BRC GLOBAL STANDARD
FOR PACKAGING & PACKAGING MATERIALS

Intertek

Audit Report

Global Standard for Packaging and Packaging Materials Issue 4 : February 2011

1. Audit Summary			
Company Name:	Kanpur Plastipack Limited	Site name:	Kanpur Plastipack Limited
Audit Category:	**High Hygiene Risk**	BRC Site Code:	9864264

2. Results			
Audit Result:	**CERTIFICATED**	Audit Grade:	A
		Audit Frequency :	12 months

3. Audit Detail			
Audit Start Date:	2015-09-14	Audit Finish Date:	2015-09-15
Re-audit Due Date:	2016-09-24	Previous Audit Date:	2014-09-22
Auditor Number (one only : team leader)		Auditor Names	
168057		Ashish Gaur-Lead Auditor	

4. Scope Details	
Packaging Field:	
04 - Plastics	
Select a packaging field	
Select a packaging field	
Select a packaging field	
Scope of Audit:	Cutting, printing, and stitching of flexible Intermediate bulk containers (FIBC) having base size from 50 cm X 50 cm to 120 cm X 120 cm, height from 50 cm to 250 cm, and load bearing capacity from 250 kg to 2000 kg by using laminated/ un-laminated PP fabric and its packing into bales & pallets for food grade applications
Exclusions from Scope:	None
Non-applicable clauses:	
2.3.2, 4.1.6, 4.2.2, 4.2.4, 4.7.7, 5.2.6, 6.3.7	
Products in production at the time of the audit:	
2561 CTR, 2571 CTR, 2389 CTR, U +2, baffle bag, circular x corner loops FIBC respectively	

5. Company Profile

Kanpur Plastipack Ltd has manufacturing locations at 3 places. This scope of this audit was the clean room food grade facility located within one unit. They have a majorly supplying to European countries (which includes countries like Netherlands, UK, Germany, France, and Italy), USA, S. Africa, and Middle East Countries. They produce approximately 6 Million FIBCs per annum. It is an ISO 9001-2008 and ISO 22000 certified Company. They have also implemented AIB requirements. Their Quality Control Department is equipped with a test rig for Bag testing and a Weatherometer for UV testing. Product Types FIBC's which includes Single Loop, double loops and U plus two loops FIBC. Unit was established in 1971 at Kanpur and which is approximately 450 KM from New Delhi (India). Total production capacity is ~ 85 MT per month. It is a Public Limited Company and is managed by a Professional Board of Directors and Managers. The unit is operating in 02 shifts with 60 personnel in each shift. Size of the facility is 1181.5 square meters. Group turnover is more than 25 M INR. Company does not use BRC Logo on any of the product and packaging material.

6. Non Conformity Summary

Summary of Non-Conformity Raised

	No.		No.
Critical non-conformity	0	Major non-conformity	0
Major non-conformity against statement of intent of a fundamental clause	0	Minor non-conformity	4

Critical

No.	Requirement ref.	Detail of Non-Conformity	Proposed audit date	Reviewed by

Major non-conformity against the Statement of Intent of a Fundamental Clause

No.	Requirement ref.	Detail of Non-Conformity	Proposed audit date	Reviewed by

Major

No.	Requirement ref.	Detail of Non-Conformity	Corrective action taken (with consideration of root cause)	Evidence provided Document Photograph Visit/Other	Date signed off	Reviewed by

Minor

No.	Requirement ref.	Detail of Non-Conformity	Corrective action taken (with consideration of root cause)	Evidence provided Document Photograph Visit/Other	Date signed off	Reviewed by
1	2.2.11	There is no evidence that last review of hazard and risk management system covered/ considered **product failures, internal and customer audit results and experience of mock test recall.**	**Root Cause-:** HACCP review is conducted on monthly basis in our organization. Product failure is covered in the process compliance point in the format F-SYS-16B (Monthly HACCP review records). We were not aware of inclusion of Internal and customer audit results and experience of mock test recall in the HACCP monitoring report hence these were not included. Month may not be sufficient to consider these factors for review. Hence one comprehensive review considering these factors was required. **Correction:** Now the format has been modified incorporating all these points. HACCP review for the month of Aug 15 has been carried out again on 19.9.15 after revision of format. **Corrective Action:** Provision is made in the HACCP study to conduct one comprehensive review in a year and the same will be verified during internal audits.	Duly filled Format F-SYS-16B for the month of Aug 15	2015-09-21	Mr. Ashish Gaur
2	3.5.2	Audit of one of the subcontracted unit located at Indore is not performed.	**Root Cause:** Indore supplier has been added recently in the approved supplier list on the basis of supplier's food compliance declaration and approval of samples by QA dept. It happened due to urgency. **Correction:** Supplier's audit was conducted on 17.09.15 by Mr Kamran & Mr SK Saxena. **Corrective Action:** Purchase dept. has been advised by circular for not buying material from any vendor without compliance of standard in future. Purchase procedure is amended for more clarity.	Audit report Circular Amended purchase procedure	2015-09-21	Mr. Ashish Gaur
3	3.9.3	Forward traceability test is not conducted in last one year.	**Root Cause:** Due to some exigencies and project work we could not depute resources for the same. However backward traceability test was conducted. **Correction:** Now Forward Traceability Test (Rec. No: F-SYS-21, Rev. No.: 00 w.e.f. 01.10.2012) has been carried out on 18.9.15. **Corrective Action:** Procedure is amended to conduct it more frequently before each internal audit round where it will be verified specifically..	Record of the forward traceability test Amended traceability procedure	2015-09-21	Mr. Ashish Gaur
4	4.11.5	Catch analysis is not evident in last one year although the program is reviewed and updated and data is being collected.	**Root Cause:** Catch analysis was not done though the data was available. It is a lapse on the part of HR team as their members could not assess the importance of the same. **Correction:** Now, catch analysis has been conducted. **Corrective Action Taken:** HR dept.	Catch analysis Circular to pest contractor	2015-09-21	Mr. Ashish Gaur

			has been advised to collect the catch analysis from the vendor on quarterly basis. This will be provided to the quality team and will be review for improvement in the program.			

7. Company Details

Company Name : Kanpur Plastipack Ltd	
Site Name : Kanpur Plastipack Ltd	
Address : A1-A2,Unit: Udyog Kunj, Site V, Panki Industrial Area, Kanpur, U.P.	
Country : India	Postcode : 208022
Telephone : +91-9839101671	Fax : +91 (512) 2691-117
Company Representative Name: Mr. Sunil Mehta, Director Operations	
Email : smehta@kanplas.com	

8. Key Personnel

Name/Job Title	Present at Audit (x)			
Note: the most senior operations manager on site should be listed first and be present at both opening & closing meetings	Opening Meeting	Site Inspection	Procedure Review	Closing Meeting
Sunil Mehta- Director operations	X			X
AK Bhargava- GM (Technical and QMS) & PSTL	X	X	X	X
A K Garg, DGM-HR	X			X
S N Singh, Senior Manager	X	X	X	X
Sanjeev Ranjan, Senior Manager- Marketing	X		X	X
Manoj Kumar Maurya, Manager QA	X	X	X	X
Karan Singh Rai, QMS Engineer	X	X	X	X
Santosh Kumar Saxena, Manager - Stores & Purchase	X	X		X

9. Audit Duration Details

On-site audit duration 12 Man Hours
Duration of production facility audit 3 Man Hours
Reasons for deviation from typical (12 hours) or expected on-site audit duration or typical (3 hours) site inspection duration. none

10. Audit Duration per day

	Start time	Finish time
Day 1	12:00	20.30
Day 2	10:00	14:30

Detailed Audit Report

BRC Requirement No.	REQUIREMENT	Conforms Y, N or N/A	Details

1. SENIOR MANAGEMENT COMMITMENT AND CONTINUAL IMPROVEMENT

1.1 Product Safety and Quality Management System

SOI	The company's senior management shall develop and document a product safety and quality management policy, which is authorised, reviewed, signed and dated by an appropriate senior manager.	Y	Food safety Policy dated 01.10.2012 is established. This states the company's intention to meet its obligation to produce safe and legally compliant packaging materials to specified quality, and its responsibility to its customers. It is authorized & signed by Managing Director Mr Manoj Agarwal. Employees have understanding about the basic elements of the policy. Trainings are also conducted on policy. It is reviewed six monthly during management review meeting(11.07.15).Policy is displayed on the shop floor, both in English and Hindi and awareness of policy is satisfactory as per interview of staff and operators.

	1.1.1	Y	1.1.2	Y	

1.2 Senior Management Commitment — FUNDAMENTAL

SOI	The company's senior management shall demonstrate that they are fully committed to the implementation of requirements of the Global Standard for Packaging and Packaging Materials. This shall include provision of adequate resources, effective communication and systems of management review to effect continual improvement. Opportunities for improvement shall be identified, implemented and fully documented.	Y	Senior Management demonstrated full involvement in standard implementation and towards continual improvement. A continuous improvement programme is in place and identifies the following, BRC/IOP training, budgeting & recruitment.
1.2.1	The company's senior management shall ensure that product safety and quality objectives are measurable, established, documented, monitored and reviewed.	Y	The management has derived business objectives related with product safety, quality and operations and these are measurable and documented. Few Objectives are– Process waste reduction < 2%, repairable rejection during final inspection < 5%, conducting advance hygiene and food safety training >45%, customer complaints <3% and customer satisfaction > 80%.
1.2.2	The company's senior management shall provide the human and financial resources required to implement the processes of the quality management system and product safety programme.	Y	Adequate resources in terms of Human & Financial are provided for implementation & for Improvement of the Quality Management systems.
1.2.3	Clear communication and reporting channels shall be in place to report on and monitor compliance with the Standard.	Y	Team Leader- Mr. AK Bhargava is responsible for communication & the progress of system for monitoring on standard implementation.
1.2.4	The company's senior management shall have a system in place to ensure that the company is kept informed of all relevant legislative requirements in the country of manufacture and, where known, the country in which the packaging material will be sold. The company shall also be aware of any scientific and technical developments and industry codes of practice applicable.	Y	Relevant information is gathered mainly from, Customers, Scientific journals for getting legal updates. Also updates are through external body like Indian Institute of Packaging. List of applicable requirements for raw material like plastic material and articles intended to come into contact with food- commission regulation EU No 10/2011 amending and correcting Commission regulation No 1282/2011. Printing inks are in conformity with the EuPIA (CEPE). For FIBC IS 14738 is being followed.
1.2.5	The company shall ensure that the materials manufactured comply with the relevant legislation (including any legislation concerning the use of recycled content) in the country of manufacture and in which the products are intended to be sold and/or ultimately used, where known.	Y	Products manufactured are fully in line with local legislative requirements like Factory License, Weights and Measures Act, Pollution consent.
1.2.6	The company's senior management shall ensure that non-conformities identified at the previous audit against the Standard are effectively actioned.	Y	All the 04 non conformities identified at the previous audit are actioned effectively.

1.2.7	The company shall have a current, original copy of the Standard available on site.	Y	The company has a copy of the Latest BRC/IoP standard and was available in English Version.
1.2.8	Where the company is certificated to the Standard they shall ensure that recertification audits occur on or before the audit due date indicated on the certificate.	Y	Recertification is conducted within time frame.

1.3 Organisational structure, responsibilities and management authority

SOI	The company shall have a clear organisational structure and define the responsibilities, reporting relationships and job functions of those personnel whose activities affect product safety, legality, regulatory compliance and quality.	Y	Company has an organization chart demonstrating the structure of the company. Ref. RD/18: Organizational Chart (Food Grade facility) dated 10.08.2015. Mr. AK Bhargava- Team Leader/MR is responsible for coordinating. He is having 37 years of industrial experience. Since four years he is working here. Mr. Umang Sharma is deputy Team Leader for coordinating compliance with the standard. He is 6 years of industrial experience. Roles and responsibilities are detailed for various functions and communicated. Refer F/HR/02of FSM/01. Verified for Quality control In charge/ Deputy MR. Arrangements are in place to cover for the absence of key staff. In case of non availability of any key staff an immediate subordinate to him is responsible for the same, whereas for authority one step up in organization chart will be responsible. Refer Job responsibility & authority – F/HR/02.

1.3.1	Y	1.3.2	Y	
1.3.3	Y	1.3.4	Y	
1.3.5	Y			

1.4 Management Review

SOI	The company's senior management shall ensure that a management review is undertaken to ensure that the product safety and quality programme is fully implemented, effective and that opportunities for improvement are identified	Y	The management review is planned twice in a year. Refer QPR/04. All the related points including BRC IoP, ISO 22000, and AIB Packaging etc. are reviewed in these meetings. Team consists of the core team members, HODs & chaired by Managing Director. This is addressed in Management Review Procedure which includes evaluation of all topics required by the standard. Circular was made on 06.07.2015 and 12 personnel including MD attended the review as per attendance sheet (F/SYS/04). Reports on the previous MRMs action points are detailed in F/SYS/22. The objectives are monitored every six months and reviewed during Management review meeting. Refer F/SYS/04 for management review meeting record dated 11.07.2015 and previously on 10.01.2015. MRM report is communicated to key staff by sending copy of minutes to key members; with documentary evidence for monitoring of actions implemented within agreed timescale.

1.4.1	Y	1.4.2	Y	
1.4.3	Y	1.4.4	Y	
1.4.5	Y			

2. HAZARD AND RISK MANAGEMENT SYSTEM

2.1 Hazard and risk management team

SOI	A multidisciplinary hazard and risk management team shall be in place to develop and manage the hazard and risk analysis system and ensure this is fully implemented.	Y	The hazard and risk management system is developed, reviewed and managed. Company has established a quality and food safety team also referred as Food safety team. Team comprising of 7 members of various departments such as production, maintenance, quality, purchase and operations implementing the requirement of the standard HACCP team and team Leader is defined- SP/D/FSPP-17-07 for selection criteria & FSPP-17-08 for team chart. Mr. AK Bhargava is team Leader with 35 years of experience and training on HACCP. Refer Page 8 of 26 of HACCP-ML-01, dated 01.07.13. Training on HACCP given on 18.06.14 to all team members by internal trainer.

	2.1.1	Y	2.1.2	Y	
	2.1.3	Y			

2.2 Hazard and Risk Analysis — FUNDAMENTAL

SOI	A formal hazard and risk management system shall be in place to ensure that all hazards to product safety and integrity are identified and appropriate controls established.	Y	The hazard and risk study includes and analyses hazards & risks of each production process step, including receipt of Raw materials, warehousing, storage of raw materials, Issue to production, Process steps, WIP and finished products, including FG storage.
2.2.1	The scope of the hazard and risk analysis shall be clearly defined and shall cover all products and processes included within the intended scope of certification.	Y	The hazard and risk study includes and analyses hazards & risks of each production process step, including receipt of Raw materials, warehousing, storage of raw materials, Issue to production, Process steps, WIP and finished products, including FG storage & dispatch to Customers.
2.2.2	The hazard and risk analysis team shall maintain awareness of and take into account: historical and known hazards associated with specific processes, raw materials or end use of the product relevant codes of practice or recognised guidelines legislative requirements.	Y	All possible hazards & risk have been considered for Biological (due to cross contamination and infestation), Chemical (heavy metals) & Physical (foreign particles) hazards. All hazards have been identified and analyzed based on the basis of codex a/ HACCP & BRC Guide lines. Customer requirements are also considered for hazard analysis. Ref. Doc: Hazard Analysis. Work sheet-Appendix -4.
2.2.3	A full description of the product shall be developed, which includes all relevant information on product safety and integrity. As a guide this may include: composition, e.g. raw materials, inks, varnishes, coatings and other print chemicals origin of raw materials including use of recycled materials intended use of the packaging materials and defined restrictions on use; for instance, direct food contact, physical or chemical conditions.	Y	Full description of the products is developed, which includes all relevant information on food safety e.g. composition (e.g. raw materials as PP, origin of RM, physical and chemical properties, packaging system, storage and distribution, shelf life under dry conditions. Shelf life indefinite when not exposed to UV rays. FIBC's are used by different sector of industries for food packaging.
2.2.4	A process flow diagram shall be prepared for each product, product group or process. This shall include each process step from the receipt of raw materials to despatch to the customer. The process flow shall as a guide include, as relevant: • receipt and approval of art work • receipt and preparation of raw materials such as additives, inks and adhesives • each manufacturing process step • the use of rework and post-consumer recycled materials • any sub-contracted operations • customer returns. The accuracy of the process flow shall be verified by the hazard and risk analysis team.	Y	Flow diagram is constructed including all the processing steps within the scope. This includes the sequence and interaction of all steps in the operation, where raw materials, and where end products and waste are released or removed. Kept as record and reviewed, including steps of warehouse (raw materials receiving of webbing/fabric, cutting, stitching, bag cleaning, metal detection, packing/bailing, stretch wrapping, storage. HACCP study includes all the process flow diagrams covering all activities. Refer Appendix 3 of HACCP-ML-01. On site verification of the process flow chart by hazard and risk analysis team is conducted dated 01.10.2012, no changes noted in the process, but process review is conducted once in six months during management review meeting.

2.2.5	The hazard and risk analysis team shall identify and record all potential hazards that are reasonably expected to occur at each step in relation to the product and process. The hazards considered shall include, where relevant: • microbiological • foreign objects • chemical contamination (e.g. taint, odour, allergen, component transfer from inks, varnishes and glues) • potential problems arising from the use of recycled materials • legality • defects critical to consumer safety • hazards that may have an impact on the functional integrity and performance of the final product in use.	Y	A hazard analysis to identify hazards which need to be prevented eliminated or reduced to acceptable levels. Consideration has been given to likely occurrence of hazard, severity of the effects on consumer safety, chemicals or foreign bodies, contamination of raw materials, intermediate/semi-processed product or finished product. Hazard analysis is covering all the steps of the process chart. There is no use of recycled material.
2.2.6	The hazard and risk analysis team shall identify control measures necessary to prevent, eliminate or reduce each hazard to acceptable levels. Where control is through a prerequisite programme these shall be reviewed to ensure they adequately control the risk identified and where necessary improvements implemented.	Y	The control measures necessary to eliminate or reduce the hazard to acceptable levels are identified. Justification for acceptable levels in the finished product for each hazard is determined and documented. Ref. Doc: Hazard Analysis. Work sheet- Appendix -4.
2.2.7	For each hazard that requires control, other than by an existing prerequisite programme, the control points shall be reviewed to identify those that are critical. This process shall include an assessment of the risk level for each hazard based on the likelihood of the occurrence and the severity of the outcome. Critical control points shall be those control points that are required to prevent, eliminate or reduce a product safety or integrity hazard to acceptable levels. Where controls are not classified as critical and control may be achieved through a prerequisite programme, a programme shall be developed that is sufficiently specified to effectively control the identified hazards.	Y	For each hazard that requires control, control points are reviewed to identify those that are critical. There is a logical approach in identifying CCP's as 02 CCP's are identified. CCP-01 – at Bag cleaning and CCP-02 at Metal detector. Refer HACCP Plan –Appendix -05.
2.2.8	For each critical control point, the appropriate critical limits shall be defined in order to identify clearly if the process is in or out of control. Critical limits shall be measurable where possible and the rationale for their establishment clearly documented. Relevant legislation and codes of practice shall be taken into account when establishing the limits.	Y	Critical Limit is free from foreign material at step CCP-01 Limits defined for bag cleaning are: Bags up to a height of 140 cms are cleaned for 18 seconds and above 140 cms and upto 180 cm are cleaned for 25 seconds and bag height of more than 180 Cm- 38 sec on bag cleaning machine and for CCP-02 free from metal parts by passing Fe- 3.0 mm, Non Fe- 4.5mm and SS-5.0 mm.
2.2.9	For each critical control point a monitoring system shall be defined in order to ensure compliance with critical limits. Records of the monitoring shall be maintained. Procedures relating to the monitoring of critical controls shall be included in internal audits against the Standard (refer to clause 3.3).	Y	For CCP-01 Limits defined for bag cleaning are: Bags up to a height of 140 cms are cleaned for 18 seconds and above 140 cms and upto 180 cm are cleaned for 25 seconds and bag height of more than 180 Cm- 38 sec on bag cleaning machine and for CCP-02 free from metal parts by passing Fe- 3.0 mm, Non Fe- 4.5mm and SS-5.0 mm.by supervisor for each and every bag. For CCP-02 monitoring of every individual bag by supervisor and validation of metal detector every 02 hours.
2.2.10	The corrective action that shall be taken when monitored results indicate a failure to meet the control limit shall be established and documented. This shall include the procedures for quarantining and evaluating potentially out of specification products to ensure they are not released until their safety can be established.	Y	Re adjustments of cleaning time and rechecking of bags of previous 02 hours for CCP-01 and rechecking of previous 02 hours production by supervisor for CCP-02.

2.2.11	A review of the hazard and risk management system shall be carried out at least once per year and following any significant incidents or when any process changes. The review shall include a verification that the hazard and risk analysis plan is effective and may include a review of: • complaints • product failures • recalls • product withdrawals • results of internal audits of prerequisite programmes • results from external third-party auditors.	**N**	HACCP review is conducted every month. Review covers RM & PM, production process, pre-dispatch inspection, calibration status, CCP monitoring, plant and personal hygiene compliance, customer complaints and training. Last Review of HACCP Plan was done on 28.08.2015. However, **There is no evidence that last review of hazard and risk management system covered/ considered product failures, internal and customer audit results and experience of mock test recall. (Minor NC 01)**

2.3 Exemption of requirements based on risk analysis

SOI	The site has demonstrated adequate compliance with the requirements of this clause.			**Y**	A hazard and risk analysis had been fully supported. There were no exemptions.
	2.3.1	Y	2.3.2	NA	

3. PRODUCT SAFETY AND QUALITY MANAGEMENT SYSTEM

3.1 Product safety and quality manual

SOI	The company shall have a manual which describes how the requirements of the Standard are met. These requirements shall be fully implemented, reviewed at appropriate planned intervals and improved where necessary.			**Y**	The company has a Food Safety Management Manual-KPL.BRC describes the requirements of the Standard related to BRC IoP. Copies are circulated to relevant key staff. Refer list of copy holders at page 1 of KPL. List holders include MD, Director operations, Director Technical, Manager. Master Copy is with FSTL.
	3.1.1	Y	3.1.2	Y	

3.2 Customer focus and contract review

SOI	The company's senior management shall ensure that processes are in place to determine customer needs and expectations with regard to quality and safety and ensure these are fulfilled.			**Y**	Senior Manager Marketing is responsible for communication with customers. In his absence MD will communicate with customers. Customer requirements are received by Marketing Manager refer PO No KAN 23-14 for 75x100x126 cm ID 1896 grams, Normal U+2 design, and unprinted, base fabric 160 +30 gsm, 04 lifting loops. Initiated on 22.07.13. For 10320 pieces. Customer requirements are reviewed during execution of each order or if any changes to the contract are undertaken. They are discussed with the customer and changes are agreed upon before proceeding for final production.
	3.2.1	Y	3.2.2	Y	
	3.2.3	Y			

3.3 Internal audits — FUNDAMENTAL

SOI	The company shall audit those systems and procedures which cover the requirements of the Standard to ensure they are in place, appropriate and complied with.	**Y**	The organisation has internal audit program in place to audit all relevant systems and procedures to ascertain their compliance.
3.3.1	Internal audits shall be planned and their scope and frequency shall be established in relation to the risks associated with the activity. Audits shall be scheduled so that all aspects of the Standard are audited at least annually.	**Y**	Internal audits are conducted as per QPR/03. Internal Audit –and are planned once in six months. Internal audit schedule and plan- F/SYS/05 dated 17.12.2014 and 17.06.2015 respectively for the two rounds.
3.3.2	Internal audits shall be carried out by appropriately trained competent personnel who shall be sufficiently independent from the department being audited to ensure impartiality.	**Y**	Carried out by trained internal team of auditors. Total 15 personnel are trained, refer RD/08 dated 10.08.2015. Trained for BRC IoP, ISO 9001, ISO 22000, HACCP and AIB.

3.3.3	Deficiencies and details of non-conformities shall be notified to appropriate supervisory staff and corrective action implemented within a specified and appropriate time period.				**Y**	Internal Audit was conducted on 22.12.2014 and 29.06.2015. Total 09 and 07 findings identified, refer F/SYS/08. Details of findings are communicated to concerned Auditee and implementation of corrective action is documented in the audit summary - refer Annexure -II
3.3.4	The completion of corrective action shall be recorded and verified.				**Y**	The completion of corrective action was recorded and verified, refer Annexure –II.
3.3.5	Internal audit reports shall be sufficiently detailed to ensure that conformity as well as non-conformity can be clearly identified and verified.				**Y**	Internal audit reports are detailed to ensure that conformity as well as non-conformity can be clearly identified and verified.
3.4 Supplier approval and performance monitoring						
SOI	The company shall operate procedures for approval and monitoring of its suppliers. This shall include suppliers of materials and services to the company and ensure that materials and services procured conform to defined requirements.				**Y**	Company has established procedure for the purchasing of materials & services. The procedure allows selection of supplier QPR-25. Company has suppliers for Fabric, thread /yarn, webbing, tie string, filler cord, tie cord, printed panel, document pocket, liner, safety label, stretch film, lubricants. The vendor qualification program includes approval and evaluation criteria, refer FMT/PUR/07. Criteria like food safety weightage, Quality weightage, delivery weightage. Overall rating is if >99.5. Refer Supplier performance monitoring record-F/PUR/0401. Supplier rating is done once in a months. Last conducted in December 2014. There is no other way of purchasing than the identified system. Company always keeps a stand by stock in place of all basic items. COA is taken for every lot purchased. Supplier audit checkpoints are sent to suppliers. Procedure addresses how exceptions are handled. If the supplier is not interested for audit, then questionnaire is sent to him. For supply of lubricants, zip lock safety label alternative suppliers are developed. Refer Approved supplier list- 01.09.2015, (F/PUR/02)
	3.4.1	Y	3.4.2	Y		
	3.4.3	Y	3.4.4	Y		
3.5 Subcontracting of production						
SOI	Where production processes are subcontracted this shall be with the agreement of customers. Procedures shall be in place for the effective control of subcontractors and the work undertaken.				**Y**	QPR/25 is followed. 4 subcontracting unit are there for document pocket and liner and safety label. Arjun Industries are new subcontractors. Supplier registration form is available as F/PUR/01 rev. Trial order is placed. There is not much risk. 01 Offset Printing is performed in-house. Specifications are available. QPST/01 sheet number 03 and 23 for safety label, document pocket and liner respectively. **Audit of one of the subcontracted unit located at Indore is not performed** (Minor NC 02)
	3.5.1	Y	3.5.2	**N**		
	3.5.3	Y	3.5.4	Y		
3.6 Documentation control						
SOI	The company's senior management shall ensure that documented procedures and recording forms critical to the management of product safety, legality and quality are in place and effectively controlled.				**Y**	All documents are numbered with revision date with authorization by Director Operations Ref. RD/18: Organizational Chart (Food Grade facility) dated 01.01.2014. Documents are legible and correct. All amendments are authorized by Director Operations. Ref. RD/18: Organizational Chart (Food Grade facility) dated 01.01.2014.
	3.6.1	Y	3.6.2	Y		
	3.6.3	Y				
3.7 Specifications					**FUNDAMENTAL**	

SOI	The company shall ensure that appropriate specifications exist for raw materials, intermediate and finished products, and any product or service which could affect the integrity of the finished product and customer requirements.	Y	Specification for raw material used in the manufacturing process, finished goods and any product or service which could affect the integrity of the finished product are defined. Specifications maintained for all the raw materials, and Finished goods in the form of Quality Plan.
3.7.1	Specifications shall be suitably detailed, accurate and shall ensure compliance with relevant product safety and legislative requirements.	Y	Specifications are derived from customers' requirements for each container being developed. This material is procured, handled and converted in to final product. Refer QPST: 01 Fabric (incoming material), Document Pockets and liners, stitching thread, webbing, and Stitching oil.
3.7.2	The company shall seek formal agreement of specifications with relevant parties. Where specifications are not formally agreed then the company shall be able to demonstrate that they have taken steps to put an agreement in place.	Y	Company seeks PO from each customer and maintains agreement which contains the specifications against identified standards. Checked Purchase order for Customer requirements are received by Marketing Manager for 75x100x126 cm ID 1896 grams, Normal U+2 design, and unprinted, base fabric 160 +30 gsm, 04 lifting loops. Initiated on 22.07.13. For 10320 pieces.
3.7.3	A declaration of compliance shall be maintained, which enables users of the packaging materials to ensure compatibility with the product with which the materials may be in contact. The declaration of compliance shall contain as a minimum: • the nature of the materials used in the manufacture of the packaging • confirmation that materials meet relevant legal requirements • the inclusion of any post-consumer recycled materials • this shall identify any limitations of use of the declaration of compliance. Products shall meet at least minimum legal requirements in the country of manufacture and use, where known.	Y	A declaration of compliance was available, for the Fabric-laminated/unlaminated, thread, webbing, complying to EU regulation no. 10/2011 and its amendment EU directive 1282/2011 for plastics intended to come in contact with food stuff.
3.7.4	Trademarks for application on packaging materials shall, where appropriate, be formally agreed between relevant parties.	Y	All trademarked material if undelivered is destroyed.
3.7.5	The company shall operate a specification review procedure.	Y	Whenever there is change from customer, specifications are reviewed and changed.
3.8 Record Keeping			
SOI	The company shall maintain records to demonstrate the effective control of product safety, legality and quality.	Y	Records are legible and genuine and authorized by respective department heads. Alterations are controlled and access of records is restricted to managerial level. Control of Records QPR/02 highlights the requirement of controlling of the quality records. Retention period of individual records is identified which ranges between 2 years which is more than the product usable life.
	3.8.1 Y 3.8.2 Y 3.8.3 Y 3.8.4 Y		
3.9 Traceability			**FUNDAMENTAL**
SOI	The company shall have a system in place to identify product batches and to trace and follow all raw materials through processing to distribution of the finished product to the customer. Records shall be retrievable in a timely manner.	Y	Procedure for Identification and Traceability is established. Identification and traceability is well evidenced in all stages of operation. Batch records are filled for every shift. For each batch all relevant & important details are recorded in the log book.
3.9.1	The company shall have a system that has the ability to trace and follow all raw materials from the supplier through all stages of processing to distribution of the finished product and vice versa. Where continuous processes are used or raw materials are in bulk, the traceability of silos shall be achieved to the best practical level of accuracy.	Y	Procedure for identification, traceability –QPR/24 is followed. All the products during the incoming stage after the inspection if found accepted is identified through the batch number supplied by supplier. Last test of backward traceability 08.06.2015 –CTR 15/434.
3.9.2	An appropriate system shall be in place to ensure the customer can identify a product or production lot number for the product, for the purposes of traceability.	Y	The customer can identify a product by Contract Number, refer CTR for 1804.

3.9.3	The system shall be tested to ensure traceability can be determined from raw material to the finished product and vice versa. This shall take place on a predetermined frequency, at least on an annual basis, and results retained for inspection.	**N**	The system was tested to ensure traceability can be determined from raw material to the finished product and vice versa. CTR1699 Vehicle inspection- F/DISP/01-09.07.15 Specification QC/20 for the bag COA-QC/11B-Final Inspection Report- dimensions, weight Quality Head releases the product. Date-09.07.2015 In-process inspection-QC/08B Bag Measurement Report-dated 07.07.2015 CCP-1: Bag cleaning F/PROD/01- date 01.07.2015-07.07.2015 CCP-2: metal detector F/PROD/04-date 04.07.15-07.07.2015 Metal detector validation F/PROD/06 date 04.07.2015 Material requisition Slip F/STR/04-29.06.2015 13 RM are issued from the store Packaging material is issued separately Challan cum Raw material inspection report for belt-QC/24A dated 29.06.2015. However, **Forward traceability test is not conducted in last one year** **(Minor NC 03)**

3.10 Complaint handling

SOI	The company shall have a system for the effective capture, recording and management of product complaints.			**Y**	Company records the entire customer complaint CCR/02. Checked summary report for current year. Total 05 complaints have been recorded till date. All complaints are analyzed once in a year for trends and then discussed in management review meeting. Refer QM/CS/KPL/02- analysis of trends for customers complaints from 27.02.14 onwards till date. Corrective actions undertaken for each complaint is maintained. Refer Customer complaint dated 28.05.14 for liners were breaking from the sealing.
	3.10.1	Y	3.10.2	Y	
	3.10.3	Y			

3.11 Management of incidents, product withdrawals and recalls

SOI	The company shall have a plan and systems in place to effectively manage incidents, product withdrawals and recalls, in order to ensure that all potential risks to the quality, hygiene and legality of products are controlled.			**Y**	Management of Incidents has been established. Refer QPR/35. Incidents such as flood/ spillage of oil, fire, needle breakage, blade policy are identified as incidents. No incident. Actions to be taken to manage each of these incidents are identified in the procedure. A product withdrawal/recall procedure is documented. Refer QPR/07, which includes identification of key personnel and communicating plan. Director Operations/senior Manger Marketing is responsible for communication with customers. The product withdrawal/recall procedure has been tested to evaluate the procedure and implement improvement. Tested once in 06 months. . Last test of backward traceability 08.06.2015 –CTR 15/434. There is no actual recall till date. Director Operation is responsible for ensuring preventive action.
	3.11.1	Y	3.11.2	Y	
	3.11.3	Y	3.11.4	Y	
	3.11.5	Y	3.11.6	Y	

4. SITE STANDARDS

4.1 External standards

SOI	All grounds within the site shall be finished and maintained to an appropriate standard.			**Y**	Site is located on an identified industrial plots in an industrial estate sufficiently demarcated in plot area which has no activities that may affect the production. The external areas are well maintained and in good order and Grounds are concrete and maintained. Building fabric is permanent are enclosed to prevent against pest entry. Drains are external and suitable. External traffic routes, under site control, are surfaced and made of concrete to avoid contamination of the product. **No external storage of raw materia**l. Refuse is stored properly.
	4.1.1	Y	4.1.2	Y	
	4.1.3	Y	4.1.4	Y	
	4.1.5	Y	4.1.6	NA	
	4.1.7	Y			
4.2 Building fabric and interiors					
SOI	The internal site, buildings and facilities shall be suitable for the intended purpose and shall be designed, constructed, maintained and monitored to effectively control the risk of product contamination.			**Y**	Walls and Floors are maintained in good condition and facilitate cleaning. **Suspended ceilings are not used**. Suitable and sufficient lighting is provided for adequate working environment. **There are no internal drains**. Windows and roof are designed and screened to prevent any pest entry. Windows inside production facility were found protected. Air Handling units are installed and sufficient ventilation is provided.
	4.2.1	Y	4.2.2	NA	
	4.2.3	Y	4.2.4	NA	
	4.2.5	Y	4.2.6	Y	
	4.2.7	Y			
4.3 Utilities					
SOI	All utilities to and within the production and storage areas shall be designed, constructed, maintained and monitored to effectively control the risk of product contamination.			**Y**	The processes do not use water in any form which can come in contact with raw material or finished product. Drinking water is analyzed against IS 10500-2012. Water, steam, ice, or other gases is not used in the process. Air sampling is conducted once in a year from external laboratory for yeast and mould count and Total plate count. Refer test report dated 02.01.2015 from change room, cutting area, production area and finished goods area.
	4.3.1	Y	4.3.2	Y	
4.4 Security					
SOI	Security arrangements shall be assessed to ensure the integrity of products and processes.			**Y**	Site is walled and a team of security personnel are provided. Access is controlled through main gate for premises and entry gate to the office as well as production area. Visitor reporting system is in place. A company SIS security services is deputed to oversee the control and trained to challenge unknown visitors. Necessary reference checks are made for temporary workers who are recruited through a contractor. All other personnel are permanent employees. Maintenance is conducted by internal maintenance departments who are adequately trained to maintained hygiene conditions. Access to the site by third-party transport personnel is controlled and possible only till the loading gate of the warehouse. Site IT Systems are controlled.
	4.4.1	Y	4.4.2	Y	
	4.4.3	Y	4.4.4	Y	
	4.4.5	Y	4.4.6	Y	
	4.4.7	Y			
4.5 Layout and Product Flow					

SOI	Premises and plant shall be logically designed, constructed and maintained. Procedures shall be in place to control the risk of product contamination and to comply with all relevant legislation.				**Y**	Process flow from intake to dispatch is arranged to minimize the risk of contamination. Dedicated stores for Raw material and packaging material are provided. Premises designed with sufficient working space and storage capacity in line with the quantity of product handled. All Work in progress is clearly identified using CTR no, stitcher no, checker no, month of manufacturing on label. All activities are conducted in a closed production area. Removal of outer product covering is carried out in identified area.
	4.5.1	Y	4.5.2	Y		
	4.5.3	Y	4.5.4	Y		
	4.5.4	Y				
4.6 Equipment						
SOI	Equipment shall be suitably designed for the intended purpose and shall be maintained and used so as to minimise the risk to product safety, legality and quality.				**Y**	Equipment is suitably designed for the intended purpose. Equipment is constructed of appropriate material suitable for making of FIBC. All the tables at stitching and cutting are cladded with Stain less Steel. No notices on equipment.
	4.6.1	Y	4.6.2	Y		
	4.6.3	Y				
4.7 Maintenance						
SOI	A documented system of planned maintenance shall be in place, covering all items of equipment and plant that are critical to product safety, legality and quality.				**Y**	87 machines are covered. These are listed in F/MAINT/01 rev.04 01.07.2015. Each equipment has a tag which identifies inspection and preventive maintenance status. A condition-based or preventative maintenance programme is in place. Refer Inspection and preventive maintenance for Fabric Cutting Machines FG-01/01 and FG/01/02 conducted on weekly, monthly basis. Refer record dated 01.09.13. Refer FG/20 –stitching machine conducted fortnightly for ensuring sufficient oil in the oil cup, motor and clutch. The frequency of Planned maintenance has been scheduled keeping in mind equipment failures. Spare cost is monitored on company level. Metal detector FG/04- by FG/MT/03 dated 13.09.2015; Machine History Card FG/MT/01 is maintained – one breakdown on 14.08.2015 for bearing issue. Bag cleaning Machine FG/03 – preventive maintenance on 13.09.2015. Stitching Machine FG/36- preventive maintenance on 13.09.2015. Maintenance work if any is carried out without possible risk to the product. Recording clearance is a part of maintenance checklist. Refer F/MAINT/05 engineering hygiene clearance record dated 14.08.2015 for metal detector. Details of tools and other material are documented in Engineering hygiene clearance record-F/MAINT/05. No incident of temporary repairs seen at the time of visit to the facility. Wooden equipment such as tables and chairs are not used. Engineering workshops are well maintained and do not open directly into production areas kept separately in the next building. It is away from food bag clean room. no new machines added since last visit. Metal detector is the only machine which is replaced this year.
	4.7.1	Y	4.7.2	Y		
	4.7.3	Y	4.7.4	Y		
	4.7.5	Y	4.7.6	Y		
	4.7.7	NA	4.7.8	Y		
	4.7.9	Y				
4.8 Staff Facilities						

SOI	Staff facilities shall be sufficient to accommodate the required number of personnel, and designed and operated to minimise the risk of product contamination. Such facilities shall be kept in a good and clean condition.	**Y**	Hand washing facilities with sufficient quantity of warm water, unscented liquid soap, air dryer are provided to enable cleaning of hands before commencing work. Toilets are segregated and do not open directly into storage, processing or production areas. Toilets are provided with hand-washing facilities, with provision of warm water and hand dryers. Locker rooms are provided before the entry to the production areas. Lockers are provided for all personnel who work in material handling area and are of reasonable size to store all the items. Company-issued protective clothing is provided and personal clothing is not stored in the same locker. Eating and smoking is not allowed in locker and changing rooms. Monitoring of visitors for complying with the company's hygiene policy is implemented. All personnel are required to keep food in designated area and also there is a provision of food in the cafeteria. No food is stored in the locker room area. Smoking is not allowed in facility.

4.8.1	Y	4.8.2	Y	
4.8.3	Y	4.8.4	Y	
4.8.5	Y	4.8.6	Y	
4.8.7	Y	4.8.8	Y	
4.8.9	Y			

4.9 Housekeeping and Cleaning		**FUNDAMENTAL**	
SOI	Housekeeping and cleaning systems shall be in place, which ensure that appropriate standards of hygiene are maintained and that risk of contamination to the product is minimised.	**Y**	The cleaning systems are maintained as per GMP requirements. Cleaning activities of equipment and housekeeping activities are recorded. No risk of product contamination was observed during the audit. Cleaning schedules are in place and are recorded. Cleaning schedules are established as daily / weekly / Monthly / Yearly.
4.9.1	Good standards of housekeeping shall be maintained, which shall include a 'clean as you go' policy.	**Y**	Facility encourages good housekeeping standards and has provided cleaning mechanisms before entry to the production areas. Activity is outsourced to Service master Clean Ltd. (contract started on 29.06.2016)
4.9.2	All internal surfaces of buildings, equipment and vehicles shall be subject to documented scheduled cleaning. Cleaning schedules shall include the following information: • responsibility for cleaning • item/area to be cleaned • frequency of cleaning • method of cleaning • cleaning materials to be used • cleaning record and responsibility for verification.	**Y**	Company has documented Daily Housekeeping schedule-RD/03A and includes area of cleaning, equipment used for cleaning, frequency, cleaning agent used, make dilution ratio, cleaner, checker. Monitoring is done on Daily Cleaning Record F/HR/17 rev. 01 every day. Wall and ceilings are done on weekly basis.
4.9.3	Cleaning equipment and materials shall be kept in a secure designated location such as a locked cupboard.	**Y**	Cleaning equipment like Candice mop, cotton cloth and vacuum cleaner are kept in an identified area for Housekeeping section in an identified room.
4.9.4	Cleaning chemicals shall be fit for purpose, suitably labelled, secured in closed containers and used in accordance with manufacturers' instructions.	**Y**	Cleaning chemicals like Sterishine LFRA, SteriMop, R3, R-6 are kept in an identified area identified for Housekeeping and stored in an identified room.
4.9.5	Chemicals that are strongly scented or could give rise to taint and odour contamination shall not be used.	**Y**	Anti-microbial Professional Hand wash soap and sanitizer (Sanitz Instant Hand Sanitizer by Haylide Chemicals) are odourless and it cannot give any odour to the product.

4.9.6	Materials and equipment used for cleaning toilets shall be segregated from those used elsewhere.			**Y**	Separate equipments are used for toilets and production areas.
4.10 Waste and waste disposal					
SOI	Suitable facilities shall be provided for the storage and disposal of process and other waste.			**Y**	Suitable and sufficient refuse and waste containers are provided. Waste is removed from waste area once in a day. Waste is handled as per Procedure for waste disposal- QPR/12. Waste is categorized like fabric waste, webbing waste based on the intended means of disposal, segregated and collected in appropriate designated waste containers. Refer F/PROD/07 01.09.2014 onwards. Collected waste is collected and sent to unit for granules making. If for some reason they do not meet the requirement then the material is sent as a waste to other unit for granules making. All the material if required to be destructed is done internally. Waste holding area is identified. There is no recycling of waste.
	4.10.1	Y	4.10.2	Y	
	4.10.3	Y	4.10.4	Y	
	4.10.5	Y			
4.11 Pest control					
SOI	The company shall be responsible for minimising the risk of pest infestation on the site.			**Y**	RD/22 –Pest control schedule is documented and describes how the pests are being controlled in the organization. Pest control is through external agency. A contract is made with Pest control Of India from 01.08.2015 to 31.07 2016. The contract indicates the frequency of services: Pied Piper for rodent management system at a frequency of 2/week, integrated fly management on Month wise, integrated spider services on monthly basis. The building is suitably proofed against the entry of all pests via doors, windows, ducts, and cable entry points. No infestation has been found in the premises. An up-to-date authorized site plan identifying numbered pest control device locations is available as RD/23. Rodent boxes, air-curtains and EFKs are mentioned on the map dated 01.10.2015. Records of pest inspections for Roda-Boxes are maintained and detail the date of observation, Refer F/HR/22C for the month of August 2015. **Catch analysis is not evident in last one year although the program is reviewed and updated and data is being collected (Minor NC 04)**
	4.11.1	Y	4.11.2	Y	
	4.11.3	Y	4.11.4	Y	
	4.11.5	N	4.11.6	Y	
4.12 Transport, storage and distribution					

SOI	The transport, storage and distribution of raw materials and finished products shall be undertaken in a manner to minimise the risk of contamination or malicious intervention.			Y	All finished material is transferred in covered condition in closed body containers. Procedure for transportation of Raw material and finished products is handled as per QPR/14. All receipt of raw material is recorded and identified. All incoming goods are checked visually and recorded in the incoming inspection record. It covers vehicle inspection for insect infestation, damage, grease/water etc. Pallets are used for storage of material are metal or of plastic. Wooden pallets are used for palletisation are treated. Fumigation certificate is available for pallets and treated pallets are identified by a unique Number. There is no off- site storage and storage in the facility are kept in order. Adequate segregation is maintained in the warehouses. All work in progress material is identified using CTR (Contract number). There is no recycling undertaken. Vehicle drivers are made to comply with the site rules relevant to this Standard. F/DISP/01- Container stuffing and Vehicle inspection report is maintained; and covers truck body status, for contamination dents, holes, and foul smell. There is no Company owned vehicles. Contracts are made with transport providers with conditions agreed and maintained and provided by the customer. Checked transporter agreement details- F/DISP/02 dated 18.12.12 which is still in force.
	4.12.1	Y	4.12.2	Y	
	4.12.3	Y	4.12.4	Y	
	4.12.5	Y	4.12.6	Y	
	4.12.7	Y	4.12.8	Y	
	4.12.9	Y	4.12.10	Y	
	4.12.11	Y	4.12.12	Y	
	4.12.13	Y			

5. PRODUCT DESIGN AND PROCESS CONTROL

5.1 Product design and development

SOI	Product design and development processes shall be in place to ensure the production of safe and legal products to defined quality parameters.			Y	All requirements from customers are taken to design food packaging suitable for its intended use. Purchase confirmations & orders are received from customers and contain specific product requirements. The requirements are converted in to job order for execution. The details of job card are grade of raw material, and dimensions of the container. There is no use of recycled material. Product specification is converted in to Export specifications. Final product specifications are formally accepted and maintained in soft as well as hard copies. For each Production Order finalized production sample approval is taken from customer. Once approval is received commercial production is executed and monitored to achieve agreed product quality. All product jobs are thoroughly verified on site and by Quality personnel as per Quality plan before final product is passed. Checked COA for length, width, height, lifting loops including long leg, short leg, filling spout, discharge spout for CTR 1804. Reference samples are retained for 02 years as agreed with the specifier.
	5.1.1	Y	5.1.2	Y	
	5.1.3	Y	5.1.4	Y	
	5.1.5	Y	5.1.6	Y	

5.2 Packaging print control

SOI	Where packaging is printed with allergen/safety/legal information, procedures shall be in place to ensure that the information is fully legible and correctly printed to the customer's specification.	**Y**	Assessment of the printed process is conducted. The checklist also covers blocks. Check for overall migration is conducted once in a year from external Laboratory. Refer report dated 10.01.15 and covers simulants like Ethanol, Acetic acid, Ethanol 20%, Ethanlol-50%, vegetable oil and Poly (2, 6-Diphenyl –p-phenylene oxide). The sample meets requirement laid down in EU 10/2011 for overall migration. The last Print proof is wrapped on the individual blocks for next run and traceability of the job by art work number. Printing blocks are stored in identified room. A master sample is retained which is referred to for every bag produced. Conditions for monitoring colours or shades are defined. All printing errors are cross checked for compliance in the Quality control department and printed rolls if defective are segregated and rejected. Refer CTR-13/651. All printing errors are cross checked for compliance in the Quality control department and printed sheets if defective are segregated and rejected. There is no composite print. Retained for 02 year. Unused printed product is returned back to stores with the same Batch Code given at the time of receiving. 04 people are trained for print quality checks. Lighting in print inspection cabinets are as per agreed norms with customer and are as per accepted industry standards.

5.2.1	Y	5.2.2	Y	
5.2.3	Y	5.2.4	Y	
5.2.5	Y	5.2.6	NA	
5.2.7	Y	5.2.8	Y	
5.2.9	Y	5.2.10	Y	

5.3 Process control — FUNDAMENTAL

SOI	Procedures shall be in place to ensure effective quality assurance of operations throughout the process.	**Y**	Process control system is established. Procedures has in-place to ensure effective control as defined to HACCP Plan.
5.3.1	The company shall undertake a review of the manufacturing and, where applicable, printing process to identify critical manufacturing process control points that could affect the quality of the products produced.	**Y**	Steps which are critical to the product safety and quality are identified and controlled; monitoring and recording system is established.
5.3.2	For each critical manufacturing process control point, machine settings or process limits shall be established and documented – the process specification.	**Y**	Basic check of raw material is established. General checks for raw material is through COA. Also incoming material is checked through external laboratory once in six months.
5.3.3	Documented process checks shall be undertaken at start up, following adjustments to equipment, and periodically during production, to ensure products are consistently produced to the agreed quality specification.	**Y**	Machine wise inspection report, printing department inspection report, cutting department inspection report, Roll/ other packing material inspection report are maintained.
5.3.4	A clearance procedure shall be in place to ensure that at start up, the line is clear of all previous work and production documents.	**Y**	Clearance procedure is established and line is cleared of the previous products in case of product change. Refer fabric and webbing cutting line clearance QC/36-B and stitching line clearance QC/36-A for CTR 15/1699.
5.3.5	Suppliers of incoming materials, as appropriate, shall provide evidence of conformity.	**Y**	Verified incoming inspection through material receiving & inspection report and quality inspection report QC/24B and QC/24A along with food grade certificate dated 26/09/15 for 10096-15/1699.
5.3.6	Quality checks shall be carried out to demonstrate that the finished product is within the tolerances laid down in the agreed product specification and conforms to any critical technical/legal requirements.	**Y**	Final product is tested in-house length, width, height, lifting loops including long leg, short leg, filling spout, discharge spout for CTR 15/1699.

5.3.7	In the event of changes to product composition, processing methods or equipment, the company shall, where appropriate, re-establish process characteristics and validate product data to ensure product safety, legality and quality are achieved.			**Y**	All material undergoes documented checks for end product if there are any changes.
5.4 Product inspection and analysis					
SOI	The company shall use appropriate procedures and facilities when undertaking or subcontracting inspection and analyses critical to product safety, legality and quality.			**Y**	Quality plan ensures checks are conducted on Raw material, & finished goods with identified frequencies. Refer QPFG-01 for final inspection plan. Checks are carried out for each batch for 05 bags randomly selected in a shift to meet customer specified parameters. Team of lab is trained. Procedures – QPR/37 is in place to ensure the reliability of test results. Manager QA is responsible for validating the results of measurements taken by various inspectors. These are tested once in six months. For final (pre dispatch inspection and testing- 10% bales are selected and out of these 02 bags from each opened bale is taken for sampling. This is based on risk analysis. Company does not undertake or subcontracts analyses for final product however for incoming material samples are sent to external Laboratory once in six months. The laboratory used is NABL accredited.
	5.4.1	Y	5.4.2	Y	
	5.4.3	Y	5.4.4	Y	
	5.4.5	Y			
5.5 In-line testing and measuring equipment					
SOI	The company shall use hazard and risk analysis principles to determine the need for in-line product testing equipment to ensure the integrity and quality of products.			**Y**	Checked for metal detector for test probes checked every 02 hours. Metal detector is calibrated by external agency once/year, calibration is due in October. All monitoring is visual and conducted during each production run. On line defects are visually identified and programmed in such a way that for any defect these are segregated before final packing.
	5.5.1	Y	5.5.2	Y	
	5.5.3	Y	5.5.4	Y	
5.6 Calibration					
SOI	Measuring equipment used to monitor critical manufacturing process points and product safety and legality shall be calibrated.			**Y**	All measuring equipments critical to processes are identified and listed for calibration as per calibration schedule. Refer F/MAINT/09 rev. 03, 01.07.2015. All measuring equipments critical to processes are identified and listed for calibration as per calibration schedule. Refer F/MAINT/09 rev. 03, 01.07.2015. Refer record of calibration from Standard Weights and measures Department dated 04.03.2015. Being monitored for compliance such as weighing balance of 10 kg used for the weighing of bags on 04.03.2015 by legal metrology.
	5.6.1	Y	5.6.2	Y	
	5.6.3	Y	5.6.4	Y	
	5.6.5	Y			
5.7 Control of non-conforming product					

SOI	The company shall ensure that out-of-specification product is clearly identified, labelled and quarantined.			**Y**	Procedure for control of non confirming Product. QPR/05 is in place and for identification of non-conforming products. Procedure includes review and disposal of non-conforming material. Any non-conforming product observed during the process is properly identified, recorded and kept separately. A non-conforming area is also identified. All products are required to be assessed and passed before they can be sent across to the customer. Also in case of non-conforming product identification by colour tags is done and then sent for inspection. Refer F/QC/04 for disposal record. Line checks are undertaken if any faults are identified for any of the identified checks.
	5.7.1	Y	5.7.2	Y	
	5.7.3	Y			
5.8 Foreign body contamination control					
SOI	All practicable steps shall be taken to identify, avoid, eliminate or minimise the risk of foreign body contamination.			Y	Control of Glass and Brittle plastic is documented, refer QPR/23. There is no unnecessary non-production glass or brittle plastic, which may pose a risk of contamination. List of Glass/Acrylic/ceramic articles is maintained-RD/05. Glass and brittle plastic register is maintained and monitoring is done once in weekly. Refer F/MAINT/11. Glass breakage is handled as per Glass control Policy QPR/23. Refer weekly glass breakage monitoring process- F/MAINT/11 dated 21.09.2014, no incident of breakage. Procedure for usage & control of sharp QPR/28 is documented and covers needle and scissor. Knife and scissor issue and monitoring record –F/PROD/02 is maintained. A record of Needle Issue is also maintained. Fresh needles are issued only after collection of all parts of damaged needles. The above records capture sharp cutting tools used in packaging material. 4 scissors and 1 knife is issued and collected back on the daily basis.
5.8.1 Foreign body control					
	5.8.1.1	Y	5.8.1.2	Y	.
	5.8.1.3	Y	5.8.1.4	Y	
	5.8.1.5	Y			
5.8.2 Sharps control					
	5.8.2.1	Y	5.8.2.2	Y	
	5.8.2.3	Y	5.8.2.4	Y	
	5.8.2.5	Y			
5.8.3 Chemical control					
SOI	Controls shall be in place to prevent contamination from chemical or biological hazards.			**Y**	Chemical like Sterimop and R3 used are appropriate and has USFDA clearances and complying with 21CFR175.105. Microbiological testing is conducted once in a year from external laboratory, dated 02.01.2015 by Gujarat Laboratory, for personal hand swab, cutting machine table, checker table storage table, metal detector, bale press, for Total plate count, Salmonella, Shigella, E.Coli, Yeast and mold. The results are conforming to prescribed standard. Microbiological analysis for final bag is also conducted and found complying with standard limits. Refer report dated 02.01.2015 by Gujarat Lab.
	5.8.3.1	Y	5.8.3.2	Y	

6. PERSONNEL

6.1 Training and competence — FUNDAMENTAL

SOI	The company shall ensure that all employees are adequately trained, instructed and supervised commensurate with their activity and are competent to undertake their job role.	Y	Organisation has a Training Management Procedure which outlines the training related requirements. The Company has a training program for all employees. Onsite interview suggests that the implementation is satisfactory. Competence & Skill Level Matrix is made for all the functions.
6.1.1	All personnel, including temporary personnel, shall be appropriately trained prior to commencing work and adequately supervised throughout the working period. Induction training shall include the company hygiene rules.	Y	The Company has a training program for all employees, which is provided on the basis of personal competence and training history record. Refer F/HR/01-A. Onsite interview suggests that the implementation is satisfactory. New employees receive Induction training covering all areas of activity & management system orientation- refer F/HR/08 dated 07.08.2015 for Umang Sharma. A clear induction schedules governs this. New employees are supervised throughout the initial working period by shift Supervisors. On the Job training is also provided for technical skills- refer F/HR/01-B.
6.1.2	The company shall routinely review the competencies of staff and provide relevant training as appropriate. This shall cover all packaging quality assurance, potential contamination and safety hazards, including those specific to established critical process steps.	Y	Implementation of annual training plan includes gaps and needs of training activities identified through Skill gap analysis & Competency mapping.
6.1.3	Records of training shall be kept for all current and recent key employees.	Y	Training records of all employees are maintained as Training Attendance Sheet e.g. training on Product Safety and Hygiene
6.1.4	A programme of refresher training shall be in place.	Y	Programme for refresher training is established.
6.1.5	The company shall document training procedures and records to demonstrate that training is effective and regularly reviewed.	Y	Company has established a training process flow which describes the actions to be performed towards training. This includes review of training needs, deciding mode of training, based on in-house or external training, review of trainer or resources is conducted. Planning of training is done and training is imparted .Training effectiveness is evaluated and it is reviewed after one week for identifying the requirements related to training on that subject. Training evaluation and feedback record F/HR/06 covers evaluation of training by his/her superior. Training on incident by Mr. S. N. Singh dated 17.06.2015 for 11 employees. Employee, trainer and supervisor feedback is logged in F/HR/06.

6.2 Access and movement of personnel

SOI	The company shall ensure that access and movement of personnel, visitors and contractors shall not compromise product safety and quality.			Y	Company has documented a plan of site with detailed layout and an emergency evacuation plan defining access points for personnel and travel routes & facilities. Production areas & packing area is segregated. Facilities are designed with adequate working area allowing movement by simple and logical routes. Marked areas are provided in terms of walkways. Facility is designed in a logical way and facilitates movement of personnel and material from each section.
	6.2.1	Y	6.2.2	Y	
	6.2.3	Y			

6.3 Personal hygiene					
SOI	The company's personal hygiene standards shall be documented and adopted by all personnel, including visitors to the production facility. These standards shall be developed with due regard for risk of product contamination.			**Y**	Company has established jewellery policy. Refer QPR/26. Any kind of jewelry, watches, mobiles are not allowed. Personal Sanitation & Hygiene Maintenance, Monitoring and Verification F/HR/15 are used by the security and supervisor. F/SYS/15A is also used for cross check. Lockers are provided for personnel to keep their personnel items. Restriction and control the use of personnel medicine is displayed. All personnel, visitors and contractors are made to wash hands and provided with a hygiene code of conduct. Personnel hygiene rules ensure that nails are kept short and appropriate care is taken. Refer F/HR/15 for the month of July 14 onwards. Gloves are not used in the production area. Water cooler is available is locker area away from production. Eating and smoking or use of tobacco/gum/confectionery is prohibited in the premises. Drinking of water from is confined to a designated area away from equipment. Water testing is performed as per IS 10500-2012 version on 03.01.2015 by Gujarat Laboratory
	6.3.1	Y	6.3.2	Y	
	6.3.3	Y	6.3.4	Y	
	6.3.5	Y	6.3.6	Y	
	6.3.7	NA	6.3.8	Y	
	6.3.9	Y			
6.4 Medical Screening					
SOI	Health conditions likely to adversely affect product safety shall be monitored and controlled.			**Y**	Procedure for the notification (F/HR/20) by personnel, including temporary personnel, of any relevant infections, diseases is displayed before entrance to facility. Employees with any disease or cuts are not allowed to work inside production facility. Monitoring is being done by HR & all health records pertaining to all personnel's are retained & maintained by HR. Verified record for employees checked by Dr Mahesh Chandra Verma, (registration number 20684) in a camp. This is done once in a year. A health declaration F/HR/12 is provided to visitors prior to being allowed into the production areas. A health declaration F/HR/12 is provided to visitors prior to being allowed into the production areas. As per QPR/26, In case of cuts and grazes person is not allowed to work inside, however provision exists for blue coloured plaster with metal detectable strip.
	6.4.1	Y	6.4.2	Y	
	6.4.3	Y			
6.5 Protective clothing					

SOI	Appropriate protective clothing shall be worn in production and storage areas to minimise the risk of product contamination.			Y	Company has provided protective clothing (shirts & trousers) for personnel working in production area. Personnel found to wear clean identified uniform without sewn on buttons and pockets as work clothes. Clothing is provided to all personnel. 4 sets are available for every employee. Clothing covers upper torso without sewn on buttons and pockets. Change is made every alternate day. Extra protective clothing is available for emergencies. Dress and Laundry Policy is displayed and implemented to state where protective clothing can be worn away from the production environment. Refer, which states before leaving the workplace, all employees are required to hang their apron and cap in the hanger provided in the change room area. Dress and Laundry Policy is displayed and implemented to state where protective clothing can be worn away from the production environment. Refer, which states before leaving the workplace, all employees are required to hang their apron and cap in the hanger provided in the change room area. Employees use slippers provided by company at the time of entrance on the shop floor. Snoods are provided for the people with the beards and moustaches. Protective hair nets are provided to all personnel. Uniforms were clean and are laundered by Shree Laundry service (outsourced). Contract is dated 1.7.2012 which is extended every year. QC/33 assessment of service provider is available dated August 15. Initial visit report is available dated 28.09.2012.. Adequate segregation is practiced to prevent cross contamination.
	6.5.1	Y	6.5.2	Y	
	6.5.3	Y	6.5.4	Y	
	6.5.5	Y	6.5.6	Y	
	6.5.7	Y	6.5.8	Y	
	6.5.9	Y	6.5.10	Y	
	6.5.11	Y			