Volume I of I

TYPE III
DRUG MASTER FILE

INDUCTION SEALING WADS

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INDUCTION SEALING WADS

TYPE III DMF

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INTRODUCTION

1. PRODUCT DESCRIPTION:

The company is engaged in the manufacture of induction heat seals for sealing of all kinds of plastic and glass bottles. All component materials used in the manufacture of induction heat seals as detailed elsewhere are food grade certified. The range of liner materials that are produced are as under.

XL PET (15/25), suitable for sealing Pet bottles.
XL PE (60/12/30), suitable for sealing PE bottles.
XL PE (38/12/25), suitable for sealing PE bottles.
XL PE (38/25), suitable for sealing PE bottles.
XL PP (40/30), suitable for sealing PP bottles.
XL PP Retort (70/30), suitable for sealing PP bottles

Against the above liner materials that are produced by the company, DMF listing is being sought for the following liner materials only.

XL PET (15/25)
XL PE (38/12/25)
XL PE (38/25)

The above liner materials are wax bonded to pulp board substrates in varied thickness of 0.5mm, 0.7mm and 0.9mm to accommodate varying packaging needs.

Induction heat seal wads are used for sealing of rigid containers (bottles or wide mouth jars) made of plastics or even glass, such as containers made from High Density Polyethylene (HDPE), Low Density Polyethylene (LDPE), Polypropylene (PP), Polyethylene-ter-phthalate (PET), Glass and it can not be applied on metal containers.

The Induction heat seal wads are the most effective to achieving, No leakers, Tamper evident sealing, Excellent barrier properties, Hermetic seal and High production speeds.

Commonly used induction heat seal wads are “Two – piece wads”, consisting of, Pulp board wax laminated to the top side of foil which is in turn bonded to a heat sealable polymer layer on the opposite side. Induction Heat Seal Process of a two – piece wad is as under:

A. Wad is placed in the cap either manually or by applying

automatic wadding machine for high production speeds.

B. Wad is retained in the cap either by specially designed wad retainer ring in the cap or it is glued to the cap by applying hot melt glue process.
C. The duly wadded cap is applied to the filled container in the usual way either manually or by automatic capping machine.
D. Duly filled and capped container is then passed on a conveyor through induction heat sealer.
E. The magnetic field generates heat in the aluminium foil on both sides.
F. Heat causes melting of wax which is then absorbed by the board creating separation from the foil.
G. Heat also causes the heat seal layer to soften and it gets bonded to the land area of the container neck.
H. Upon opening of container the board comes out with the cap and the foil remains bonded to the neck.

THE INDUCTION HEAT SEAL PROCESS:

Induction sealing is a result of Pressure, Heat and Time. The induction seal duly wadded to the cap must be applied to the land area of the container with all around equal and uniform pressure. When container is passed on a conveyor through the induction sealer, the magnetic flux of the sealer cuts the metal and heat is produced, whereby the sealing layer gets bonded to the land area of the container neck, while on the other side, the heat generated melts the wax which is absorbed by the board and results its separation from the sealant membrane..

The proper balancing of even Pressure, full Contact, heat and Exposure time is important to achieve an effective hermetic sealing of the container. The importance of Pressure, Heat, and Time can be better understood as shown below:

PRESSURE: Specific and uniform pressure on the wad is important to ensure full, uninterrupted contact between the sealing layer of wad and the land area of the container, which is dependent on:

- Perfect matching of threads on container and closure – type of threads.
- Pitch of threads (number of threads per inch).
- Number of threads.
- Number of rotations before the cap gets locked.
- Matching of container and closure will ensure even and sufficient pressure between sealing layer and the land area of the container. The skirting of cap should under no circumstances come in contact with the shoulder of the container. The distance from the land area of the neck to the shoulder of the container is called “H”. The H-distance in the Cap must be always less than the H-distance of container.

- The land area on the containers must be absolutely smooth and free of any high spots (at parting line), depressions, burrs, flash and unevenness.

Deficiency in any one of the above or not sufficient pressure will lead to following:

- Leakers
- Damage to land area of container
- The sealing layer will be overheated, destroyed or it can even burn contaminating the packed product with a foul smell.
- Damage to secondary layer.

Therefore the importance of proper torquing must be thoroughly understood.

- Under torquing will result in improper seal,
- Over torquing may damage the threads and landing area.
- The rigidity of cap must also be right to generate sufficient torque and contact pressure.
- The cap must also be free of any distortions, warpage etc.

The test method to ensure that pressure available is correct for good hermetic induction sealing is by observing the neck impression on cap torqueing on the sealant membrane.

HEAT: Heat is the main ingredient to melt / soften the sealing layer and make it fuse to the land area of container. Therefore generation of correct quantity of heat and its uniform distribution over the entire area of wad is pre-requisite to achieve proper seal.

1 Too much of heat (too high temperature):
- will destroy the seal
- will discolor or burn the board which will cause foul smell
- will damage the rim of container

2 Less heat (too low a temperature):
- will not create proper seal
- will result in leakers.

3 Uneven distribution will not allow good and easy separation
- it will also leave wax marks on the foil after separation.

TIME: When a container passes through an induction heat sealer time is necessary:

1. to generate heat
2. to transfer heat from foil to sealing layer
3. to melt sealing layer and make it fuse to the rim of container
4. to allow the wax to melt and be absorbed by the board

The balancing of pressure, heat and time is the key to achieving a perfect tamper evident and hermetic seal. The design and power of induction heat sealer and the induction coil will matter greatly while sealing larger neck containers, and good separation with clean shining foil.

2. PROCESS DESCRIPTION:

Excel Pack Limited manufacturers Induction Sealing Wads. Induction heat seal wads are used for sealing of rigid containers (bottles or wide mouth jars) made of plastics or even glass, such as containers made from High Density Polyethylene, Low Density Polyethylene, Polypropylene, Polyethylene-teraphthalate, and even Glass. Induction Sealing Wads can not be applied on metal containers. The manufacture of induction heat seals involves various processes which are detailed as below.

Lamination:

The same relates dry adhesive lamination of foil to different films as per product requirement. The lamination is a permanent bonding of the sealant membrane to ensure a high degree of heat and chemical resistance.

Printing:

The foil, if required, is printed for specific customer print or generic print through process of roto gravure printing.

Wax Coating:

The laminated sealant membrane printed or plain as above is wax bonded to pulp board substrate on a wax coating machine.

Slitting:

The wax bonded material as above is slit into strips as per punch tool dimensions for loading on the decoiler of the punch machine.

Punching:

The slitted strips as above are fed through the automatic feeder to the punch machine for making of induction heat seals in disks of various sizes as per customer orders.

Sorting and Packing:

During punching the rejected wads are sorted out and destroyed outright. Under no circumstances any one of such rogue piece should reach the customer or leave the factory undestroyed.

Counting and Sealing:

The wads are packed in tubes by using especially designed and engineered fixtures in such a way that each tube may contain 500 wads and all wads facing single direction with sealing layer towards closed end of poly tube or pulp board facing towards open end of poly tube.

Packing in Cartons:

Duly counted wads and packed in sealed tubes are to be placed in transport worthy cartons.

3. STATEMENT OF CONFIDENTIALITY

Information presented in this DMF is confidential and should be treated as confidential to the extent possible in accordance with **21 CFR 314.430 and 21 CFR 20.61**.

Information from this file should not be provided to any unauthorized persons without the written consent of **Excel Pack Limited.**

SECTION A

ADMINISTRATIVE INFORMATION

1.	Name and address of the DMF holder	**Excel Pack Limited** 1004 – 1007, Devika Towers, 6 – Nehru Place, New Delhi – 110019 INDIA Ph.: + 91 (0)11 41655308 + 91 (0)11 41655310 Fax: + 91 (0)11 41656337 E-mail: excelpack@vsnl.in
2.	Address of Corporate Headquarters	**Excel Pack Limited** 1004 – 1007, Devika Towers, 6 – Nehru Place, New Delhi – 110019 INDIA Ph.: + 91 (0)11 41655308 + 91 (0)11 41655310 Fax: + 91 (0)11 41656337 E-mail: excelpack@vsnl.in
3.	Address of Manufacturing Facility	**Excel Pack Limited** Plot no. 8, Sector – 4. Integrated Industrial Area BHEL – Ranipur HARIDWAR – 249405. (Utteranchal) INDIA Ph: + 91(0)1334 – 239316 Fax: + 91(0)1334 – 239317
4.	Name, Address and Title of the contact person for FDA Correspondence. Name, Address and Title of the Alternate contact Person for FDA Correspondence.	Rajnish Mehra, Managing Director E-mail: rajnish@excelpack.in Subhash Sarin, Technical Head E-mail: subhashsareen@excelpack.in
5.	Name and address of Agent.	We have not appointed any Agent in USA at present.

BRIEF INFORMATION ABOUT THE COMPANY:-

Background information:

Excel Pack Ltd is a newly formed company and commenced business operations in February 2003. In its third year of operations ended 31.3.07, the company achieved a turnover INR340 Lacs. The company is growing rapidly and barring unforeseen events, the company estimates to achieve a turnover of approx. INR 750 lacs for the year ending 31st March 2008.

Promoters:

Mr. Rajnish Mehra, a qualified Chartered accountant, having nearly 20 years of corporate professional experience of which the last 14 years was with Pearl Polymers Ltd as the business Head, has promoted the company. Pearl Polymers is one of the leading producers in the country of Pet bottles and containers and during the tenure of Mr. Mehra as the business Head, the company made significant progress with growth in turnover from US $ 2,000,000 to US $ 20,000,000. Mr. Mehra was responsible for sustained growth at Pearl by opening up various markets for Pet applications relating Agro, Pharma, Personal care, Edible oil, CSD, Water and many others.

Given the vast experience of the main promoter as also the direct interface with major user Co's in India, led to the decision to form Excel Pack with an objective to carry on existing well versed activity relating to Pet bottles as also to introduce world class products to the Indian market in allied and related fields of packaging.

Business activities:

Excel Pack Ltd (EPL) is engaged in business operations as detailed below:

Company is engaged in the manufacturing of induction heat seal liners / wads. The induction heat seals produced provide 100% hermetic seal, no leakers and tamper evident desired level of barrier properties and is suitable for application with aggressive such as pesticides, veterinary medical compositions; general pharmaceutical requiring FDA and DMF approvals; food and supplementary products requiring approved materials. Company is operational for three years and has recently set up a new manufacturing facility at; plot no. 4, Sector - 8, Integrated Industrial Area BHEL - Ranipur, Haridwar - 249 405. (Utteranchal) - India. Since only one specific size is suitable for any combination of cap / container system, company has developed library of cutting tools (over 400 different sizes in number and configurations) and therefore can offer wide range of

sizes and types of induction heat seal wads. Large variety of wads offered are suitable for application with rigid bottles and wide mouth containers made from LDPE, HDPE, PP, PET, PVC, HIPS, PS and even GLASS to match customers specific requirements. Company has also developed special induction heat seal wads for retorting process.

B. PERSONS AUTHORIZED TO INCORPORATE THE DMF BY REFERENCE

Authorized Person	Description and location of information referenced	Referencing Drug Product and Application number
Nil	Nil	Nil

C. DESCRIPTIVE INFORMATION

a. Component Description

Sr. No.	Product Name	Product Designation	Product Description
1.	Induction Sealing Wads	1. XL PET (15/25), suitable for sealing Pet bottles. 2. XL PE (38/12/25), suitable for sealing PE bottles. 3. XL PE (38/25), suitable for sealing PE bottles.	Commonly used induction heat seal wads are "Two – piece wads", consisting of Pulp board wax laminated to the top side of foil which is in turn bonded to a heat sealable polymer layer on the opposite side.

b. Materials of Construction

All materials are in compliance with Federal Regulation 21 CFR.

The details of the primary suppliers for Raw Material are as per follows:-

The Substrate / Pulp Board are obtained from the following company:

Sr. No.	Company	Product Name	DMF Reference Number
1.	FI – 81750 Pankakoski Finland	Pankaseal PB244	Nil
2.	Brownville Specialty Paper Products Bridge Street Brownville, NY13615, USA.	Paper Board Product code 2301, .035/309 (500 gsm)	Nil

The films and foil required for manufacturing the sealant membrane are obtained from the following company(s):

Sr. No.	Company	Product Name	DMF Reference Number
1.	Hindalco 2nd Floor, UCO Bank Building Sansad Marg New Delhi 110 001. India.	25 micron Aluminium Foil	Nil
2.	Sui On Insulating Materials Co. Ltd 10A, Nathan Road, Kowloon, Hong Kong.	Mylar 851H of Dupont Teijin, USA	Nil
3.	The Paper	38micron LD Poly film	
4.	Garware Polyester Limited 403 – Bhikaji Cama Place New Delhi – 110066	Polyester film (12microns)	Nil

The Printing Inks and Bonding Agents are obtained from the following company:

Sr. No.	Company	Product Name	DMF/FDA Reference Number
1.	Sakata Inx (India) Limited. 10th Floor, Devika Towers 6 – Nehru Place, New Delhi – 110019.	Printing Inks	Nil
2.	Rohm and Hass India Pvt. Ltd. 121-122, Solitaire Corporate Park Chakala, Andheri – Kurla Road Andheri East, Mumbai – 400093	Bonding Agents (Solvent base), Adcote 545S and Co reactant F	Nil

3.	Glaxo Smithkline	Ethyl Acetate (99.95% Proof)	Nil

The Polytubes are obtained from the following company:

Sr. No.	Company	Product Name	DMF Reference Number
1.	A. P. Polyplast Pvt. Ltd. K – 3, Udyog Nagar, Rohtak Road Peera Garhi, New Delhi - 110041	Polytubes	Nil

The Cartons are obtained from the following company:

Sr. No.	Company	Product Name	DMF Reference Number
1.	Sumdit Industries A – 118, Okhla Industrial Area, Phase – II. New Delhi – 110020	Cartons	**Nil**

c. Alternate, interchangeable material of construction

Alternate supplier for Substrate / Pulp Board is obtained from the following company:

Sr. No.	Company	Product Name	DMF Reference Number
1.	ITC Global ark Unit 903, 9th Floor, Tower – B Gurgaon – Mehrauli Road IN – 122001 Haryana, India.	Pankaseal PB244	Nil

Alternate supplier for Sealing Layers / Laminated Foils is obtained from the following company:

Sr. No.	Company	Product Name	DMF Reference Number
1.	HINDALCO Company Limited UCO bank Building. 2nd Floor Sansad Marg, New Delhi – 110001	Laminated Foils	Nil
2.	The Paper Products Limited L.B. Shastri Marg, Majiwade P.O. Box no.–4, Thane – 400 601. Maharashtra.	Laminated Foils	Nil
3.	DuPont Teijin Hongkong	HS PET Film – 12 (microns)	Nil

The Printing Inks and Bonding Agents are obtained from the following company:

Sr. No.	Company	Product Name	DMF Reference Number
1.	CAC Henkel, India	Bonding Agents (Solvent base)	Nil
2.	WITCO, USA	Bonding agents (wax base)	Nil
3.	VT 23, Germany	Bonding agents (wax base)	Nil

The Polytubes are obtained from the following company:

Sr. No.	Company	Product Name	DMF Reference Number
1.	B. K. Polymers A – 12/4, Naraina Industrial Area, Phase – 1 New Delhi – 110028	Polytubes	Nil

The Cartons are obtained from the following company:

Sr. No.	Company	Product Name	DMF Reference Number
1.	Sheela Packers B – 21, DDA Sheds, Okhla Industrial Area, Phase – II New Delhi – 110020	Cartons	Nil

SECTION D

MANUFACTURING PROCESS DESCRIPTION

Note: Check for Line clearance before starting any step

<u>This can be broken to six major steps for effective control and best liner quality:</u>

1. INTRODUCTION TO INDUCTION SEALING WADS
2. PRINTING
3. LAMINATION
4. SLITTING
5. PUNCHING
6. SORT & PACK
7. COUNT AND SEAL
8. PACKING IN CARTONS:

1. INTRODUCTION TO INDUCTION SEALING WADS:

Induction heat seal wads are used for sealing of rigid containers (bottles or wide mouth jars) made of plastics or even glass, such as containers made from:

- High Density Polyethylene (HDPE),
- Low Density Polyethylene (LDPE),
- Polypropylene (PP),
- Polyethylene-ter-phthalate (PET),
- And even Glass.
- It can not be applied on metal containers.

The Induction heat seal wads are the most effective to achieving:

- No leakers.
- Tamper evident sealing.
- Excellent barrier properties.
- Hermetic seal.
- High production speeds.

Commonly used induction heat seal wads are "Two – piece wads", consisting of:
Pulp board wax laminated to the top side of foil which is in turn bonded to a heat sealable polymer layer on the opposite side. Induction Heat Seal Process of a two – piece wad is as under:

I. Wad is placed in the cap either manually or by applying automatic wadding machine for high production speeds.
J. Wad is retained in the cap either by specially designed wad retainer ring in the cap or it is glued to the cap by applying hot melt glue process.
K. The duly wadded cap is applied to the filled container in the usual way either manually or by automatic capping machine.
L. Duly filled and capped container is then passed on a conveyor through induction heat sealer.
M. The magnetic field generates heat in the aluminium foil on both sides.
N. Heat causes melting of wax which is then absorbed by the board creating separation from the foil.
O. Heat also causes the heat seal layer to soften and it gets bonded to the land area of the container neck.
P. Upon opening of container the board comes out with the cap and the foil remains bonded to the neck.

THE INDUCTION HEAT SEAL PROCESS:

Induction sealing is a result of Pressure, Heat and Time. The induction seal must be applied to the land area of the container with all around equal and uniform pressure. When container is passed on a conveyor through the induction sealer, heat is produced on both sides of foil, on one side it melts or softens the sealing layer of the wad and it gets bonded to the land area of the container neck, while o the other it melts the wax which is absorbed by the board and results its separation from the sealing layer.

The proper balancing of even Pressure, full Contact, Heat, Exposure time and Cooling time is important to achieve an effective hermetic sealing of the container. The importance of Pressure, Heat, and Time can be better understood as shown below:

PRESSURE: Specific and uniform pressure on the wad is important to ensure full, uninterrupted contact between the sealing layer of wad and the land area of the container, which is dependent on:

- Perfect matching of threads on 22 container and closure – type of

threads.

- Pitch of threads (number of threads per inch).
- Number of threads.
- Number of rotations before the cap gets locked.
- Matching of container and closure will ensure even and sufficient pressure between sealing layer and the land area of the container. The skirting of cap should under no circumstances come in contact with the shoulder of the container. The distance from the land area of the neck to the shoulder of the container is called "H". The H-distance in the Cap must be always less than the H-distance of container.
- The land area on the containers must be absolutely smooth and free of any high spots (at parting line), depressions, burrs, flash and unevenness.

Deficiency in any one of the above or not sufficient pressure will lead to following:

- Leakers
- Damage to land area of container
- The sealing layer will be overheated, destroyed or it can even burn contaminating the packed product with a foul smell.
- Damage to secondary layer.

Therefore the importance of proper torquing must be thoroughly understood.

- Under torquing will result in improper seal,
- Over torquing may damage the threads and landing area.
- The rigidity of cap must also be right to generate sufficient torque and contact pressure.
- The cap must also be free of any distortions, warpage etc.

HEAT: is the main ingredient to melt / soften the sealing layer and make it fuse to the land area of container. Therefore generation of correct quantity of heat and its uniform distribution over the entire area of wad is pre-requisite to achieve proper seal.

1 Too much of heat (too high temperature):
- will destroy the seal
- will discolor or burn the board which will cause foul smell
- will damage the rim of container

2 Less heat (too low a temperature):
- will not create proper seal
- will result in leakers.

3 Uneven distribution will not allow good and easy separation
- it will also leave wax marks on the foil after separation.

TIME: When a container passes through an induction heat sealer time is necessary:

1. to generate heat
2. to transfer heat from foil to sealing layer
3. to melt sealing layer and make it fuse to the rim of container
4. to allow the wax to melt and be absorbed by the board

Equally important is the time required after sealing for the duly fused seal to cool down and make a strong bond with container. It is very difficult to know at what temperature the liner seals but it is known that for polypropylene application the induction coil can heat the seal and rim of the container up to temperatures of approximately 200 degree Celsius and while cooling the bonding will start at about 130 degree Celsius. Therefore time is needed after the sealing to allow cool down and during this time it is important that the container is not handled roughly, it should not be bumped or banged otherwise the seal will be broken and result in improper sealing with possibilities of hair line leakers.

For wads with tabs it is important that tabs are not folded downwards over the sides of the container, foil vertical to the coil will not react to magnetic field and this will create some sealing problems. In some cases with tabs folded downwards on sides of the containers the magnetic field gets deflected and in such areas sealing will be weak. Tabs with rounded corners are better than tabs with sharp corners. Excessive overhang of wad will have cooling effect on that part of the liner that is on the land area and will produce weak seals or hair line leakers.

The balancing of pressure, heat and time is the key to achieving a perfect tamper evident and hermetic seal. The design and power of induction heat sealer and the induction coil will matter greatly while sealing larger neck containers, and good separation with clean shining foil.

2. PRINTING:

Most customers require their proprietary logo or some kind of message printed on the wad. The printing is done on the aluminium foil. We have a three - colour rotogravure printing machine at our plant with three in-line print stations. On this machine we can undertake printing jobs requiring up to three colours. The normally available foil is not printable without a specific surface treatment called “Shellac wash”.

The first print station is used for surface treatment of the foil, “Shellac wash” and different colour inks can be used on remaining two print stations to achieve two colour printing.

In case a three colour print is required, different colour inks can be used on all three print stations and in this case the foil can be ordered with duly treated surface or the surface treatment can be given in the first pass on our own machine and the three colour printing can then follow in the second pass.

Selection of ink is most important and the company has identified:
M/s Sakata Inx Pvt. Ltd. As the ink supplier

Any printing job will require print cylinders as per the print layout and number of colours. It also requires a corresponding shellac-wash cylinder. The quality of printing is dependent on the quality of cylinders; therefore the company has identified two print cylinder suppliers as stated below:

- M/s. Kohli gravure and
- M/s. Yuncheng Rotogravure

Each set of cylinders is ordered as necessary from the cylinder manufacturer. The printing must confirm to following:

1. Colour shade and print layout matching
2. Sharpness
3. Heat resistance to withstand temperatures induced during induction sealing process
4. Chemical resistance
5. It must also pass following tests
    a. Tape test
    b. Nail test
    c. Crease test

The shellac wash cylinder and the print cylinders are loaded on different print stations as per the print layout. The plain foil roll is loaded on the unwind station of the printing machine in such a way that the print ready surface is exposed to the print station. The printing inks and especially suitable chemical is filled in the tanks available at respective print stations. The foil is then passed over various guide rollers, the print stations, through the drying tunnel and finally attached to the rewind station. A small print run is taken and machine stopped. The print is checked for quality and matching with the approved sample. If everything is found in order final printing can begin and the printing is completed.

The print quality is once again checked with the duly approved sample and the duly printed rolls are tagged for customer details, Start up Memo details, Batch number, Shift, Date, Operator details and allowed to cure for 24 hours before taking these to next process of lamination.

3. LAMINATION:

Lamination is a process where two materials are bonded together by applying a bonding agent, either permanently or temporarily depending upon the application requirements. In the case of induction heat seal wad manufacturing we need both types of lamination at different stages. In the first stage the sealing layer is permanently bonded to the aluminium foil and in the second stage the first laminate so achieved is temporarily bonded to the pulp board.

The selection of the boding agent is important and it is selected with respect to various factors such as:

- Type of materials to be bonded
- Is bonding permanent or temporary
- Extent of chemical resistance
- Toxicity status of end product
- Heat resistance

Adhesives used for permanent bonding are always solvent based for achieving high degree of chemical and heat resistance to the sealant membrane. The lamination process for permanent bonding is carried out on the dry adhesive lamination plant available with the unit. For best results in induction heat seal wads the company has narrowed down on solvent based adhesives and identified two suppliers of same, namely:

- Rohm & Haas and
- CAC Henkel

For temporary bonding where the duly laminated sealant membrane laminated as above is temporarily bonded to the pulp board (substrate) hot melt adhesives are used which can be melted to a specific viscosity (flow characteristics) at a given temperature of about 100 degrees Celsius with solidifying temperatures of about 65 degrees Celsius. Such adhesives can be paraffin waxes, microcrystalline waxes, polyethylene waxes or a combination of these. We have through trials and experience narrowed down on microcrystalline wax and identified following two suppliers of it, namely:

- Shell - Holland and
- Witco - USA

The dry adhesive lamination machine consists unwind station, coating station, pressure rollers, drying tunnel and a set of guide rollers. The coating station consists of an adhesive tank, an especially designed pick-up roll and doctor's blade. The pick-up roll is so designed and engineered to ensure specific amount of adhesive is transferred as necessary to give an even 27 and permanent bonding. The application/coating of adhesive is measured in GSM (Grams per Square

Meter) and it is maintained as per

guide lines by the adhesive manufacturer based on its type and grade. Fine tuning of recommended GSM is necessary as per application by the user.

In the first stage where a sealing layer is to be permanently bonded to the aluminium foil, the sealing layer or the inner barrier depending on whether the required construction is 2 ply or 3ply is loaded at the primary unwind roll and the foil to be bonded is loaded on the secondary unwind roll. Solvent based adhesive is filled in the adhesive tank at the coating station. The film whether sealing or inner barrier layer is passed through the coating station to evenly pick-up the required quantity of adhesive and then passes through a drying tunnel of 7 meters long with three hot air blowing stations to completely remove the solvents from the adhesive. The adhesive coated now solvent free film comes into contact with the foil release from the second unwind station through a hot nip roller and the two substrates are pressed for bonding through pressure rollers. The two bonded substrates as above are rewound on a core at the winding station.

The duly laminated substrate rolls are then put to cure for 48 hours in a specially designed hot air chamber of 50 ℃. The cured rolls are then checked for bond strength with a tensile testing machine as also for chemical and heat resistance before these are subject to further processing.

In the second stage a temporary bond is created between pulp board and the laminate as produced at first stage. The wax lamination machine in principal is similar to as explained above except that there is no drying tunnel. The duly laminated sealant membrane roll is loaded on to primary unwinding station in such a way that the foil side of laminate comes in contact with the wax coating cylinder. The pulp board roll is loaded on the secondary unwinding station. The bonding agent, microcrystalline wax (in this case) is loaded in a tray which is electrically heated to the required temperature. The absolute temperature and precise temperature control are very important to achieve desired levels of GSM application as explained earlier. Once the wax pick-up roll is standardized the GSM will depend upon viscosity of the melted wax which is a function of temperature hence the precise temperature control.

The laminate is passed through the rolls, over the wax coating cylinder where the foil side of the laminate gets coated with melted wax and then meets the pulp board which is released by secondary unwind station. Both materials the laminate and the pulp board are then passed through pressure rolls to bond the two materials and rewound on a paper core at the rewinding station. 28 It is important to maintain a pre determined tension in the laminate and pulp board to achieve even wax coating

and uniform pressure to get a good bond between the laminate and the board.

Duly laminated rolls are allowed to cure for 24 hours at room temperature, before these are subject to further processing. The rolls after curing are being checked for separation of board and absorption of wax by test induction sealing as also for delamination by placing in a chamber of 45 ℃ for 5 minutes to ensure that the sealant membrane does not disengage from the board (to ensure heat resistance of product during transit) before they are released for further processing.

4. SLITTING

Each punching tool is designed to handle rolls of a specific width for automatic and uninterrupted production. This width is dependent on the specific punching tool on which it is to be used. Therefore the duly wax laminated and cured rolls are required to be slit to standard widths as per the punching tool requirement for a given wad diameter before it can be transferred to the punching station. For this the company has a dedicated slitting machine consisting of an unwinding station, cutting station, rewinding station and a set of guide rolls.

The cutting station consists of blades, the distance between any two cutting blades can be controlled indefinitely from 25 to 450 mm in steps of 0.5 mm. Distances between blades are set to given distance as specific to a punching tool e.g. a three cavity tool for 43.85 mm diameter wads requires a fixed roll feed of 127mm width and a 6 cavity tool for 23.5 diameter requires a fixed roll feed of 137 mm width.

Laminated rolls are loaded on the unwind station, the blades are set to required width, the pulp laminate is passed through cutting station and rewound on individual paper cores of the required widths, at the rewinding station. It is necessary to control and maintain through out the operation of slitting a pre-determined tension in the laminate to ensure smooth edges and rolls with smooth edges without any telescoping. This tension can be controlled through an automatic servo regulated electro magnetic brake system at the unwind station.

Standard tags are applied to duly slit rolls on the inside of core as well as on the top surface of the rolls providing information on type of laminate, width and wad dia, customer, batch number, date and name of operator. These rolls can be sent to punching station as instructed.

5. PUNCHING

Duly laminated pulp boards need to be punched to wads of specific diameter. A wad of only one specific dimension has been found to be effective for each combination of cap and container to achieve perfectly fused and hermetic seal; therefore we have a large number of libraries of punching tools.

A. The punching line consists of an automated motorized unwinding stand, an automatic feeder and the power press in that sequence. The "Punching Job Order" is tagged on the press which gives details of:

1. Diameter of wad with tolerances
2. Punching tool details
3. Roll width
4. Customer name
5. Details of printing or unprinted as required
6. EPL Material Code
7. Quantity of this production run
8. Date and shift
9. Name of die setter to be filled at punching station
10. Name of authorization official to be filled at punching station

B. The punching tool is loaded on the power press by the die setter and he tests the tool for proper fitment and functioning. Following checks are undertaken by the die setter before regular production is authorized by the quality assurance department:

Check point	Desired observation
1. Any burr or flash	: Should be none
2. Smooth edges	: Should be smooth
3. Rounding of edges	: None
4. Diameter	: Must be within tolerances
5. Dust formation	: None
6. Warpage	: None

C. The designated roll of laminated pulp board is loaded on the unwinding stand and passed through the feeder, through the punching tool and drawn out at the other end of the press. This operation works from left to right when standing in front of the station. Power press is put into auto – operation and the feeder pushes the board through the tool by the set length with each cycle of the press, it is also synchronized with each stroke of press. The automatic and motorized unwinding stand senses the tension of the roll and unwinds the roll as needed. The punched wads are collected in "blue coloured bin" under the tool and punched board/roll sheet moves out side the press

on the right. This duly punched board is called web-wastage and is total wastage. It is collected at the right side of press and moved away to web collection bin out side the production premises.

D. When the "blue coloured bin" is full it is replaced with an empty bin. The full bin is tagged giving details:

1. Wad diameter
2. Printing status
3. EPL Material Code
4. Customer

These "blue coloured bin" is covered and kept ready for moving to next production stage i.e. "Sort & Pack"

6. SORT & PACK

During punching rejections can take place due to following defects, which have been designated as "Rogues". Utmost importance and attention is given that such rogue pieces are sorted out and destroyed outright. Under no circumstances any one of such rogue piece should reach the customer or leave the factory undestroyed. These can be diagnosed / identified as under:

1. Intolerable flash / burrs
2. Dust
3. Moon cuts
4. Oval pieces
5. De-lamination
6. Wrinkles
7. Creases
8. Air bubbles
9. Any other visible defects
10. Printing status
11. Wrong materials

Wads received from punching station in "blue coloured" bins are moved to a specially created clean room and are spread on a clean table under well illuminated conditions, the inspector checks each wad:

A. Visually for any of the rogues as listed above from 1 to 9.
B. From every lot that is put on table for inspection at least two wads are checked for correct printing and if found in conformity, the inspector proceeds further, otherwise reports to the QA manager for further advice.
C. Similarly from every bin that comes to the inspector, at least two randomly selected samples are taken for actual sealing test. If sealing is perfect he proceeds further, otherwise rejects the bin, puts a yellow tag on the bin, and keeps this duly yellow tagged bin on the demarcated side for further instructions from the QA manager.
D. Checked and 'PASS' wads are pushed into the right side "Green coloured bin" and rejected wads are pushed into left side "red coloured bin".
E. Wads from the green coloured bins are packed into tubes with help of designated fixtures which are designed to hold 500 wads, in such a way that the sealing side of all wads is facing open end of the tube.
F. The tubes are then temporary closed and passed to the count and seal station.

7. COUNT AND SEAL

The wads packed in tubes are received at "Count & Seal" station. Wads are packed in tubes at the last "Sort & Pack" station by using especially designed and engineered fixtures in such a way that each tube may contain 500 wads.

However to avoid any errors each tube is checked again by weigh and count method to ensure that exact quantity of 500 $\pm$ 1 wads are in each tube. For this purpose an electronic weighing scale with a least-count of 0.1 gram is used. The operator at this station has a standard guide for weight of 500 wads for each size and type of wad, the weight of tube is "Tared" on the scale. Each tube is individually checked and wads are added or removed to ensure correct weight and count. Thereafter tubes are permanently sealed to make them worthy of handling and transportation so that these reach the customer's consumption point without any damage. In this way wads are also protected from any dust or other contamination during handling, transportation and storage.

These duly counted and sealed tubes are sent to the carton station for packing into them.

8. PACKING IN CARTONS

Duly counted wads and packed in sealed tubes are to be placed in transport worthy cartons. Company has standardized carton size and each size of wad has a pre-determined quantity for each size and type of wad. The orders are also booked on full carton basis and it is endeavored that no order for part carton is booked and as consequence of that no partly filled carton is dispatched.

The tubes are placed in cartons and original packing slip is pasted on the out side of the carton second copy of the same packing slip is placed inside the carton. The packing slip displays following information:

1. Wad size
2. Wad type with EPL material code
3. Batch no.
4. Date of packing
5. Packing details i.e. 45 x 500 = 22 500pcs.
6. Signature and name of packer

Ready cartons are shifted to finished goods store or to the dispatch point as per instructions.

SECTION E

SPECIFICATIONS

1.0 Specifications for Material of Construction

1.1 Physical Specifications

a) Pulp board - Pankaseal

Sr.No.	Parameters	Specifications
1	Thickness	Not less than 820 microns
2	Grammage	Not less than 468 g/cm^2
3	Print quality	Unprinted
4	Moisture	Not more than 10 %
5	Internal bond strength J/m2	Not less than 170
6.	Cobb Value	Not less than 50gms per sq. meter.

b) Laminate 38/25 (LD Poly /Foil)

Sr.No.	Parameters	Specifications
1	Thickness	Not less than 58 microns
2	Grammage	Not less than 106 gms
3	Print quality	Unprinted
4	Winding	No wrinkles, tightly wound, no telescoping of edges
5	Coil O.D.	Not more than 310 mm
6	Coil width	254$\pm$ 1 mm
7	Bond strength (Gm/25mm)	Not less than 600
8	Seal strength (Kg/25mm)	Not less than 1.5

c) Laminate 25 / 15 (Foil / Heat seal Pet)

Sr.No.	Parameters	Specifications
1	Thickness	Not less than 43 microns
2	Grammage	Not less than 91
3	Print quality	Unprinted
4	Winding	No wrinkles, tightly wound, no telescoping of edges
5	Coil O.D.	310 ± 10 mm
6	Core diameter	76 ± 1 mm
6	Coil width	264 ± 1 mm
7	Bond strength (Gm/25mm)	Not less than 1200
8	Seal strength (Kg/25mm)	Not less than 1.5

d) Laminate 25 / 12 / 38 (Foil / PET / LD Poly)

Sr.No.	Parameters	Specifications
1	Thickness	Not less than 81 microns
2	Grammage	Not less than 125
3	Print quality	Unprinted
4	Winding	No wrinkles, tightly wound, no telescoping of edges
5	Coil O.D.	305 ± 10 mm
6	Core diameter	76 ± 1 mm
7	Coil width	254 ± 1 mm
8	Bond strength (Gm/25mm) a. Foil / Pet b. Pet / PE	 Not less than 1200 Not less than 750
9	Seal strength (Kg/15mm)	Not less than 1.5

g) Bonding Agent (Wax base):

Sr.No.	Parameters	Specifications
1	Melt point (deg. C)	Not less than 65°C
2	Congealing point (deg. C)	Not less than 62°C
3	Viscosity @ 100 deg. C (D455)	15 Typ
4	Color (visual)	Clear white

i) Printing Ink

Sr.No.	Parameters	Specifications
1	High heat resistant	Not less than 220 deg C
2	Solid content in %	Not less than 20 %
3	Viscosity for each supply	To be advised by supplies in Zahn Cup No. 3 @ 25 deg C OR in measurements of DIN Cup B4.
4	Solvent system	Suitable for Ethyl Acetate
5	Retarder system	Suitable for Diacetone Alcohol (DAA) maximum 10 %.

J) Poly Tubes

Sr.No.	Parameters	Specifications
1	Thickness in microns	Not less than 50 microns
2	Grammage (per meter)	Not less than 3.7 g/m^2
3	Layflat width (Inches)	Not less than 3 inches
4	Clarity (Visual)	Should be clear
5	Air bubbles	Not more than 5 nos. per meter
6	Contamination spots (Visual)	Not more than 5 nos. per meter

k) Cartons

Sr.No.	Parameters	Specifications
1	Grammage (GSM)	Not less than 950
2	Burst strength	Not less than 15
3	Printing matter (visual only)	As per approved art work
4	Print quality (visual only)	Clear print, no smudging
5	Color (visual only)	Blue as approved

2.0 IN PROCESS TESTS

1. Processing conditions at various stations can have significant influence on the final quality and behavior end products. Through experience and PDS (Product Data Sheets) of different input materials, the Company has endeavored to standardize optimum processing conditions at each station.

The standard processing conditions are seen as broad guidelines and fine – tuning of the individual parameter is the responsibility of the operator so as to ensure that the end product from one particular station meets the desired quality levels for which the operator needs to comply with respective SOP.

Process records are maintained in pre-designed formats at all stations listed below:

1. All incoming materials are checked with respective SOP.
2. Printing machine running parameters.
3. Lamination machine running parameters.
4. Press shop.
5. Sort and Pack.

LISTING OF TESTS CARRIED OUT:

A. One Time Checks:
1. Incoming Materials (Separate sheet for each material received).
2. New die validation.
3. New die Start – Up.
4. Seal integrity check on start up of new batch.
5. Printing Start – Up.
6. Printing quality at the end of each roll.
7. Lamination Start – Up.
8. Lamination quality at end of each roll.
9. Finished materials leaving factory, Dispatch – Report.

B. Hourly Checks:
1. Punching Line – 1.
2. Punching Line – 2.
3. Punching Line – 3.
4. Punching Line – 4.
5. Punching Line – 5.
6. Punching Line (hand press).

C. Continuous Check At:
1. Printing Station.
2. Lamination Station.
3. Sorting Station.
4. Counting & tube packing.
5. Packing in cartons.
6. Labeling of cartons.

DETAILS OF QUALITY SYSTEM BEING COMPLIED WITH:

1. All vendors are validated and approved for quality product and reliability by the management.
2. Inputs as tested and approved by the management are procured only from duly approved suppliers.
3. All receipts are checked and compared with the purchase order with respect to supplier, quantity, quality as per respective SOP(s) number of days in transit, Certificate of Compliance.
4. Materials are issued to production against specific job order giving details of customer, product, application, order quantity, components to be used for each individual process.
5. Printing quality is checked for colour shade, tape test, scratch test, nail test, wrinkle test and heat resistance.
6. Duly laminated materials are checked for bond strength and seal strength.
7. Wax bonded materials are checked for fiber tear, wax coating and separation properties.
8. Validation of cutting tool with respect to Diameter, Ovality, Burr, Flash, Edge quality and Dust formation.
9. Finished product "The Seal" is checked for seal credibility and separation properties.
10. Sorting, packing, labeling of standard cartons.
11. Dispatch documents and dispatch.

REJECTION PARAMETERS:

Quality checks are made at each stage of the entire process and the deviations have been categorized as under:

I. Pass: All criteria within tolerances, materials accepted and sent to store
II. Minor: Deviations are non – relevant, materials accepted with information to supplier.
III. Major: Such deviations where HO intervention is considered necessary. A yellow flag is attached to such materials and these are kept in abeyance awaiting further instructions from HO.
IV. Critical: Material not acceptable and is rejected outright. A red flag is attached to such materials and sent to "Goods Rejected Stores". A written information is sent to HO.

Rejections can take place at various stages of the entire process. Each stage of process and rejection parameters are listed below:

1. PRINTING:

Printing is undertaken as per Work Order and checked for following parameters:

CRITERIA	PASS	MINOR	MAJOR	CRITICAL
Tape test 5 tests are done	No colour on tape	Single dot comes on two of the tapes	A dot or two comes on more than two tapes	Colour comes on tape
Scrub test 5 checks done	No scratches seen	Point like scratch in two checks	Point like scratches in more than two checks	Clear scratches seen
Creasing test 5 checks done	No cracking in print	Point like crack in the print in two samples	Point like crack in the print in more than two samples	Print cracks
Sharpness of print checked with 5x magnifier	No smudging seen	Very little smudging visible	Very little smudging visible with naked eye	Clear smudging visible with naked eye
Colour and shade to be match with the standard	Matches with standard	--	Slightly more than the standard	Major difference
Heat resistance by induction sealing test	No change in original colour	$\pm$ 5% change	Change is more than 5% but less than 10%	Significant change

2. LAMINATION:

Lamination is undertaken as per Work Order and the laminate is checked for following parameters:

CRITERA	PASS	MINOR	MAJOR	CRITICAL
Type of pulp board	As per work order	--	Different from work order	--
Sealing foil	As per work order	--	Different from work order	--
GSM of wax	Within ± limits	Varies by 1 gram	Varies by more than 1 gram	--
Fiber tear if required (applicable to open fiber BSPP board)	All paper comes with foil when peeled in cold condition	Less than 10% paper does not come with foil	More than 10% but less than 20% paper does not come with foil	More than 20% paper does not come with foil
Fiber tear not required (Applicable to bleached paper StoroEnso Board)	No paper comes with foil	Less than 10% paper comes with foil	More than 10% but less than 20% paper comes with foil	More than 20% paper comes with foil
Induction sealing test for standard 38mm neck bottle at sealing speed of 100 bottles/minute	Easy separation of board and no wax seen on foil	Easy separation of board with minor remanent of wax seen on foil	Easy separation but wax visibilty is more than 10% but less than 20% wax seen on foil	Non separation of board.

3. SLITTING:

Slitting is undertaken as per Work Order and the slit rolls are checked for following:

CRITERIA	PASS	MINOR	MAJOR	CRITICAL
Width of slit roll	As per work order	Within $\pm$ 1 mm	If more than std. width or if less than std. width	--
Smooth sides of roll, no telescoping	Yes	As above	If more do rewinding	--
Tightness of roll	Yes	Slightly loose	If very loose do rewinding	--

4. PUNCHING:

Punching is done on power press as per the Work Order instructions. Die setter loads the die and checks the punched wads for following:

CRITERIA	PASS	MINOR	MAJOR	CRITICAL
Diameter	Within ± tolerances	--	--	If not check tool
Burr or Flash	None	--	--	If yes, check & correct tool
Edges	Smooth	Not visible to naked eye but some roughness seen with magnifier	--	Rough and clearly visible, check & correct tool
Pulp dust	None			
Wrinkles	None			
Punch marks	None			
Air bubbles	None			l
Ovality	None			
Moon cuts	None			--
Warpage / curling	None			
De-lamination of edges	None	--	--	--

Duly punched wads are collected in blue colour bins and sent to "Sort & Pack station".

5. SORT & PACK:

The wads received from punching station are checked for following parameters as under:

CRITERIA	PASS	MINOR	MAJOR	CRITICAL
Diameter	Within ± tolerances	--	--	--
Burr or Flash	None			
Edges	Smooth			
Pulp dust	None			
Wrinkles	None			
Punch marks	None			
Air bubbles	None			
Ovality	None			
Moon cuts	None			
Warpage / curling	None			
De-lamination of edges	None			
Pack in tubes with pulp board facing open end of tube	All wads with board facing open end of tube	--	--	

Duly punched wads are collected in blue color bins and sent to "Sort & Pack station"

6. COUNT & SEAL:

All packed tubes are checked for correct quantity by weigh and count method. Following parameters are observed at this station:

CRETERIA	PASS	MINOR	MAJOR	CRITICAL
Tubes are checked that all wads are in single direction	Yes	--	--	If not, return tubes for repacking in single direction

Pulp side of wads must be facing open end of tubes	yes	--	--	If not, return tubes for correct repacking
Tubes are weighed to standard weight	As per standard weight	--	--	If not, add or remove wads to correct weight
Seal open end of tubes as prescribed	Yes	--	--	--

Duly counted and sealed tubes are sent for packing into cartons,

7. CARTONS:

CRITERIA	PASS	MINOR	MAJOR	CRITICAL
Packing slip inside the carton	Yes	--	--	If not, put packing slip in carton
Packing slip out side of carton	Yes	--	--	If not, paste packing slip on carton
Are cartons in good health	Yes	--	--	If not, change carton
Are cartons properly sealed as prescribed	Yes	--	--	If not, seal cartons properly

Duly packed cartons are sent to finished good stores.

3.0 SPECIFICATIONS FOR FINISHED PRODUCTS

EXCEL PACK LIMITED
1004-05-06, Devika Tower,
6, Nehru Place, New Delhi-110019, INDIA
Tel. : 0091(11) 41655 308 / 310
Fax : 0091(11) 41656337
E-mail : excelpack@vsnl.net

XL GLOBAL EXCELLENCE

CERTIFICATE OF CMPLIANCE Dated: 21 / 03 / 2007

Product: THE WAD

1. Wad Diameter / Date of production : 31.3 ± 0.1 / 20 – 03 – 2007
2. Name of the customer : General
3. Job number / Item : Line – 5 / No Print
4. Print matter / Colour : No Print / No Print
5. Specifications / structure : PP Foam/PET/Paper/Foil/PET/HSPE
6. Excel Product Code No. : TG2 TSPE
7. Sample size for quality check : Check 6 randomly selected pieces
8. DMF Listing : Under process

PARAMETER	SPECIFICATIONS	OBSERVATIONS
Excel Product Code Number	TG2 TSPE	TG2 TSPE
Diameter (mm) 4 readings	31.3 ± 0.1	31.3 / 31.3 / 31.3 / 31.3
Thickness (mm)	0.95 ± 0.5	0.95 to 0.96
Air bubblers	Nil	Nil
Wrinkles	Nil	Nil
Edges	Smooth	Smooth
Burr / Flash	Nil	Nil
Printing	No Print	No Pint
Ink Leaching on sealing	No Print	No Print
Ink discoloration	No Print	No Print
Seal strength (Vacuum)	150 mm (min)	Pass
Separation	Should be clean	Pass

Prepared by
Signature:.....
Name:.....

Approved by
Signature:.....
Name:.....

EXCEL PACK LIMITED
1004-05-06, Devika Tower,
6, Nehru Place, New Delhi-110019, INDIA
Tel. : 0091(11) 41655 308 / 310
Fax : 0091(11) 41656337
E-mail : excelpack@vsnl.net

XL GLOBAL EXCELLENCE

CERTIFICATE OF COPLIANCE

Dated: 21 / 03 / 2007

Product: THE WAD

1. Wad Diameter / Date of production : 45.8 ± 0.1 / 20 – 03 – 2007
2. Name of the customer : General
3. Job number / Item : Line – 3 / No Print
4. Print matter / Colour : No Print / No Print
5. Specifications / structure : Foil/PET/HSPE
6. Excel Product Code No. : PE 130
7. Sample size for quality check : Check 6 randomly selected pieces
8. DMF Listing : Under process
9. Quantity produced : 11 600 pieces

PARAMETER	SPECIFICATIONS	OBSERVATIONS
Excel Product Code Number	TG2 TSPE	TG2 TSPE
Diameter (mm) 4 readings	45.8 ± 0.1	45.8 / 45.8 / 45.8 / 45.8
Thickness (mm)	0.95 ± 0.5	0.95 to 0.96
Air bubblers	Nil	Nil
Wrinkles	Nil	Nil
Edges	Smooth	Smooth
Burr / Flash	Nil	Nil
Printing	No Print	No Pint
Ink Leaching on sealing	No Print	No Print
Ink discoloration	No Print	No Print
Seal strength (Vacuum)	150 mm (min)	Pass
Separation	Should be clean	Pass

Prepared by
Signature:.....
Name:.....

Approved by
Signature:.....
Name:.....

EXCEL PACK LIMITED
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Fax : 0091(11) 41656337
E-mail : excelpack@vsnl.net

XL GLOBAL EXCELLENCE

CERTIFICATE OF COPLIANCE

Dated: 21 / 03 / 2007

Product: THE WAD

1. Wad Diameter / Date of production	: 55.9 ± 0.1 / 20 – 03 – 2007
2. Name of the customer	: General
3. Job number / Item	: Line – 4 / No Print
4. Print matter / Colour	: No Print / No Print
5. Specifications / structure	: PET/PE Foam/Foil/PET
6. Excel Product Code No.	: TS PET / 2
7. Sample size for quality check	: Check 6 randomly selected pieces
8. DMF Listing	: Under process
9. Quantity produced	: 37 600 pieces

PARAMETER	SPECIFICATIONS	OBSERVATIONS
Excel Product Code Number	TG2 TSPE	TG2 TSPE
Diameter (mm) 4 readings	55.9 ± 0.1	55.9 / 55.9 / 55.9 / 55.9
Thickness (mm)	0.95 ± 0.5	0.95 to 0.96
Air bubblers	Nil	Nil
Wrinkles	Nil	Nil
Edges	Smooth	Smooth
Burr / Flash	Nil	Nil
Printing	No Print	No Pint
Ink Leaching on sealing	No Print	No Print
Ink discoloration	No Print	No Print
Seal strength (Vacuum)	150 mm (min)	Pass
Separation	Should be clean	Pass

Prepared by
Signature:.....
Name:.....

Approved by
Signature:.....
Name:.....

EXCEL
PACK LIMITED
1004-05-06, Devika Tower,
6, Nehru Place, New Delhi-110019, INDIA
Tel. : 0091(11) 41655 308 / 310
Fax : 0091(11) 41656337
E-mail : excelpack@vsnl.net

XL GLOBAL EXCELLENCE

CERTIFICATE OF COMPLIANCE

Date: 21 / 03 / 2007

Product: THE WAD

1. Wad Diameter / Date of production : 26.4 ± 0.1 / 20 – 03 – 2007
2. Name of the customer : General
3. Job number / Item : Line – 5 / No Print
4. Print matter / Colour : No Print / No Print
5. Specifications / structure : PP Foam/PET/Paper/Foil/PET/HSPE
6. Excel Product Code No. : TG2 TSPE
7. Sample size for quality check : Check 6 randomly selected pieces
8. DMF Listing : Under process

PARAMETER	SPECIFICATIONS	OBSERVATIONS
Excel Product Code Number	TG2 TSPE	TG2 TSPE
Diameter (mm) 4 readings	26.4 ± 0.1	26.4 / 24.6 / 26.4 / 24.6
Thickness (mm)	0.95 ± 0.5	0.95 to 0.96
Air bubblers	Nil	Nil
Wrinkles	Nil	Nil
Edges	Smooth	Smooth
Burr / Flash	Nil	Nil
Printing	No Print	No Pint
Ink Leaching on sealing	No Print	No Print
Ink discoloration	No Print	No Print
Seal strength (Vacuum)	150 mm (min)	Pass
Separation	Should be clean	Pass

Prepared by
Signature:.....
Name:.....

Approved by
Signature:.....
Name:.....

F. TEST METHODS

Following test methods are followed for incoming raw materials and finished products.

DETERMINATION OF GRAMMAGE PER SQUARE METER

Cut one piece each in size 10 x 10 Cm and 25 x 25 Cm as per templates from one roll of each batch and check GSM using grammage machine.

Calibrate the machine in square meter to centimeter.
Hang the Aluminium pieces on the ring of the scale, which reads the grammage.

MOISTURE CONTENT

SPECIFICATIONS:

The moisture content relates mainly to the substrate pulp board. High initial moisture content in the pulp board can lead to lower absorption properties at the time of induction heat sealing. Good absorption properties are a prerequisite for easy separation after induction heat sealing. The pulp board supplier has specified moisture content of 9 $\pm$ 1.5%. The company has found this limit of moisture content as acceptable and has been using the selected grades of pulp board successfully over the years with excellent separation under normal heat sealing conditions.

DETERMINATION OF MOISTURE CONTENT:

Equipment used:
1. Incubator
2. Quadrant scale

Moisture content in the pulp board can be determined by cutting a piece of 25 x 25 Cm from the pulp board roll which to be taken up for lamination and its GSM "X" is noted with help of a quadrant scale, the sample is than placed in incubator at 65 deg C for not less than 12 hours and its GSM "Y" is noted again. The following calculations will determine the percentage moisture in the sample:

$$\text{Moisture Content in \%} = \frac{(X - Y) \times 100}{X}$$

The resultant reading should be with in the limits as specified by the supplier i.e. 9 + 1.5% at maximum, the roll is cleared for further processing.

If the resultant reading is found to be beyond the maximum limit, the roll is rejected, a yellow flag attached to it and sent to "Disputed Goods Store". A report of the roll along with 5 samples cut to size 25 x 25 Cm is sent to HO for further instructions.

BOND STRENGTH

SPECIFICATIONS:

In the manufacturing process and application of induction heat seal wads we have to deal with two types of bonds:

1. Permanent bond is required between layers of:

Aluminium foil/Polymer film
Aluminium foil/Polymer film/another Polymer film
Paper/Aluminum foil/Polymer film
Paper/ Aluminium foil/Polymer film/ another Polymer film

The permanent bond between any two layers of laminate must sustain through out the life span of the wad that is from the manufacturing process to the point of opening of seal by the end consumer (Slitting, punching, packing, transportation, application, distribution chain until the final consumer breaks opens the seal). From its own experience and trials the company has fixed a value to the required minimum permanent bond strength of : 550 g / 25mm (minimum). This equals to permanent bond life span of 3 years.

2. Temporary bond between layers of:

Aluminum foil/Substrate (pulp board)
Paper/Substrate (pulp board)

The temporary bond between above mentioned layers must sustain the entire manufacturing process up to the point of induction sealing and after that stage the bond is to release the substrate from the sealing layer and upon opening the cap the substrate comes off with cap and the sealing layer remains fused to the container to provide hermetic and tamper evident seal. From experience and trials the company has fixed following criteria for the temporary bond strength:

a). It should sustain to a temperature of : + 45 de C for 5 minutes
b). It should sustain to a temperature of : – 15 deg C for 12 hours
c). It should withstand entire manufacturing process up to the induction heat seal is applied.
d). It should give clean separation after induction heat sealing.

DETERMINATION OF PERMANENT BOND STRENGTH:

Equipment used : Universal tensile tester

Method:

A sample is cut to 25mm width and 200mm long from the duly laminated roll under test and it is clamped in the lower and upper grips of the tester. The tester is set to a speed of 5mm/min. The machine switched on and the reading at which the sample breaks is noted. This is the tensile strength of the specimen which is also equal to bond strength if there is no delamination of layers.

This reading should be above the specified strength and the roll is cleared for further processing.

During the entire process the sample is observed for any separation of laminated films if this occurs before reaching the desired bond strength, the reading is noted and the material is rejected, a yellow flag is attached to it and sent to "disputed goods area". A report along with 10 strip samples of 25 x 200mm is sent to HO for further instructions.

DETERMINATION OF PERMANENT BOND LIFE SPAN OF 3 YEARS:

Equipment used : An Incubator

Method:

As per the simulated test conditions, a test carried out at 54 deg C for 7 days equals to six months of product life under ambient conditions. Therefore a temperature of 55 $\pm$ 2 deg. C is set in the incubator. Three wads samples of a particular size are cut from the roll under test and placed in the incubator. These samples are observed for 6 weeks which equals to 3 years of product life. After 6 weeks, if no delamination of layers is noticed the roll is cleared for further processing.

The samples are observed on daily basis and if any signs of delamination of layers are noticed, the samples are removed and time period noted. The roll is rejected, a yellow flag attached to it and sent to "Disputed Goods Store". A report along with 50 samples of wads is sent to HO for further instructions.

DETERMINATION OF TEMPORARY BOND STRENGTH:

Equipment used : An Incubator
: A Deep Freezer
: Induction Heat Sealer

Methods:

AA. Equipment used : An Incubator

Three samples of punched wads of particular size are cut from the duly laminated roll under test and placed in the incubator; the temperature is set at 45 deg C. The time at which the incubator has reached the set point is noted and samples are observed for next 5 minutess. There should be no delamination of temporary bond. The material is moved for check point BB.

BB. Equipment used : A Deep Freezer

Three samples of wads of particular size are cut from the duly laminated roll under test and placed in the deep freezer; the temperature is set at – 15 deg C. The time at which the deep freezer has reached the set point is noted and samples are observed for next 12 hours. There should be no separation of the sealing layer from the substrate board. The material is moved to check point CC.

During the entire process the samples are observed at the end of each hour and if any signs of separation of the sealing layer from the substrate board are seen the time period is noted and samples removed. The roll is rejected, a yellow flag attached to it and sent to the "Disputed Goods Store". A report along with 50 samples is sent to HO for further instructions.

CC: This temporary bond is designed to give clean separation when wad is induction heat sealed on the container rim. Upon opening the cap after induction heat sealing process is over, the substrate (pulp board) should have detached itself from the sealing layer and remain in the cap while the fused sealing layer remains on the container to provide hermetic and leak free sealing.

Method:

Equipment used : Induction Heat Sealer

Three samples of wads of particular size 58 are cut from the duly laminated roll

under test and put to inductions sealing at parameters comparable to a sealing speeds of 100 bottles per minutes. After the seal has cooled down the caps are opened. The substrate board should come out with the cap and sealing layer should remain on the container. The foil should be clean and free of any visible wax marks. If all three samples pass the test, the roll is cleared for further processing.

If any deviations are noted, a yellow flag is attached to it and roll sent to "Disputed Goods Store". A report along with 50 samples is sent to HO for further instructions.

SEAL STRENGTH

The seal strength is a measure of fusion between wad sealing layer and container rim.

Method:

Equipment used : Induction Heat Sealer
: Vacuum Desiccators with mercury

Three samples of particular size are cut from the roll under test and sealed on the container in the normal way. The cap is removed and container with the seal is put in the vacuum chamber and a vacuum is generated up to 150mm of mercury pillar. All three samples must pass the test for fifteen minutes and the roll is passed.

In case two or all three samples do not pass the test the roll is rejected, a red flag attached to it and sent to "Rejected Goods Store". A report is sent to HO along with 50 samples for further instructions.

In case one sample does not pass the test, the test is repeated with five further samples if all of them pass the test, the roll is cleared for further processing.

In case any one sample does not pass the test in the repeated test, a yellow flag is attached to it and sent to the "Disputed Goods Store". A report is sent to HO with further 50 wad samples for further instructions.

Incase two or more samples do not pass the test the roll is rejected, a red flag attached to it and sent to "Rejected Goods Store". A report is sent to HO along with 50 samples for further instructions.

WINDING CHECK

Check following points

D. Is it tight & acceptable : YES / NO.
- If "YES" proceed to next check point "E"
- If "NO" send roll for rewinding to print station
After rewinding repeat check point "D"

E. Are Roll sides aligned (no telescoping) : YES / NO.
- If "YES" proceed to next check point "F"
- If "NO" send roll for rewinding to print station
After rewinding start from check point "D"

F. Are Roll Edges neat & clean, in good shape and free of any damages : YES / NO
- If "YES" proceed to point – 6.
- If "NO" reject roll, put 'Red flag' and keep aside, to be returned to supplier, inform HO

MELTING POINT

The melting point determined by the capillary method is the temperature at which the last solid particle of a compact column of a substance in a tube passes into the liquid phase.

When prescribed in the monograph, the same apparatus and method are used for the determination of other factors, such as meniscus formation or melting range, that characterise the melting behaviour of a substance.

Apparatus The apparatus consists of:

—a suitable glass vessel containing a liquid bath (for example, water, liquid paraffin or silicone oil) and fitted with a suitable means of heating,

—a suitable means of stirring, ensuring uniformity of temperature within the bath,

—a suitable thermometer with graduation at not more than 0.5 ℃ intervals and provided with an immersion mark. The range of the thermometer is not more than 100 ℃,

—alkali-free hard-glass capillary tubes of internal diameter 0.9 mm to 1.1 mm with a wall 0.10 mm to 0.15 mm thick and sealed at one end.

Method Unless otherwise prescribed, dry the finely powdered substance in vacuo and over anhydrous silica gel R for 24 h. Introduce a sufficient quantity into a capillary tube to give a compact column 4 mm to 6 mm in height. Raise the temperature of the bath to about 10 ℃ below the presumed melting point and then adjust the rate of heating to about 1 ℃/min. When the temperature is 5 ℃ below the presumed melting point, correctly introduce the capillary tube into the instrument. For the apparatus described above, immerse the capillary tube so that the closed end is near the centre of the bulb of the thermometer, the immersion mark of which is at the level of the surface of the liquid. Record the temperature at which the last particle passes into the liquid phase.

Calibration of the apparatus The apparatus may be calibrated using melting point reference substances such as those of the World Health Organisation or other appropriate substances.

VISCOSITY

Commonly used types of rotating viscometers are based on the measurement of shearing forces in a liquid medium placed between two coaxial cylinders, one of which is driven by a motor and the other is made to revolve by the rotation of the first. Under these conditions, the viscosity (or apparent viscosity) becomes a measurement (M) of the angle of deflection of the cylinder made to revolve, which corresponds to a moment of force expressed in newton metres. For laminar flow, the dynamic viscosity, η, expressed in pascal seconds is given by the formula:

$$\eta = \frac{1}{\omega}\left(\frac{M}{4\pi h}\right)\left(\frac{1}{R_A^2} - \frac{1}{R_B^2}\right)$$

where h = the height of immersion in metres of the cylinder made to revolve in the liquid medium,

R_A and R_B = the radii in metres of the cylinders, R_A being smaller than R_B, and

ω = the angular velocity in radians per second.

The constant k of the apparatus may be determined at various speeds of rotation using a Pharmacopoeia viscometer calibration liquid. Commercially available apparatus is supplied with tables giving the constants of the apparatus in relation to the surface area of the cylinders used and their speed of rotation. The viscosity then corresponds to the formula:

$\eta = k(M/\omega)$

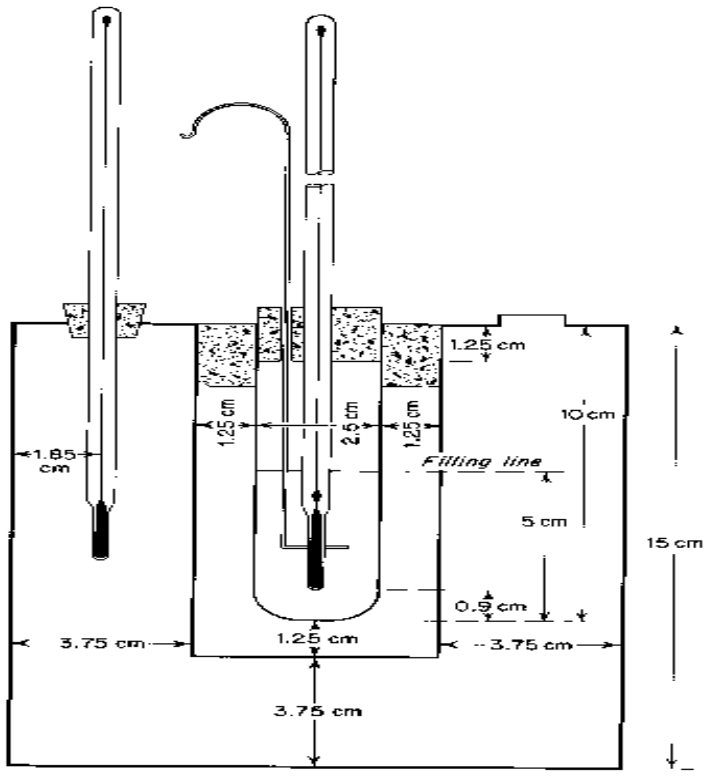
Method

Measure the viscosity according to the instructions for the operation of the rotating viscometer. The temperature for measuring the viscosity is indicated in the monograph. For pseudoplastic and other non-Newtonian systems, the monograph indicates the type of viscometer to be used and the angular velocity or the shear rate at which the measurement is made. If it is impossible to obtain the indicated shear rate exactly, use a shear rate slightly higher and a shear rate slightly lower and interpolate.

CONGEALING POINT

The temperature at which a substance passes from the liquid to the solid state upon cooling is a useful index to purity if heat is liberated when the solidification takes place, provided that any impurities present dissolve in the liquid only, and not in the solid. Pure substances have a well-defined freezing point, but mixtures generally freeze over a range of temperatures. For many mixtures, the congealing temperature, as determined by strict adherence to the following empirical methods, is a useful index of purity. The method for determining congealing temperatures set forth here is applicable to substances that melt between -20 ° and 150 °, the range of the thermometer used in the bath. The congealing temperature is the maximum point (or lacking a maximum, the point of inflection) in the temperature-time curve.

Apparatus — Assemble an apparatus similar to that illustrated



Congealing Temperature Apparatus

in which the container for the substance is a 25- × 100-mm test tube. This is provided with a suitable, short-range thermometer suspended in the center, and a wire stirrer, about 30 cm long, bent at its lower end into a horizontal loop around the thermometer. Use a thermometer having a range not exceeding 30 °, graduated in 0.1 °divisions, and calibrated for, but not used at, 76-mm immersion. A suitable series of thermometers, covering a range from -20 °to +150 °, is available as the ASTM E1 series 89C through 96C. Other temperature-measuring devices may be used if they are validated for this procedure (see Thermometers á21 ñ). Dimensions should be within ±20% of those given in the illustration.

The specimen container is supported, by means of a cork, in a suitable water-tight cylinder about 50 mm in internal diameter and 11 cm in length. The cylinder, in turn, is supported in a suitable bath sufficient to provide not less than a 37-mm layer surrounding the sides and bottom of the cylinder. The outside bath is provided with a suitable thermometer.

Procedure — Melt the substance, if a solid, at a temperature not exceeding 20 °above its expected congealing point, and pour it into the test tube to a height of 50 to 57 mm. Assemble the apparatus with the bulb of the test tube thermometer immersed halfway between the top and bottom of the specimen in the test tube. Fill the bath to about 12 mm from the top of the tube with suitable fluid at a temperature 4 °to 5 °below the expected congealing point. In case the substance is a liquid at room temperature, carry out the determination using a bath temperature about 15 ° below the expected congealing point. When the test specimen has cooled to about 5 °above its expected congealing point, adjust the bath to a temperature 7 ° to 8 ° below the expected congealing point. Stir the specimen continuously during the remainder of the test by moving the loop up and down between the top and bottom of the specimen, at a regular rate of 20 complete cycles per minute.

Congelation frequently may be induced by rubbing the inner walls of the test tube with the thermometer, or by introducing a small fragment of the previously congealed substance. Pronounced supercooling may cause deviation from the normal pattern of temperature changes. If the latter occurs, repeat the test, introducing small particles of the material under test in solid form at 1 °intervals as the temperature approaches the expected congealing point.

Record the reading of the test tube thermometer every 30 seconds. Continue stirring only so long as the temperature is gradually falling, stopping when the temperature becomes constant or starts to rise slightly. Continue recording the temperature in the

test tube every 30 seconds for at least 3 minutes after the temperature again begins to fall after remaining constant.

The average of not less than four consecutive readings that lie within a range of 0.2 ° constitutes the congealing temperature. These readings lie about a point of inflection or a maximum, in the temperature-time curve, that occurs after the temperature becomes constant or starts to rise and before it again begins to fall. The average to the nearest 0.1 °is the congealing temperature.

SECTION G

QUALITY SYSTEM

General Description of Quality Control Systems

Excel Pack Ltd has an established and maintained system of complete traceability of all raw materials used in the manufacture of Induction Sealing Wads. Products are typically packaged in corrugated boxes using a polyethylene bag liner, unless otherwise specified by the customer.

1. Products are manufactured in accordance as far as possible with Good Manufacturing Specifications and Standard Procedures of Manufacturing. This includes all manufacturing processes. All Manufacturing Specifications are derived from customer, industry specific, state, and federal requirements.

2. Excel Pack Ltd Quality Systems include the following;

    a. Bills of materials
    b. Specifications for each Component
    c. Packaging requirements and configurations
    d. Special operating instructions, if any
    e. Inspection plans.

THE
QUALITY MANUAL

TYPE III DMF FOR INDUCTION SEALING WADS
EXCEL PACK LIMITED ; NEW DELHI; INDIA
FEBRUARY – 2007 (Version 1.0)

1. Introduction

Background information:

Excel Pack Ltd is a newly formed company and commenced business operations in February 2003. In its third year of operations ended 31.3.07, the company achieved a turnover INR340 Lacs. The company is growing rapidly and barring unforeseen events, the company estimates to achieve a turnover of approx. INR 750 lacs for the year ending 31st March 2008.

Promoters:

Mr. Rajnish Mehra, a qualified Chartered accountant, having nearly 20 years of corporate professional experience of which the last 14 years was with Pearl Polymers Ltd as the business Head, has promoted the company. Pearl Polymers is one of the leading producers in the country of Pet bottles and containers and during the tenure of Mr. Mehra as the business Head, the company made significant progress with growth in turnover from US $ 20,00,000 to US $ 2,00,00,000. Mr. Mehra was responsible for sustained growth at Pearl by opening up various markets for Pet applications relating Agro, Pharma, Personal care, Edible oil, CSD, Water and many others.

Given the vast experience of the main promoter as also the direct interface with major user Co's in India, led to the decision to form Excel Pack with an objective to carry on existing well versed activity relating to Pet bottles as also to introduce world class products to the Indian market in allied and related fields of packaging.

Business activities:

Excel Pack Ltd (EPL) is engaged in business operations as detailed below:

Company is engaged in the manufacturing of induction heat seal liners / wads. of art technology provides 100% hermetic seal, no leakers and tamper evident desired level of barrier properties and is suitable for application with aggressive such as pesticides, veterinary medical compositions; general pharmaceutical requiring FDA and DMF approvals; food and supplementary products requiring approved materials. Company is operational for last four years and has recently own new manufacturing facility at; plot no. 4, Sector - 8, Integrated Industrial Area BHEL - Ranipur, Haridwar - 249 405. (Utteranchal) - India. Since only one specific size is suitable for any combination of cap / container system, company has developed library of cutting tools (over 400 different sizes in number and configurations) and therefore can offer wide range of

sizes and types of induction heat seal wads. Large variety of wads offered are suitable for application with rigid bottles and wide mouth containers made from LDPE, HDPE, PP, PET, PVC, HIPS, PS and even GLASS to match customers specific requirements. Company has also developed special induction heat seal wads for retorting process.
In order to cater to the diverse requirements of induction heat seals relating to mass consumption products relating to motor oils, edible oils etc. the company has indigenously developed sealant membranes with food grade pulp substrates for sealing various plastic containers. Our range of induction heat seals relate to the following:

XL PET (15/25), suitable for sealing Pet bottles.
XL PE (60/12/30), suitable for sealing PE bottles.
XL PE (38/12/5), suitable for sealing PE bottles.
XL PE (38/25), suitable for sealing PE bottles.
XL PP (40/30), suitable for sealing PP bottles.
XL PP Retort (70/30), suitable for sealing PP bottles

Future Outlook:

To consolidate its current business in Induction Sealing Wads and to undertake new business activity of blister foil pharma printing the company has recently (26.10.06) set up owned facilities at Sidcul, Haridwar as against present rented premises. The company expects to achieve a business turnover of approx. Rs.750 lacs in the first full year of operations (2007-08).

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2. Quality policy

EXCEL PACK LTD IS COMMITTED TO ENSURE COMPLIANCE TO CUSTOMER REQUIREMENTS AND ENHANCE CUSTOMER SATISFACTION BY CONTINUALLY IMPROVING THE EFFECTIVENESS OF THE QUALITY MANAGEMENT SYSTEM

3. Management Responsibility

Quality is an important element in the success of the organization.

A quality policy document and top management's commitment to the quality of the product, play an important role in the quality system.

Management Functions whose work affects Quality (With reference to this manual) are listed below:

- Managing Director
- Head Quality
- Head Finance
- Head Sales and Marketing
- Head Human Resources Development
- Head Purchase
- Management Representative

The aforementioned persons in the execution of their duties shall include responsibility for:

- The quality of work carried out by their respective personnel, allocation and delegations of specific quality related activities, to Nominate, Authorize and suitably Train personnel within their respective department.
- Ensuring that all personnel are adequately qualified trained and experienced in their relevant position to fulfill their assigned task.
- Verifying that approved procedures and related complimentary procedures are raised, implemented and maintained.
- Ensuring that their personnel are familiar with and have access to the company's Quality policy, Quality Manual and necessary procedures.

The Quality Assurance Manager irrespective of any other responsibilities has the authority and responsibility to ensure that the system and procedures referred to this manual are implemented and maintained, initiate action to prevent the occurrence of the problem .

Nonconformity:

a] Identify and record any product quality problems.

b] Initiate, recommend or provide solutions through designed channel.

c] Verify the implementation of solutions.

d] Control further processing, delivery [or installation] of non confirming product until the deficiency or unsatisfactory conditions have been corrected .

In the execution of these duties the Head Quality is responsible for the verification of procedures, practices and systems including the organization of audit relating to the quality system.

In this respect the Associate Manager Quality Assurance has the additional responsibility as quality assurance co-coordinator (Management Representative).

When auditing the process and quality control department, the QA coordinator shall have the responsibility and authority for this audit, and reporting to the partners.

4. Management Review

Management review is a mechanism for coordinating and controlling the activities of the quality system being carried out by different functional groups in the company at definite intervals.

Management with executive responsibility shall review the quality system at defined intervals sufficient to ensure its continuing suitability and effectiveness in satisfying the GMP requirements and the stated Quality Policy & objectives. Records of such reviews shall be maintained.

The Quality System shall be reviewed annually, a period not exceeding twelve months from the previous review meeting.

The quality system review meeting will be chaired by the Partners and attended by at least any three of the following personnel,

- Head Quality
- Head Finance
- Head Sales and Marketing
- Head Human Resources Development
- Head Purchase
- Management Representative

However if required by the Higher Management Heads of Other Functions (Division) may also form a part of the meeting

The agenda shall include,

- Minutes of the previous meeting
- Review of the site Quality System to include,
- Report on progress/status
- Review of the Internal Quality Audits and their corrective action requests
- Review of quality defects, customer complaints information
- Review of training records
- Amendments to the quality system to increase effectiveness and efficiency
- Any other business
- Date of next meeting.

5. Personnel

Specifying a set of quality requirements or issuing detailed procedures through manuals and procedures will not achieve the desired results unless adequate resources are provided for various jobs including verification.

The H R Department shall be responsible for identifying and selecting appropriate resources, inducting them with the respective departments, imparting training, looking after their welfare and providing administrative support.

Employee shall only be recruited following full consideration of the application form, tests (where applicable) and interview by the respective managers or departmental heads.

Selection shall be made purely on merit and decision to recruit lies with a panel comprising Partners, concerned Department Heads and Head H R Department.
Records of employee history, job description, appraisal shall be maintained in H R department.

To provide open culture and avenues for employees to express their opinion through Progress Reports, suggestion scheme, etc. H R Department shall look after these areas and monitors its effectiveness.

The H R Department shall also be responsible for general administration including house keeping, safety, health, fire fighting etc.

Employees shall undergo a medical examination at the time of joining the company. The medical examination consists of chest x-ray, general examination, eye check up including colour blindness, and Tuberculosis. Employee shall also be undergoes an annual medical examination.

6. Quality System

Documentation consists of several tiers of documents, each successive tier becoming more detailed. At the apex is quality manual which describes all the elements of a quality system that the organization required to meet the quality requirements.

QUALITY MANUAL
(Policies / Responsibilities and Authorities)
|
|
|
QUALITY SYSTEM PROCEDURES
(Detailed Procedure / SOPs)
|
|
|
QUALITY DOCUMENTS
(Supporting documents, reports, etc.)

The contents of this manual refers to system outlines only, detailed procedures detailing Authority, responsibility, actions and records are documented, maintained and listed within the procedures, documents, and records.

The structure of the quality system is briefly outlined below:

a) Quality Assurance documents

Documented procedures (including approval, issue and changes of documents and data) to control all necessary documents related to Quality Assurance.

b) Quality control documents

Procedures are given to test incoming, intermediate and final materials for quality specifications requirements and methods of analysis are clearly documented and calibration procedures are shown.

c) Manufacturing Documents

Manufacturing process and instructions for packaging are mentioned for in-process testing of products in the form of BPCR. Procedures are documented for handling of nonconforming product.

d) Engineering Documents

Defines the procedures and schedules for maintenance including program for preventive maintenance.

e) Ware house Documents

Contains procedures for the goods receiving system and that of packaging and dispatch. It contains the procedure for handling, storage, packing and delivery of raw material, packaging material and finished products.

f) Purchasing Documents

Contains the procedures for approval of suppliers, raising orders and to ensure that purchased raw material and packaging materials conforms to the specified requirements.

g) Training Documents

Gives records to ensure that all personnel are adequately trained to fulfill their functions and are aware of their impact on quality.

h) Personnel Documents:

Contains procedure for selection of personnel, general administration, health, clothing, pest control, medical check-ups and personnel function.

The quality system is designed to ensure that the customer receives a product to agreed specifications, delivered on time, whilst maintaining all aspects of product and package quality.

7. Contract Review

A key functional group in the organization is sales and marketing. The efficiency of these department can be gauged by the number of order secured, but executing them with full satisfaction of the customer shall play important role in the quality system.

The scrutiny of contract shall be carried out in order to prevent errors at the interface between the customer and the supplier and to ensure that, the requirements of the contract shall be correctly understood and fulfill.

All tenders inquiries and orders shall be the subject to contract review.

The receipt, review, and fulfillment of orders is the responsibility of Marketing department.

Scrutiny of contract/order shall be done on the basis of Domestic, Specialty product and Export requirement. Subsequently the order shall be forwarded to relevant section.

The review of the tender or contract/order consist of following stages :

- Examination of order in regard to technical requirements, the feasibility of the required delivery period and manufacturing capacity.

- Cost calculations

- Examination of offer for conformance to order, completeness, clarity of technical requirements, stock at depot, quantity required, feasibility of delivery period.

All above points shall be the subject for Production Planning Meeting, will be held on first week of every month. Product, pack size and quantity on each machine as per requirement (production plan) shall be planned accordingly.

Changes in orders from customers and changes in delivery period from supplier are reviewed by functional head responsible for reviewing initial orders. Approved changes are communicated to all functional affected by the modifications.

Inquiries, offers, contracts/orders, acceptance of orders and other related correspondence are maintained.

8. Documentation and Data Control

Establish and maintain documented procedures (including approval, issue and changes of documents and data) to control all necessary documents related to Manufacturing and Quality Assurance.
(NOTE: Documents and data can be in the form of any type of media, such as hard copy or electronic media).

All procedures and necessary documents relating to and in connection with the quality system of the location shall be uniquely identified by means of document name, code, amendment number and date (where applicable)

In case of controlled procedures, it is responsibility of the departmental heads to implement it effectively and maintain records.

It is responsibility of QA to ensure that documentation relating to quality system is distributed in accordance with the document control procedures.
Customer imposed standards shall also be included under the requirements of controls.

Procedures detailing authority, responsibility, actions and records are documented, maintained and listed within the SOPs & records.

9. Purchasing Control:

Establish and maintain documented procedures to ensure that purchased product shall conforms to specified requirements.

All materials should be purchased against an approved and adequate Specification, which defines not only grade and quality of the material, but also nature of the packaging and container to be used.

Materials should be purchased and sourced only from approved suppliers and manufacturers. Selection of vendor should be based mainly on quality considerations.

Purchasing procedure includes,

Evaluation and selection of vendor on the basis of, their ability to meet our requirements including quality system and any other specific requirement within specified time schedule.

In case of evaluation, Pre-shipment sample from vendor shall be checked as per STP. After passing the specified requirements three batches of same material shall be checked for consistency and then the vendor shall be included in approved vendor list.

Record of evaluation and selection shall be maintained.

All raw materials shall be purchased with reference and conforming to the agreed specification.

Prospective suppliers shall only be approved by following consideration,

- Acceptance specifications
- Quality control capabilities
- Quality assurance capabilities
- Market position
- Auditing

To confirm suitability of the material samples (and safety data wherever required) will be requested and tests carried out with reference to the requirement of specification.

Change of raw material type or grade for commercial reason will only be approved following successful testing.

Orders of raw and packaging material shall include information regarding product name, type, quantity and the date required.

It is the responsibility of purchase dept. to record and maintain all details regarding approved vendors and material orders.

10. Product identification and traceability:

All the materials are received at site, after scrutiny, through warehouse. Stores receive materials carries out general inspection and register the receipt. After approval from QC the material are issued to the manufacturing. In case of rejection, the materials are returned to the suppliers or destroyed at the site in well defined area.

Material movement i.e. Incoming materials and outgoing materials are controlled by stores/ dispatch respectively. Planning of raw materials, packaging materials, inventory is controlled by Production Planning and Stores / Purchase.

Approved raw materials are issued to the manufacturing department and final products are received by dispatch dept. Dispatch of approved final products is looked after by Dispatch dept.

Raw materials, Packaging materials shall be identified by name and unique code no. and final products by name and Batch No. system to ensure a secondary specific identification for products, raw materials and packing materials.
All products during manufacturing will be identifiable by the product name and batch number.

Upon completion products will be clearly labeled to include the product name and batch no.

Throughout production, testing, storage, and dispatch all accompanying documentation, product will display clearly the product name and batch number.

11. Process control

Process control is the integral part of all the manufacturing activities.

Critical process parameters have been set for all manufacturing and ancillary processes being carried out for manufacturing induction sealing wads.

These parameters have been established against prior research and development performed on all starting materials, intermediate products and finished goods and research performed in processing the same. Further all these parameters have been provided with certain limits within which they will not affect the quality of the product.

In process checks are performed to check that all the processes are performed exactly as intended within the set limits.

12. Inspection and testing

The Quality Control Department is part of the Quality Assurance Department shall be responsible for Inspection and Testing. The major activities of the Quality Control Department Are :

i) Testing of raw material and packaging materials
ii) Testing of in-process samples
iii) Testing of finished products

Raw material, packaging material, In-process and finished products will be tested by quality control personnel to ensure compliance with the specification.

Raw material and packaging material shall be strictly controlled upon receipt to ensure that all activities relating to inspection and testing are carried out prior to use in production department.

Analysis procedures as required will be in accordance with Pharmacopoeias And/or in-house tests as mentioned in respective STPs.

In case of final product release the Batch Production Control Record shall be reviewed by the Quality Assurance department who checks for the completeness of the document and releases the batch for distribution by signing the Batch Production Record.

All analytical data shall be recorded and retained with the QA department for the specified period.

13. Control on Inspection, Measuring and Test Equipment

Inspection, measuring and test equipments shall be controlled by Quality Control Department through Preventive Maintenance and Calibration Programme.

Maintenance and calibration of plant equipments is carried out by Production Head as per their scheduled programs and SOP.

These procedures give details of periodicity of preventive maintenance, methods of preventive maintenance and special checks/replacements to be done. The production department is responsible for preventive maintenance of each equipment. Details of such maintenance are recorded in the Equipment Log Sheet.

After carrying out scheduled maintenance and calibration, its report should be prepared and maintained.

Incase due to some problems instrument or equipment is not available on a scheduled date, a manually agreed date (by maintenance and production dept.) is fixed up for the said job.

In case of any discrepancy noted during maintenance or calibration, it will be noted down in the maintenance report along with corrective/preventive action planned or corrective/preventive action taken to over come it.

Besides scheduled maintenance checks, unscheduled, planned and routine jobs shall be carried out as and when required and to the extent possible a record of critical and major jobs shall be maintained.

Each equipment/system/facility/process is validated prior to use as per Standard Operating Procedures.

Process revalidation is undertaken when a change occurs in a previously validated process, which is likely to have an impact on product characteristics.

All equipments in the Control Laboratory are calibrated as per the pre-determined frequency. Records of such calibration are maintained.

Computerized systems are used in the issue of batch Production Records and Inventory Control of raw material and packaging materials shall also be validated as per SOP.

14. Inspection and Test Status

Objective of quality system is to ensure that only products conforming to the specifications shall be delivered to the customer.

All materials (raw, packaging, in-process and finished) shall be used/distributed strictly only when inspected and identified by QA department.

Status of all materials shall be identified physically by the labeling. Which indicate name, batch no./ product code, manufacturing date, expiry date etc.

Material failing to comply to specification shall be identified and stored in well defined area, labeled and documented accordingly.

15. Control of non conforming products

All materials failing to conform to specification shall be clearly identified and handled as per SOP.

No corrective actions for the material failing to conform to specification shall proceed prior to authorization or instructions by Quality Assurance Manager.

Any raw material or packaging material which does not conform to the approved specifications is treated as rejected material. On completion of the testing, the Quality Control Department affixes 'Rejected' label on each such container and a Rejection Note is prepared giving reason for rejection. The stocks are moved to an area designated for rejected material. The Purchase Department informs the vendor on the rejection along with reasons for rejections. The rejected stocks are then sent back to the vendor.

In case a batch does not conform to specifications, then decision for corrective actions shall be taken by the Quality Assurance Manager in consultation with Chief Executive Officer (Partner).

Records of quality defects will be maintained for future assessment to facilitate and initiate corrective and preventive actions as required.

16. Corrective and Preventive Actions

The corrective actions for the material failing to conform to specification shall be proceed as per instructions and authorization by Quality Assurance Manager.

Corrective and preventive actions in case of product / batch, does not conform to specifications, shall be taken by the Quality Assurance Manager in consultation with Chief Executive Officer (Partner).

The vendor is informed via mail or telephone about non conformance of the raw material with the standard.

The vendor is called to inspect the material, after inspection the rejected material is returned to the vendor along with the rejection note.

17. Handling, storage, packaging, preservation and delivery:

Proper handling requires careful planning, effective control and documented procedures from the time the materials enter the factory until the finished product reaches the customer. Organization shall develop its own procedures and instructions to comply the requirement of quality system.

Warehouse department shall playing important role in the requirements for handling, storage, packing, delivery and safety of the products and materials.

Handling during transfer, storage, dispatch and delivery shall be in accordance with the relevant procedure.

In-process material shall be handled as specified within manufacturing procedures.
All products and materials will be labeled indicating name, batch no., product code.

Procedures detailing authority, responsibility, actions and related records are documented and maintained within the respective SOPs.

18. Control of quality records

Quality records provide the objective evidence that the requisite product quality has been attained, and that the various elements of the quality system have been effectively implemented.

The respective departmental manager/ head or his representative shall ensure all records are maintained to avoid deterioration, damage or loss.

19. Internal Quality Audits: (Self Inspection)

A quality audits is a systematic and independent examination to determine whether quality activities and related results comply with planned arrangements, and whether these arrangements are implemented effectively and are suited to achieving the desired objectives.

Self Inspection on all systems, procedure and operations shall be conducted regularly in order to monitor compliance with and the effectiveness of Quality Assurance Principles in the various operations and to allow for improvement and corrective measures where required.

Inspections may be in house or carried out by local regulatory authorities or the regulatory authorities of countries to which company wish to export.

Self Inspections shall follow a pre-arranged programme by self inspection team as per SOP.

Inspection reports shall be made and corrective measures agreed upon, recorded and followed up.

20. Training

The specification, control and assurance of product quality can be carried out only by competent personnel. Therefore it requires documented procedures for identifying training needs and for training all personnel performing activities affecting quality, specifies qualifications, training and motivation as the key factors in achieving quality.

The employees working within Excel Pack Limited shall receive sufficient training as and when necessary to fulfill all activities related to their defined position. The responsibility of such training has been assigned to external experts along with QA department as per SOP.

Training is a continues process and the management and departmental head shall, by request or observation identify and initiate the ongoing training requirements of employees, to maintain and develop the quality and efficiency of operations.

All new employees will provide induction training to emphasis company rules and to initiate familiarization with the company and workplace operations.

Staff/employees appraisal will be conducted annually by their relevant manager to identify and mutually agree the development and training requirements of the employee within the organization.

The in-house training program consists of:

- Induction program
- cGMP requirements
- Safety
- Hygiene
- Training on use of equipment (on-the job training)

Process operators shall be trained in accordance with the need as assessed by the departmental head.

Managers/Departmental heads are also send for training program conducted by various professional bodies / outside experts. Records of such training shall be maintained.

All records are maintained by the QAM. On the job training records are maintained by respective department. The records include who was trained, topics covered, venue and dates of training. An evaluation of the effectiveness of the training is done and records are maintained.

21. Statistical Techniques:

Quality Assurance Manager and Production Manager shall identify the need for statistical techniques required for establishing, controlling and verifying process capability and product characteristics.

Establish and maintain documented procedures to implement, control and application of statistical techniques identified.

Commonly used statistical techniques is sampling inspection. This determines the quality of a lot or batch of products on the basis of a small sample of the product. This can be used for receipt inspection, in-process inspection and final inspection.

The aim is to eliminate the causes of quality problems and thus to prevent product nonconformity.