazard or Quality defect	List Hazards for each Process Step	Hazard Source	Acceptable level of Hazard	Preventive measures for each hazard	Likelihood	Severity	Rating	Significant Risk	Q1	Q2	Q3	Q4	Q5	CCP	Remarks / additional preventive measures
		Foreign Objects	Pests, dirt, glass and brittle plastic, Jewellery , blades, pests. Charger Plug for Counting Scales Plastic and Sharps from Broken Tape Gun	I	None	Glass and brittle plastic procedure in place Housekeeping & Cleaning Procedure in place Sharps Policy Personnel Hygiene Procedure & Standard in place Pest control procedure in place Incident Reporting	U	Mo	M	N	-	-	-	-	-	-	Product is handled on outside Carton sealed once full Carton Liners Glass and brittle plastics register Personnel trained on personal hygiene practices Bright Lights above machines.
		Microbiological	Bacteria from product handling	I	None	Personnel Hygiene Procedure & Standard in place Chemical & Biological Control Procedure in place	U	Mo	M	N	-	-	-	-	-	-	Washing / sanitising of Hands Hand Wash Basin. Based on this risk assessment the water used in the hand washing facilities is tested on an annual basis. Annual validation of hand washing by swab tests
58	Storage and Processing of waste: Waste (Machine Waste, set-up, running and off-cut) removed and stored for removal (Spout Inserter Machines) . Baling Process	Quality	Fraudulent use of trademark waste	I	None	Waste Management Procedure in place	U	Mo	M	N	-	-	-	-	-	-	Trademark waste is rendered unusable through an in-house destruction process.
		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-	-	No chemicals used at this process step
		Foreign Objects	Punch Outs Pieces of Trim	P	None	In-Process Control in place: Documented Process Checking Waste Management Procedure in place	P	Mi	M	N							
		Microbiological	None	-	-	-	-	-	-	-	-	-	-	-	-	-	No product handling at this step
59	Palletise / shrink wrap	Quality	None	-	-	-	-	-	-	-	-	-	-	-	-	-	Product labelled
		Chemical	None	-	-	-	-	-	-	-	-	-	-	-	-	-	Product is stored in designated area. Cleaning in place, Good Storage practices
		Foreign Objects	None	-	-	-	-	-	-	-	-	-	-	-	-	-	Product is stored in designated area.

HAZARD ANALYSIS

Step #	Process Activity	Potential Product Safety Hazard or Quality defect	List Hazards for each Process Step	Hazard Source	Acceptable level of Hazard	Preventive measures for each hazard	Likelihood	Severity	Rating	Significant Risk	Q1	Q2	Q3	Q4	Q5	CCP	Remarks / additional preventive measures
																	Cleaning in place, Good Storage practices
		Microbiological	None	-	-	-	-		-	-	-	-	-	-		-	Product is stored in designated area. Cleaning in place, Good Storage practices
60	Storage & Distribution	Quality	Incorrect product dispatched Malicious intervention Product damaged during loading. Foreseeable misuse by the consumer. *Cartons in unacceptable condition upon arrival at customer caused by Freight Company	I	None	Traceability procedure in place Transport, storage and distribution procedure in place Security procedure in place. Specifications Procedure	P	L	L	N	-	-	-	-	-	-	Product clearly identified (Labelled) Picking slip Delivery Note Vehicle inspection before loading, SLA in place with 3rd party transport companies. Product is secure in corrugated box with plastic liner and outer pallet wrap if 3rd party transport Trained forklift operators Pouch Specification Forms available. COCs available upon request.
		Chemical	Contamination during transportation. Malicious intervention	I/P	None	Transport, storage and distribution procedure in place Housekeeping & Cleaning Procedure in place Security procedure in place	R	Mo	M	N	-	-	-	-	-	-	Vehicle inspection before loading, SLA in place with 3rd party transport companies. Product is secure in corrugated box with plastic liner and outer pallet wrap if 3rd party transport
		Foreign Objects	Dirt, pests, wood chips. Jewellery, Blades. Malicious intervention Glass/brittle plastic from forklift	I	None	Transport, storage and distribution procedure in place Housekeeping & Cleaning Procedure in place Personal Hygiene Standard in place. Sharps Policy	R	Mo	M	N	-	-	-	-	-	-	Vehicle inspection before loading, SLA in place with 3rd party transport companies.

HAZARD ANALYSIS

Step #	Process Activity	Potential Product Safety Hazard or Quality defect	List Hazards for each Process Step	Hazard Source	Acceptable level of Hazard	Preventive measures for each hazard	Likelihood	Severity	Rating	Significant Risk	Q1	Q2	Q3	Q4	Q5	CCP	Remarks / additional preventive measures
						Security procedure in place Glass and brittle plastic procedure in place											Product is secure in corrugated box with plastic liner and outer pallet wrap if 3rd party transport
		Microbiological	None	-	-	-	-	-	-	-	-	-	-	-	-	-	
61	**Returns:** **Customer Returns:** Complaint Handling procedure/Control of Non-Conforming Product Procedure. **Supplier Returns**: Control of Non-Conforming Product Procedure. Quality.	Quality	Cross contamination	I	None	Control of non-conforming product	U	Mo	M	N	-	-	-	-	-	.	Segregated area for "on hold" product
		Chemical	None		None	-	-	-	-	-	-	-	-	-	-	-	-
		Foreign Objects	Wood Chips, Pests, Glass, Brittle Plastic, Hair, Jewellery, Blades	P	None	Transport, storage and distribution procedure in place Housekeeping & Cleaning Procedure in place Foreign body control in place Pest control procedure in place Personnel Hygiene Procedure & Standard in place Sharps policy.	U	Mo	M	N	-	-	-	-	-	-	Vehicle Inspection Pouches are closed and very unlikely that foreign objects will be introduced into pouch.
		Microbiological	Bacteria from product handling	I	None	Personnel Hygiene Procedure & Standard in place Chemical & Biological Control Procedure in place	U	Mo	M	N	-	-	-	-	-	-	Hand Sanitises. Hand Wash Basin. Part of pouch that is handled is not in contact with food. Based on this risk assessment the water used in the hand washing facilities is tested on an annual basis. Annual validation of hand washing by swab tests

ABNORMAL CONDITIONS CONSIDERED:-	HAZARDS	CONTROL METHOD

NO ABNORMAL CONDITIONS

OUTSOURCES OPERATIONS AND SUBCONTRACTED WORI	HAZARDS	CONTROL METHOD

NO OUTSOURCED OPERATIONS

STEP 8 - Establish critical limits &
STEP 9 - Establish monitoring procedures &
STEP 10 - Establish corrective procedures &
STEP 11 - Establish verification procedures &
STEP 12 - Establish record keeping / documentation &

CRITICAL CONTROL POINT CONTROL CHART

Describe the Hazards to be controlled	**Name CCP**	**CCP Number**
Control Measure for Hazard	**Validation Of Control Method** (refer to Validation study or method)	**Define Critical Limit for CCP**
On line Monitoring Frequency (Hourly, every shift, daily...)	**Results of Ops Monitoring Recorded on Form**	**Responsibility**
Method for Monitoring		**Responsibility**
Remedial And Corrective Action when Critical limits exceeded		**Responsibility**
Verification Method	**Frequency of Verification**	**Responsibility**

No CCP's identified