5
PAPER- AND BOARD-BASED PACKAGING MATERIALS AND THEIR USE IN PACK SECURITY SYSTEMS

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Introduction and history

In this chapter, packaging materials based on 'cellulose' or natural fibres will be discussed. They provide a major contribution to the packaging of pharmaceuticals, the size and nature of which can readily be overlooked since the number of applications is far more diverse and more paper and board is used than glass, metal or plastics.

The history of paper-making in particular is long, and the earliest recorded British mention is in the thirteenth century. It has always used forms of cellulose fibre, but began to use wood pulp in the mid-nineteenth century, which has continued gradually to replace the older materials, so that 98%+ of the papers and boards made today are from the wood pulp route.

Boards (in the case of pharmaceuticals, lined folding box boards) were introduced in the mid-nineteenth century, as hand-made constructions to help protect and transport products. Only at the end of the nineteenth century were machines invented to produce what we would now know as cartons.

Corrugated boards are a fairly recent introduction, starting in the early 1870s and becoming widely commercially available in the late 1890s. From then on there has been a continuous development, both where corrugated board is used and in the technical production processes of developing better, stronger and more hazard-resistant boards.

Papers and boards are used in the following pharmaceutical packaging applications (the list may not be comprehensive):

- labels and leaflets
- wrapping materials
- bags and sacks
- collapsible and rigid cartons and boxes
- shipping and transit outers, both corrugated and solid
- gummed tape
- fitments for cases
- composite tubes and drums
- moulded pulpboard containers
- paper liners, linings and laminations.

Being based on 'natural' fibres, i.e. cellulose, potentially from a wide range of sources, paper and board are seen as renewable resources as distinct from petroleum- and metal-based resources. However, in some circumstances the energy required for conversion of the natural fibres into packaging materials may be more than that required for non-renewable sources in a competitive form. This is part of the debate on environmental/ecological factors which is exercising the minds of the packaging profession, and will be discussed as we go through the chapter in relation to the use of recycled material in paper and board.

There is a major problem with 'natural' products. They are not as consistent as synthetic products, therefore anything made from a natural material cannot be guaranteed to be exactly the same all the time, i.e. they usually need wider tolerances than, for example, glass, metal or plastics. Its easy to see why. Living organisms grow with a large number of factors influencing that growth: availability of nutrients, light conditions, damage to seedlings by animals, local environment, difference in age of each tree, etc.

Sources of cellulose fibre

Although trees are the major source of wood pulp, other cellulosic fibres such as cotton, flax, bamboo, esparto, jute, hemp, straws, bagass (from sugar cane), grass, rags and sisal have been used in the manufacture of papers and some of them for boards. The quality of the fibre varies according to the source, with certain hardwoods being excluded on the grounds of cost

or undesirable constituents. Softwoods such as spruce, fir, pine and eucalyptus are usually commercially preferred, as they are grown in colder climates where they are arguably the best use for the land. In the past 20 to 30 years the 'farming' of softwood forests has developed into an environmentally friendly industry, under the term 'silviculture'.

The basis of all paper and board is 'pulp', which is in fact refined cellulose $(C_6H_{10}O_5)_n$, where n is between 800 and 1500. The crude extracted cellulose is made up of three parts, as follows.

1 Holocellulose—this is 70–80% of the wood. It is the whole water-insoluble carbohydrate fraction comprising:

- alpha-cellulose, which is insoluble in strong caustic soda
- hemi-cellulose, which is soluble in dilute caustic soda
- beta-cellulose, which is reprecipitated by dilute acid
- gamma-cellulose, which is the remainder of the cellulose fraction.
  There is in fact no single compound holocellulose, since the structures and crystallinity of the cellulose fibres vary with the source of the wood. This is part of the reason for the variation in properties of pulps.

2 Lignin—this varies between 17% and 30% of the bulk and is an amorphous phenylpropane polymer which is found intimately associated with the holocellulose. It is not a fibrous material and therefore is of no value in the pulping process.
3 Extractives, which form between 3% and 8% of the bulk, are mainly other carbohydrates, soluble mineral salts, resins, fats and tannins which may be washed out with water.

The individual fibres of cellulose are very strong and of varying lengths, e.g. esparto grass 1.5 mm, coniferous wood 3.5 mm and broadleaf wood 1.2 mm, and those that are preferentially used for paper and board are between about 1 and 4 mm in length.

The manufacturing process

To manufacture paper or board there are two basic processes: pulping, then machine conversion into paper or board.

Pulping

The treatment of the fibres (pulp) is the major influence on the properties and costs of the paper or board produced. The objective in pulping is to 'tease' out undamaged fibres from the mass of the wood, so that these fibres can be reworked into the smooth paper/board required.

There are three major processes which reduce raw material, i.e. any of the cellulose-containing materials mentioned above, to 'pulp':

1 mechanical pulping
2 chemical pulping
3 semi-chemical or combination pulping.

For practical purposes only wood pulp will be considered. The wood pulp is supplied from the two most popular sources which are the managed softwood forests, mentioned above, and 'recycled' fibres, which will be covered later.

Most label papers are chemical pulp, with additives, only. Most box boards are layers of mechanical or semi-chemical pulps with chemical pulps on the face and sometimes the back facings. Corrugated will probably, today, be nearly all recycled material, whereas unbleached semi-chem would have been used in the past for the corrugated medium. Any Kraft facing paper will probably still be 80–90% virgin Kraft pulp in make-up.

Bleaching

If this is required it is achieved by using either hydrogen peroxide or chlorine (or a hypochlorite) dissolved in water to remove the coloured residues that are in the cellulose fibres. It is usual to bleach only the chemical pulp made from the sulphite or soda processes, as these are grades probably used for white paper and the white plies of board.

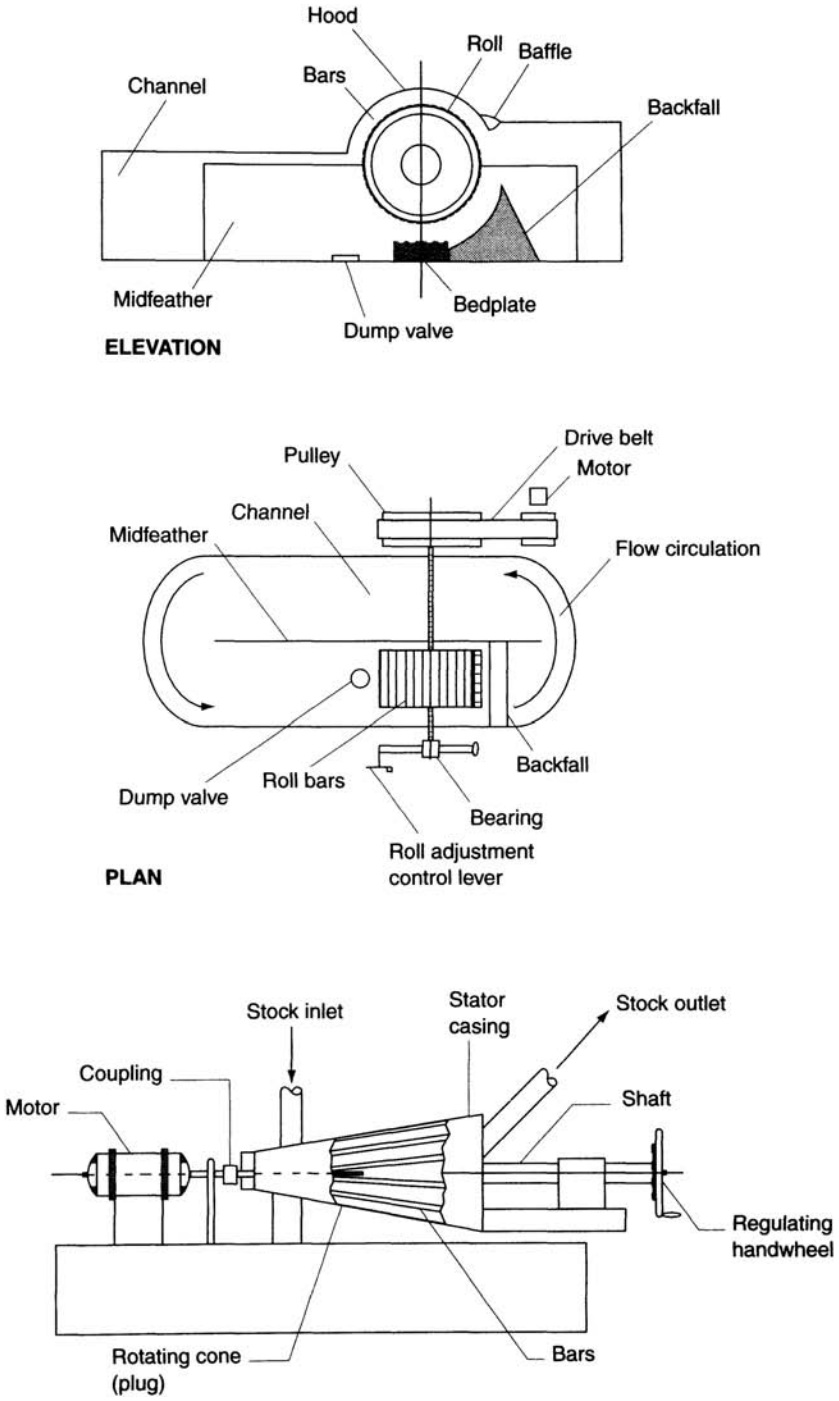

Figure 5.1 Beating

Beating and refining

Beating is the batch process where the pulp suspension is recycled through a specially designed vessel which shortens the fibres and softens (plasticises) them (Figure 5.1). Refining is a continuous process whereby the pulp suspension is pumped between a static outer housing and a tapering rotor (Figure 5.2). Figure 5.3 shows the properties of paper/board influenced by beating.

Mixer stage

Here the pulps are stirred vigorously in a hydropulper with copious amounts of water and the additives are added to make the final mixture.

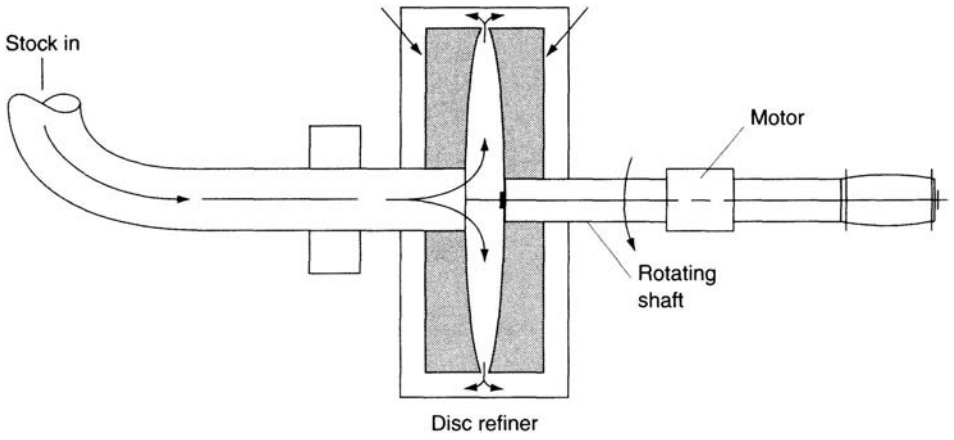

Figure 5.2 Refining

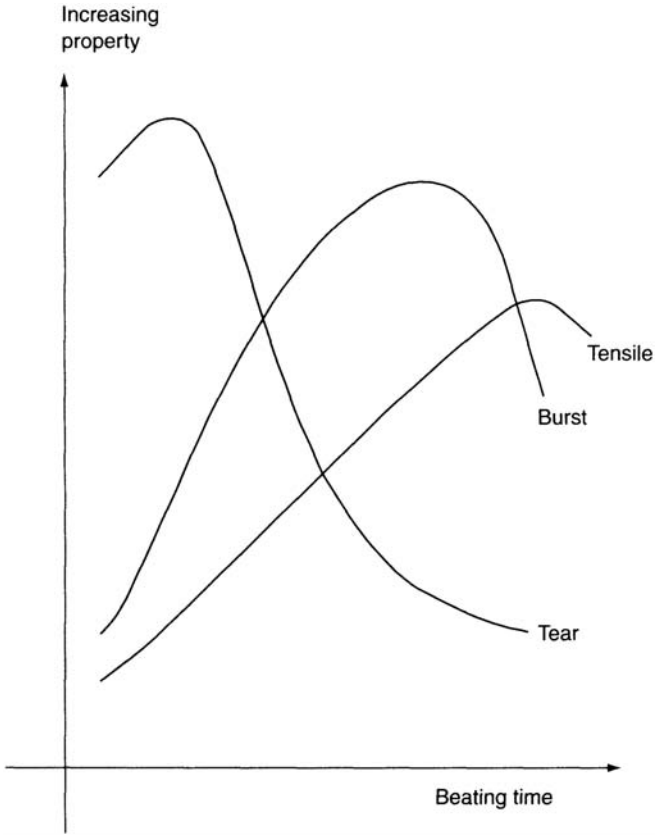

Figure 5.3 Effect of beating on strength

Additives

These are added to the beaten or refined pulp to produce the final form of the paper. Typical additives are loadings and fillers (to improve opacity/brightness), colouring materials, sizing agents which reduce the penetration of water and inks, binding agents to increase strength, gums, antifoam agents, wet strength resins and optical brightening agents (OBAs). It is at this stage that the pH of the paper can be adjusted to make it ‘acid free’.

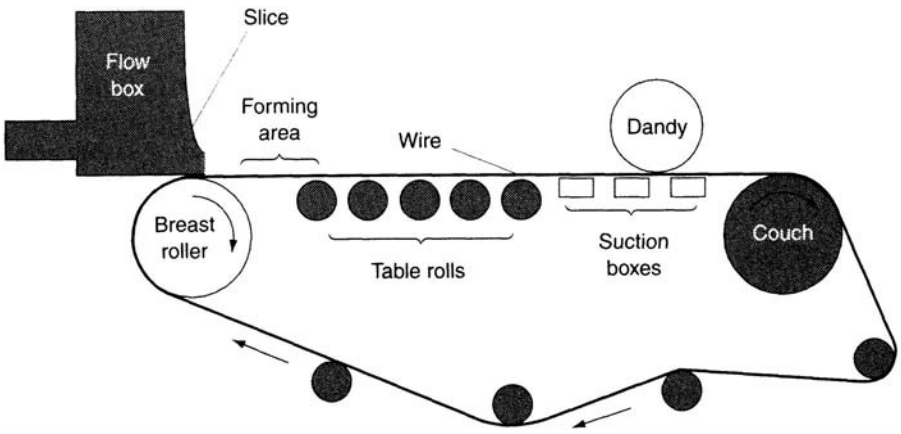

Figure 5.4 A Fourdrinier system

Machine conversion into paper

Fourdrinier system

This is the most popular system still used today, even though the basic system was invented in the early nineteenth century (Figure 5.4). The machine starts at the 'wet end' (1–4) and finishes at the 'dry end' (5–9), thus:

1 a stuff chest
2 a breast box or head box
3 a slice
4 Fourdrinier wire with vacuum boxes
5 presses
6 driers
7 machine glaze drier
8 calender stacks
9 reeling.

Pulp, including all the additives needed for a particular paper, in suspension is pumped into the stuff chest then let down into the 'head box' which sits over a continuously fast moving fine 'wire' (nowadays usually nylon) mesh, i.e. the Fourdrinier wire.

The suspension (99% water) is fed onto the wire mesh through the variable 'slice' in the bottom of the head box. (The aperture of the slice and the speed of the wire mesh control some of the physical properties of the paper, i.e. caliper.) The water from the suspension drains away and then is pulled through the wire by a vacuum, leaving a mass of solids on the wire. The movement of the wire induces the fibres to align themselves preferentially in the machine direction (MD), producing the 'grain' of machinemade papers, although a cross-directional oscillation is built into the machine to try to minimise the orientation of the fibres.

Towards the end of the wire the water content is below 85%. The material leaving the 'wire' is called the 'felt'. This 'felt' is pressed through speed-synchronised cold rollers (the presses) to reduce the water content to 65–70%. This is followed by the drying section, which is a series of steam-heated cylinders over which the felt winds its way with alternate sides being dried.

Sizing or coating is carried out about two-thirds of the way through the drying section. A machine-glazed (MG) finish is applied towards the end of the drying section, by a very large diameter steam-heated highly polished roller.

The paper is then taken up the calender stacks which are stacks of rollers that press onto the alternate sides of the paper. Only the bottom roller of the calender stack is driven; all the other rollers burnish the paper by slippage.

The paper has by now been dried down to 3–4% water content. It is then conditioned to 7–10% water so that the paper is no longer brittle, prior to reeling. The reels are stored on end on skillets under covered conditions, until needed for reel slitting and/or sheeting.

Papers in use in the pharmaceutical industry vary from about 40 g/m^2 substance up to about 175 g/m^2.

Finishing processes

These consist of additional treatments which are carried out on the material after the paper-making process. Surface sizing may, for example, be performed by applying a solution of gelatin, together with other chemicals, to the paper. This improves water resistance and printing properties, and is called 'tub-sizing'. Coating suspensions, e.g. containing china clay, may also be applied to the surface by spraying, air knife or rotating brush methods.

Other surface treatments

These processes include coatings (Figure 5.5), impregnations and laminations which are mainly aimed at reducing moisture, gas, permeation, etc. or for creating a heatsealing capability. Typical examples include both dry and wet waxing processes.

Paper may also be solvent or aqueous coated, e.g. PVdC, emulsions, varnishes, lacquers, or laminated to plastics by adhesion or direct extrusion or to foils by adhesion, all to form laminates. These laminates containing paper are dealt with in Chapter 9.

All surface treatments are used either to enhance the 'printability' of the paper or to modify and 'improve' the characteristics of the paper.

The more common types of paper used in pharmaceutical packaging are as follows.

1 'Kraft' paper used as an outer facing for corrugated board, solid board, spirally wound kegs and fibreboard drums.
2 Uncoated paper, usually from high-grade chemical pulp source, used in thin calipers for small labels and leaflets. One-side coated and MG papers are used for the heavier weighted labelling material. Two-side coated lightweight papers are used for leaflets. Glassine paper is super-calendered greaseproof paper. Greaseproof paper relies on the closing-up of the pores between the fibres achieved by beating the fibres for a very long time.
3 White wood-free paper for laminates is usually one-side coated paper that has been super-calendered to make the outside (coated) surface less permeable.
4 So-called test liners in two grades are made entirely from recycled material. Used for internal liners in corrugated board production and as both liners for corrugated fitments.
5 Vegetable parchment paper is made by a process of treating the absorbent paper with sulphuric acid, which enhances the wet strength of the paper. This is the most water-resistant paper of all. It is usually used for 'dressing' packs. It has good resistance to fats and greases.

Machine conversion into board

In many ways this is very similar to the making of paper, except that the multi-ply production systems are more suitable than the basic single wire Fourdrinier system. Board covers rigid and folding boxboards, solid and corrugated fibreboard, fibre drums and components of composite containers.

One of the different types of machine used at present for making board is the vat or cylinder machine. The machine starts at the 'wet end' (1–4) and finishes at the 'dry end' (5–9) just like the Fourdrinier machine:

1 pulp preparation
2 make-up tanks with different pulps
3 vats with a constant level of pulp
4 vacuum applied cylinders in vats
5 presses
6 dryers
7 machine glaze drier
8 calender stacks
9 reeling

Figure 5.6 shows a vat system.

Twin wire machines are Fourdrinier-type processes which are drained between the two forming fabrics or wires in a horizontal plane. There are also multiwire Fourdrinier types of machine in operation today. Figure 5.7 shows a twin wire system.

Vertiform machines are twin wire machines arranged vertically. Figure 5.8 shows a vertiform system.

The inverform process is that in which the slurry is forced between two wires. Figure 5.9 shows an inverform system.

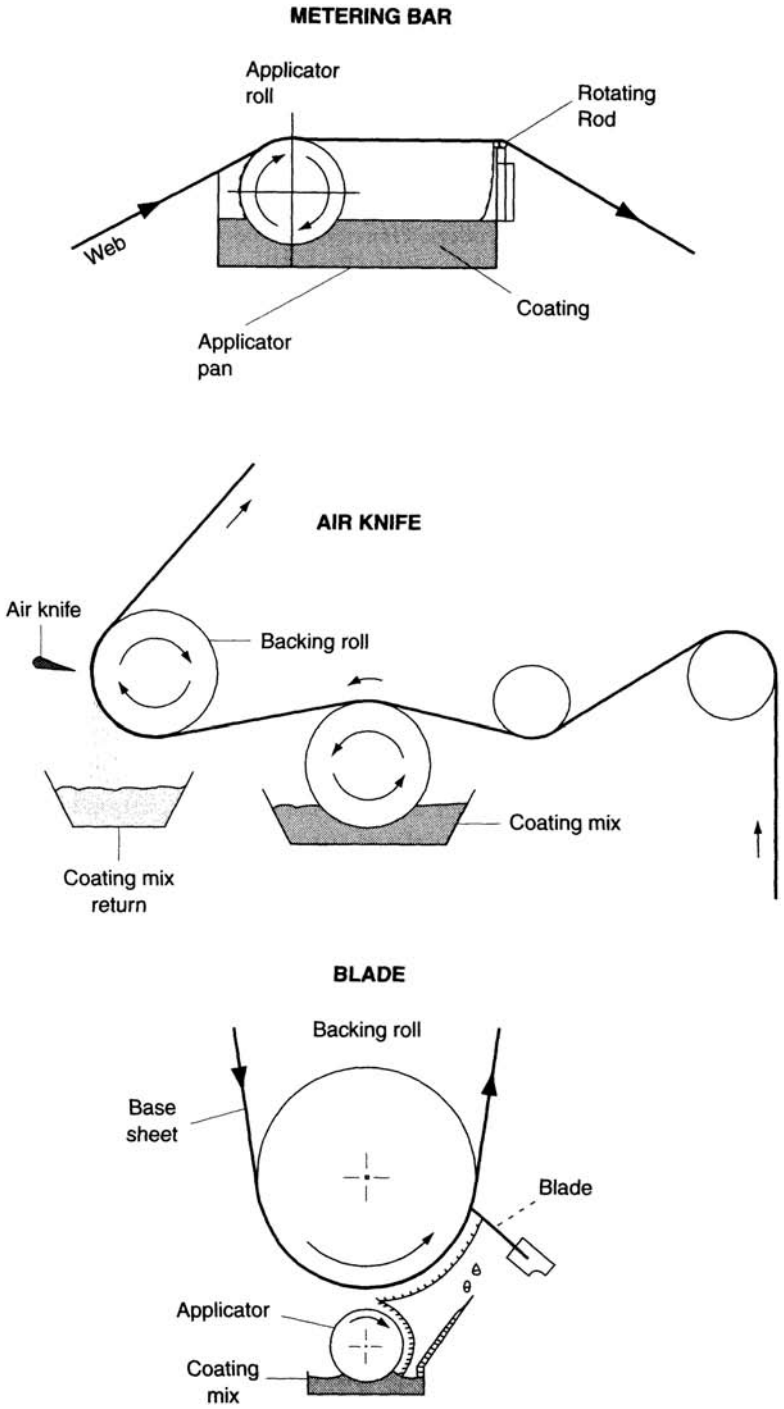

Figure 5.5 Coating methods

Common types of board in use

Millboard

This can be made on a single cylinder or vat machine, where a moist web of thick paper is built up in plies and then milled between heavy rollers.

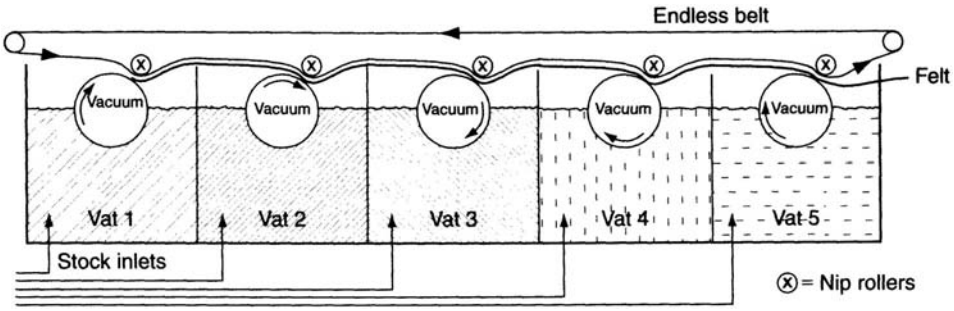

Figure 5.6 A vat system

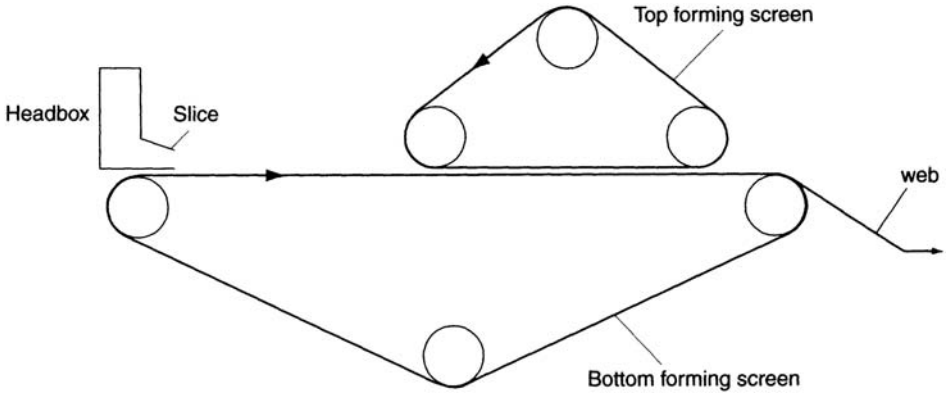

Figure 5.7 A twin wire system

Chipboards

These use post-industrial waste (PIW) and some post-consumer waste (PCW) in their middle plies. They can be faced with better quality facing materials and may or may not have a quality backing used for low-grade small boxes and cartons.

Box boards and coated box boards

VIRGIN PULP USED

Figure 5.10 shows a white lined folding boxboard in section. High-grade mechanical pulp is usually used for the centre plies of the board, with high-grade bleached sulphite pulp in front and behind the core plies. On the face 'printing' side of the sulphite pulp there is a base coating and finally a clay/size coating (up to 20–25 g/m).

'RECYCLED' BOARD

Figure 5.11 shows a typical high-quality recycled board structure. Typical 400 µm grade plies from printside inwards consist of: 28 g/m^2 clay coating; topliner 47 g/m^2 bleached virgin sulphite pulp; under-liner 69 g/m^2 unprinted recycled newspaper pulp; main body up to six plies of general recycled pulp adding up to 134 g/m of mostly PIW waste; back-liner 22 g/m bleached virgin sulphite pulp. This means that the average percentage of recycled fibre is about 75% by fibre weight and 68% of total board weight, including coatings. Most recycling mills will claim to be to be well inside *any* current or proposed limits on any part of effluent control.

It is also claimed that the bacterial count in the finished recycled board (which is obviously variable) compares with virgin board. For polybichlorinated phenols (PBCs) the claim is <l ppm against a limit of 2 ppm specified for the contact of greasy foodstuffs. See Table 5.1 for contamination levels.

Strawboards (lined or unlined)

Used for some rigid boxes, e.g. solid board enema boxes where the slight odour and high chlorine content are of little importance. Fibre is provided by straw and is made on a conventional board machine. Lining is achieved by pasting paper, of

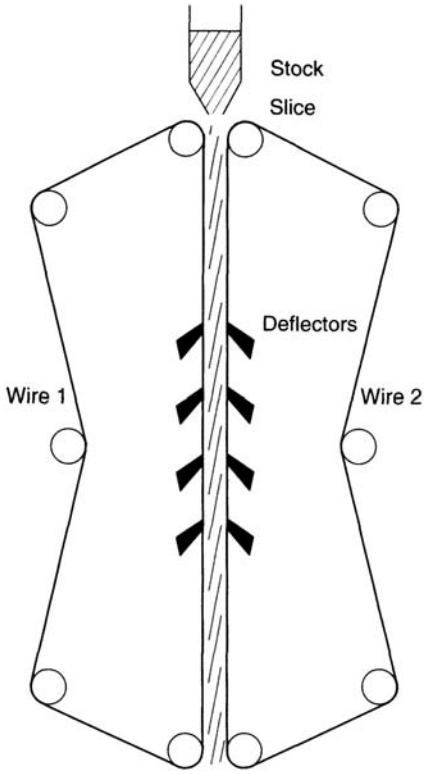

Figure 5.8 A vertiform system

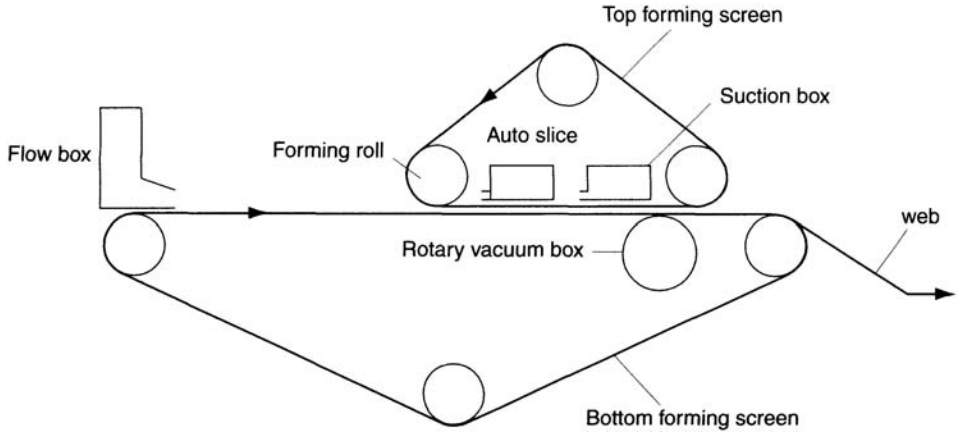

Figure 5.9 An inverform system

the desired type, to one or both sides on a continuous process machine. It is quite rigid, but has limited use in pharmaceuticals because of the slight odour.

Paper and board merchandising

Usually the larger paper and board mills do not sell their final 'jumbo' reels direct to printers or converters. They sell them to merchants who store the reels of the many specifications of paper and board available (in controlled conditions) and market the papers and boards to the printers and converters. These jumbo reels can vary from 1 to 4 m wide and be up to 2 km long.

All paper merchants market the papers and boards to users; many convert the paper or board into a form in which it can be used directly. The latter type of merchant has substantial quantities of machinery to slit the jumbo reels down for reel-fed printing equipment or slit, sheet and pack for sheet-fed equipment. The slit reels are usually delivered on end to the printer, but the sheets could be anything from packed on special skillets to wrapped in Kraft paper parcels.

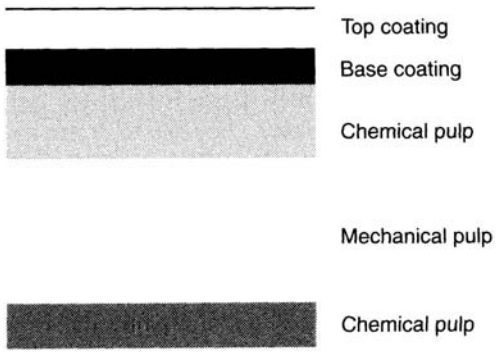

Figure 5.10 A white lined folding boxboard in section

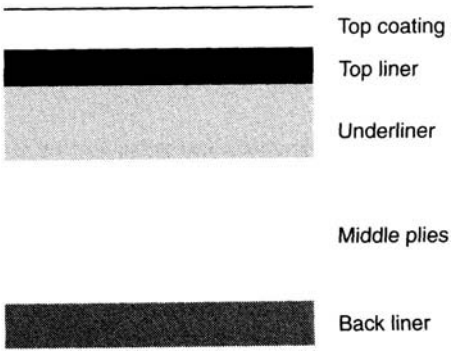

Figure 5.11 A typical high-quality recycled board structure

Labels and labelling

The following discussion covers the requirements for labelling with paper onto various types of packaging material used in this industry. Specific reference is made to the four main types of paper labels, i.e. plain with adhesive added, pregummed, heat sensitive and pressure sensitive.

Printing can be basically divided between information which is 'fixed' and information which is 'variable'. Variable information is usually that which is added either immediately prior to the production line process or as part of the production line process (see below).

Table 5.1 Contamination data (mean values) based on samples taken and tested by the University of Graz (Austria) in 1992

Heavy metal	*Virgin fibre (ppm)*	*Recycled (ppm)*
Cadmium	0.3	0.2
Arsenic	5.45	4.2
Lead	7.6	10.6
Mercury	0.15	0.14
Chromium	0.8	4.1

Label systems are also found in combination with leaflets, of which the Denny Bros FIX-A-FORM system is an example (PEEL 'N' RESEAL from Harlands, INSEAL from Instance, MULTIPEEL and DOUBLE-DRI are others).

A dictionary definition of a label is 'a slip of paper, cardboard, metal, etc. for attaching to an object and bearing its name, destination, description, etc.'. A label may therefore be made of any material and may be attached to its parent item or pack by any means, e.g. tying, stapling, nailing, adhesion. Decoration or wording may be achieved by any printing process (depending on the material), i.e. embossing, debossing, letterpress, flexographic, offset litho, gravure, screen, dry offset, etc.

Labels are, if anything, increasing in importance as carriers of more and more information about the product, e.g.:

- product identity
- corporate image and sales appeal
- pack contents and ingredients (in ever more detail)

- legal and moral warnings
- bar codes (of both the retail and security variety)
- security (increasingly a problem in manufacture, retail, distribution and transportation)
- identity and address of manufacturer (and marketing company)
- instructions/warnings for use
- information on handling, disposal, destination, hazardous goods, etc.
- promotional information.

This list is not exclusive, but is a guide to the pieces of information which one part or another of the packaging chain could be required to affix to a product, not forgetting the warehousing and transportation systems. The amount of information is more likely to increase than to decrease, due to consumer demand for more and more relevant information on what they buy:

- more awareness of health and safety issues
- better inventory control needed, therefore more bar coding to carry more easily automatically retrievable information
- more environmental pressure
- more legislation by the UK and the EU
- more security, either as devices or preventive.

Will it be necessary to design packs where the information will dominate the design parameters? This is already a reality in some limited areas of packaging, e.g. leaflets on small parenteral antibiotic packs! More importance is now placed on eye appeal with the creation of consumer preference for the product, particularly in the case of OTC medicines. However, less ornate and more functional forms of labelling must not be ignored, i.e. identifying features for parcels, cases, crates, etc. and as seals to show when a product has been tampered with.

Labels may be used in addition to the main pack decoration (special offers, price tags, etc.) and, as in the case of certain materials, for instance glass, are the most economical means of applying printed detail. (Ceramic printing has limited applications to reusable glass containers.)

As this chapter is concerned only with paper label material, the foils, foil laminates and plastics are not considered.

Label fundamentals

When working with labels and the designs thereof, the prime responsibility of the packaging specialist is to look after the technical side, i.e. paper, adhesive, carriers, etc. However, in order to perform that function correctly the fundamentals of decoration need to be understood. (This chapter does not deal specifically with the printing processes: see Chapter 16.)

1 A good design—prominent brand image.
2 Well printed, full use of colour: note that a single printing on a coloured surface gives a two coloured label at the cost of one printing. The method of printing is important as the best overall effect is what matters, allied with the best price. For example, do not use gravure printing on short run labels for outer cases.
3 Best paper for the purpose, i.e. white, tinted, coloured, coated, substance (most label papers between 60 and 110 g/m^2), etc.
4 Features that may be critical for machine application:

- direction of grain
- dimensional tolerances—frequently dependent on the method of paper cutting (punching or guillotining)
- paper substance/caliper
- absorbency (Cobb test)—water absorbency
- porosity—vacuum pick-up is used on many labelling machines
- method of storage and handling, i.e. top and bottom card stiffeners, wrap around banded (not rubber bands), restrict number per bundle (say 500s) for block cut labels
- shape—artistic value, radiused or square corners
- size of area (and tolerances) to which label is being applied.

5 Surface finish (also critical to (4) above):

- varnished (roller coated, plate varnished—varnish type (water varnish, spirit varnish), coating weight)
- high melt varnish—critical for heat sealing areas or export markets

- nitrocellulose or PVdC coating systems
- laminated to other materials—PVC, PP, cellulose acetate, etc.
  Note that any external coating (varnishes etc., solid print, bands of print) can have a direct effect on the 'curl' of the paper, which is liable to occur when the paper is wetted or dried. This is because inks and varnishes 'stiffen' the paper in both the machine direction and the cross direction. Coatings may vary from matt to high gloss.

6 Print requirements:

- colour standards—target plus light/dark tolerances (e.g. Pantone)
- rub resistance, fade resistance, odour level (see Chapter 16)
- product resistance
- ink thickness.

7 Suitable adhesive (mechanical or specific)—dependent on the surface to which the label is being applied. Note the importance of tack, setting time, polarity (polar or non-polar) of materials.
8 Cut or roll form (i.e. singles or rolls).

The fact that paper has fibres oriented mainly in one direction, i.e. 'grain' or 'machine direction' and 'cross direction', plus the fact that it consists of hygroscopic vegetable fibres, frequently has a strong influence on the labelling process. The application of an aqueous based adhesive to a paper label causes a swelling of the fibres. This change in dimension is greater in the cross-grain direction, hence the paper curls around or parallel to the machine direction. This 'curl' is away from the wetted area and may be accentuated if the outer surface is covered by a less moisture sensitive covering: varnish, printing ink, etc. Any labelling process which involves the application of water must recognise 'curl' as a distinct problem which can be reduced to a minimum by consideration of a number of factors, i.e. label shape, size, grain direction, adhesive (solid to water content, tack), method of application, speed of application, etc.

Label 'curl' also occurs when paper is heated and moisture is 'lost'. In addition to the relationship grain direction has with moisture (this applies to both loss and gain), two other factors associated with it are as follows.

1 Tear strength—this is lower along the grain; note difference on edge appearance when paper is torn in both directions (at right angles to each other). Tear along the cross-grain direction shows a more fibrous (feathered) edge.
2 Rigidity or stiffness—paper bends more easily in the cross direction. Another test for grain: cut two strips of paper 0.5 inches×6 inches at right angles from the same sheet. The length which shows the greatest bend has grain parallel to the 0. 5 inch measurement.

Grain can also be detected by a Mullen burst test (and tensile strength)—see 'Paper and board testing' below.

Types of paper labels

As indicated above there are basically four types of paper labels, as follows.

1 Plain paper—applied after the addition of an adhesive.
2 Pregummed paper—where the label is applied after wetting with water. The paper is pre-coated with dextrine or gum arabic using single to treble coatings.
3 Heat sensitive labels—applied after the activation of a thermoplastic coating by the use of heat. Two types of thermoplastic resin exist:

- instant type—activation is a factor of heat, pressure, time; sets immediately the source of heat is removed
- delayed action type—activation by heat, pressure, time but once activated, adhesive remains tacky.

4 Pressure sensitive or self-adhesive—applied by the application of pressure. Paper is pre-coated with a permanently tacky adhesive which is attached to a separate backing paper (which has an easy release coating on it).

In addition to the above, there are shrink-and-stretch plastic sleeving and pressure sensitive plastic labels. These two are not dealt with here, but they are making considerable headway in pharmaceutical labelling at the present time.

The above labelling methods are listed in ascending order of cost; using for example a label printed in two colours, size 90×63 mm, prices quoted in Table 5.2 are per 1,000 labels delivered, based on orders of 100,000 and 10,000 using 1991 prices.

Plain paper labels plus suitable adhesive

The thin film of adhesive applied costs only a few pence per 1,000 labels, plus labour costs. Plain paper is most widely used for glass, but can be applied to metal, particularly in the form of a complete wrap around label. Application can be by hand, semiautomatic or fully automatic methods. Speeds of 1,000 or more per minute can be achieved. Pharmaceutical labelling usually ranges from 10 to 300 per minute.

Hand application

This routine is not covered in detail here, but application speeds can reach as high as 400–600 units per operator hour.

Semi-automatic labelling

In this operation the machine selects, glues and applies the label but the item to which it is applied is placed into position by hand. Labels may be picked up by vacuum or the adhesive. Higher tack is necessary than that used for hand labelling. Speeds range from 25 to 60 per minute, i.e. 3,600 per hour maximum.

Fully automatic labelling

The item is positioned and labelled automatically. This requires even more critical limits in terms of setting-up, material and adhesive tolerances. Change over time or adjustments also take longer. Speeds can range from 3,500 to 60,000 per hour.

Table 5.2 Costs of labelling methods (1991 prices)

	Order-size		*Approximate ratio (plain paper=1)*
Type of label	*100,000*	*10,000*	
Plain paper	£6.00	£13.00	1
Pregummed paper	£8.00	£18.50	1.3
Thermoplastic coated	£9.00	£20.00	1.5
Self-adhesive	£12.50	£26.00	2.0

Adhesives

The type of adhesive used depends on the surface of the item to be labelled. The adhesive must provide an adequate bond between the label and container. Labelling of paper-based materials (unless specially treated) and glass usually presents little difficulty. Tinplate, although slightly more difficult, can involve problems of corrosion unless special corrosion inhibitors are incorporated into the adhesive. Labelling to plastic surfaces requires the use of specialised adhesives which may be based on latex or synthetic resins, e.g. poly vinyl acetate (PVA). In certain instances pre-treatment of the plastic (in common with printing) with flaming or corona discharge can aid adhesion.

Dextrine is the most widely used adhesive involving different levels of solid content. For instance, a low solid content is used for hand labelling since low tack (after initial placement it may be slid into position) and a long setting time are necessary. On mechanical labelling, particularly where the label is picked up by the adhesive, a high tack plus quick set is important. In addition, the adhesive must be non-threading and non-foaming. The addition of borax increases tack and setting speeds.

Problems of curl

Although this has already been mentioned, it is always a factor to consider when any label is applied by a wetting adhesive. Both printing inks and coatings tend to reduce the moisture absorbency of a paper and thereby increase any curl (which is

always parallel to the grain direction). If the amount of water used in an adhesive can be kept to a minimum, curl will be reduced. Using a thin film of adhesive is also effective. When labelling a round container there is a choice between a complete wrap around (probably leaving a varnish-free area on the under lap) and using, say, three-quarter wrap with a gap. It should be recorded that many containers (particularly injection moulded plastic) have a natural taper which may cause problems of alignment.

It is normal to have the grain direction parallel to the base of the label, but there are occasions where this does not apply, i.e. some labels on circular containers.

Pregummed labels

Paper is pre-coated with dextrine or gum arabic. As only water is required to activate the adhesive, the labels are clean to apply and a complete labelling operation can be carried out by one operator. They are ideally suited to small runs or intermittent production, such as parcel labels. They provide good adhesion to paper, board, glass, but as the range of adhesive types is very limited, they lack flexibility in terms of adhering to a wide range of surfaces.

Pregummed labels are difficult to apply if large, due to problems of creasing. They also have a high tack and therefore cannot be adjusted readily once on the item to which they are being applied.

Heat sensitive or thermoplastic adhesive-based labels activated by heat

As indicated above, two types are in use: instant tack and delayed tack. Both are based on synthetic resins; the former has to have heat and pressure applied to affect the transfer but sets immediately the source heat is removed. The latter is usually activated to tacky state after which it can be affixed to any item without a heat source. However, most frequently the heating operation plus pressure of application are applied simultaneously. The tacky state remains for some time after the source of heat is removed.

As heat sensitive labels do not rely on conventional gums or water as a wetting agent they will adhere to a wider range of materials including metals, plastics, and varnished, coated and printed surfaces. However there is one criterion that is very important in storage of thermoplastic materials either as flat sheet prior to printing or as labels after printing. All heated areas (pipes, radiators, overhead heaters) must be avoided; also high stacking pressures, both of which can cause partial activation and/or blocking. Care also has to be taken in the selection of printing inks and varnishes, as certain volatile constituents of these decorative materials will also cause activation and blocking.

As the delayed action resin takes up a permanent set very slowly, the grain direction (shrinkage after heating) will cause curl to occur. In certain circumstances this can be greater than the adhesive forces so the label may lift, particularly if the radius to which it is applied is tight. For this reason labels should be produced with the grain parallel to the axis of curvature of the container to which they are applied.

During activation, temperatures above 100°C are used, causing drying-out of the paper and shrinkage. Labels return to normal after exposure to the atmosphere, but on larger sizes (say 100 cm^2) there is a tendency towards creasing and blistering. Activation by steam can partially overcome these problems provided the outer (printed) surface is not waterproof.

Instant tack labels

There are a few well-known makes on the British market. They may be applied by hand (hot plate), semi-automatically or automatically. Machinery is similar in price to conventional gluing/labelling machines but those with more sophisticated heating systems can be more expensive. The machines involve far less cleaning time and generally get less ‘gummed up’.

Instant tack labels find special usage on seals, pleated overwraps, various header labels (cellulose films must be heat sealable variety). They are not used for bottle or can labelling.

Delayed action labels

These are more versatile than the instant tack type, particularly in their application to bottles, tinplate, plastics, coated or laminated surfaces. Speeds of around 600 per minute can be achieved.

Both instant tack and delayed action labels are more costly than the conventional paper—adhesive labelling. Selected advantages may offset the cost increase, i.e.:

1 virtually no cleaning down, no wastage of adhesive
2 shorter setting-up time
3 adhesion to a wider range of surfaces

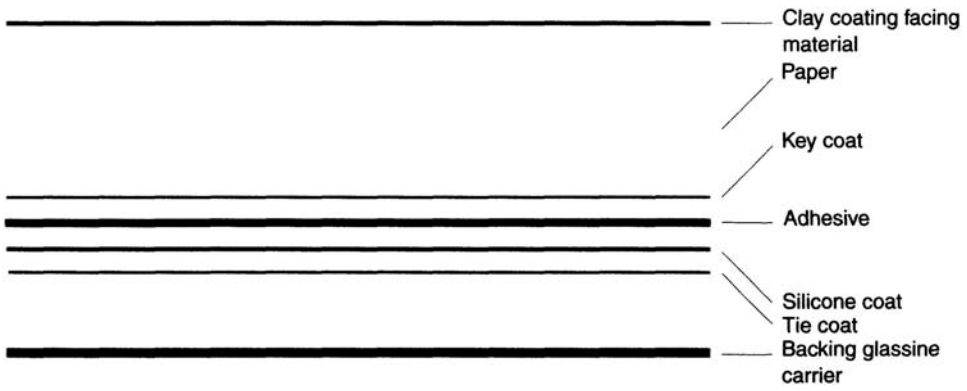

Figure 5.12 Structure of a pressure sensitive label

4 less affected by powder contamination or varying ambient atmospheric conditions (humidity and temperature)
5 provide a high standard of cleanliness—no labour for wiping down.

Thermoplastic adhesive labels generally find a special usage and are now meeting increasing competition from self-adhesive or pressure sensitive labels.

Pressure sensitive labels (created by RS Avery 1935)

It is preferable to call these pressure sensitive labels, rather than self-adhesive, as both the pre-gummed and heat sensitive labels can be thought of as self-adhesive.

They consist of a suitable label paper coated on the reverse side with a permanently tacky adhesive which is in contact with a backing paper that protects it prior to use. The backing paper is coated with a special release coating which permits the label to be removed easily. Labels may be provided in reel or sheet form; both can have the label 'laid on', i.e. the non-printed area has been cut and removed. Sheet label forms also exist as split top type—both printed and non-printed area is present but printed area is 'split' away so that it can be removed. Split back type has the backing paper split or cut so that it can be removed. (Applies to larger sizes.)

Numerous papers, usually of the single face coated types, are now available with a wide range of pressure sensitive adhesives. These adhesives may be:

- *temporary*—can be easily removed from the item onto which it has been placed
- semi-permanent—difficult to remove
- permanent—virtually impossible to remove without a fibre tear.

Pressure sensitive labels are removed from the backing paper and then applied by pressure. Ideally they should be removed by turning the backing paper over a right angle so that the label comes off straight. If some labels are peeled off (backwards) a curl is induced, which in the less permanent form may result in a peel back or lifting from the item to which it is applied. Figure 5.12 shows the structure of a pressure sensitive label.

Self-adhesive labels normally have the following type of structure (layers):

- facing material (90 μm)
- key coating adhesive (12 μm)
- silicone release backing (50 μm)

giving a total thickness of 150 μm (0.006 inches).

The silicone release usually has a coating weight of approx. 0.5 g/m^2. Die cut accuracy is usually ±5 μm.

Self-adhesive labels can be applied to most materials: wood, plastic, metal, glass, paper and board. As the adhesives are resin-based (plasticised thermoplastics), migration problems can occur when they are applied to certain plastics (PVC, LDPE, etc.). Adhesive systems for pressure sensitive labels include latex and acrylic bases and adhesives which may be applied as a hot melt, or via a solvent, emulsion or dispersion base. Water-based adhesives are currently increasing in use.

Until recently the printing processes have tended to be limited, i.e. flexographic, rotary letterpress (four colours), with gravure (occasionally). The labels are produced in accurate register on the backing paper—on reel-fed machines, printing, punching and removal of trim are carried out as a continuous operation (platens are also used.)

Labelling can be carried out by hand, semi-automatically or fully automatically. In all instances accurate positioning is essential as the label cannot be slid into position. Machine speeds of 800 per minute are attainable. The cost of pressure sensitive labels is higher (than that of all other forms).

Reel-fed labels offer one huge advantage in security—they dramatically reduce the risk of admixture, which is particularly important in the case of pharmaceuticals.

Applying labels to tight radii still may give butterflying (edge lift) with certain label types and styles. Improvements can be achieved either by an adhesive change or using a paper of a lower substance weight (i.e. replace 90 g/m^2 with 65 g/m^2), or by reducing the stiffness of the printed face by reducing the amount of ink used, ceasing to use a varnish or using a lighter coat weight paper.

Modern adhesives for self-adhesive labels include acrylic, polyethylene combinations. There is a distinct move away from solvent-based adhesives (for ecological reasons) to water-based dispersion/emulsion systems.

Adhesion can be normally checked by a press-down test, followed by removal after 3 s, 6 h, 24 h. Bond normally improves with time due to the cold flow of the adhesive. Long-term adhesion may use a test involving 7 days at 70°C, which gives an indication of any change over 12 months. Be certain that 70°C is well below the degradation temperature of the adhesive, otherwise the results are spurious.

Leaflets

Leaflets have loomed large in the minds of packaging people in the industry in the past few years, primarily with the implementation (from 2 January 1994) of the relevant parts of the European Community Directive 92/27/EC, which brings together requirements for labelling and package leaflets into one directive by repealing parts of Directives 65/65/EEC and 75/319/EEC. In addition, the obligatory nature of Article 3 of Directive 89/341/EEC on packaging leaflets (unless *all* the required information is on the pack or label) is confirmed and reinforced.

Paper leaflets can be found broadly as one of four types, as follows.

1 *Cut sheet*. Usually printed both sides, delivered as blocks of cut sheet and folded on the cartoning machine. The restrictions on block cut papers are also relevant, i.e. they should be backed and fronted with band bound card.
2 *Reel-fed*. Like reel-fed labels, but with no backing paper. They are both guillotined and folded on the cartoning machine. Claimed to be more secure than all other types of leaflet.
3 *Pre-folded*. Are delivered as bundles (these need to be 'broad banded', *not* with elastic bands round them) or contained in plastic cartridges and fed via a hopper system direct to the cartoning machine,
4 *Combined label/leaflet*. Delivered as a thick pressure sensitive label (either reel-fed or block cut), containing a fold-out portion which is the leaflet itself. Applied as one would apply a pressure sensitive label. These have now been around for a number of years. As far as can be ascertained, at least six patents have been taken out in this field. Recently there has been more use of multi-ply construction of these types of label, often using dissimilar materials with rather specialist adhesive systems. Probably the best known are Fix-a-Form from Denny, Peel 'n' Reseal booklet labels, Multipeel, a peel off promotional leaflet or sticker, Dri-peel, Incore and the Double-Dri system. Leaflets use high-opacity (80%+EEL) lightweight (40–70 g/m^2) coated or uncoated papers.

In order to maximise the smooth production of these thin (lightweight) papers, the following facts about paper should be borne in mind when designing the leaflet.

1 *Grain direction*. The grain of paper has been mentioned several times already, but with lightweight papers it becomes once again a critical feature, as the papers are both thinner and weaker than label paper or board.
2 *Stiffness*. Paper is nearly twice as stiff in the machine direction as it is in the cross direction. The degree of stiffness is related to the caliper (substance), so that the thinner the paper, the lower is the stiffness, to the extent that the stiffness factor is proportional to the cube of thickness. Arising from this is a basic recommendation that the thinner the paper the more advantageous it is to print in the machine direction because of its greater stiffness.

The other parameter of lightweight paper to be considered is the porosity of the chosen paper. This is because many cartoning machines use a vacuum type of pickup for the leaflet no matter in what form it may be presented to the cartoning machine. Even so-called reel-fed leaflets have to be cut, picked and moved through folding plates up to the insertion point into the carton. For this reason both specification of paper porosity to air and pick tests (to keep down the amount of lint or dust) are sensible.

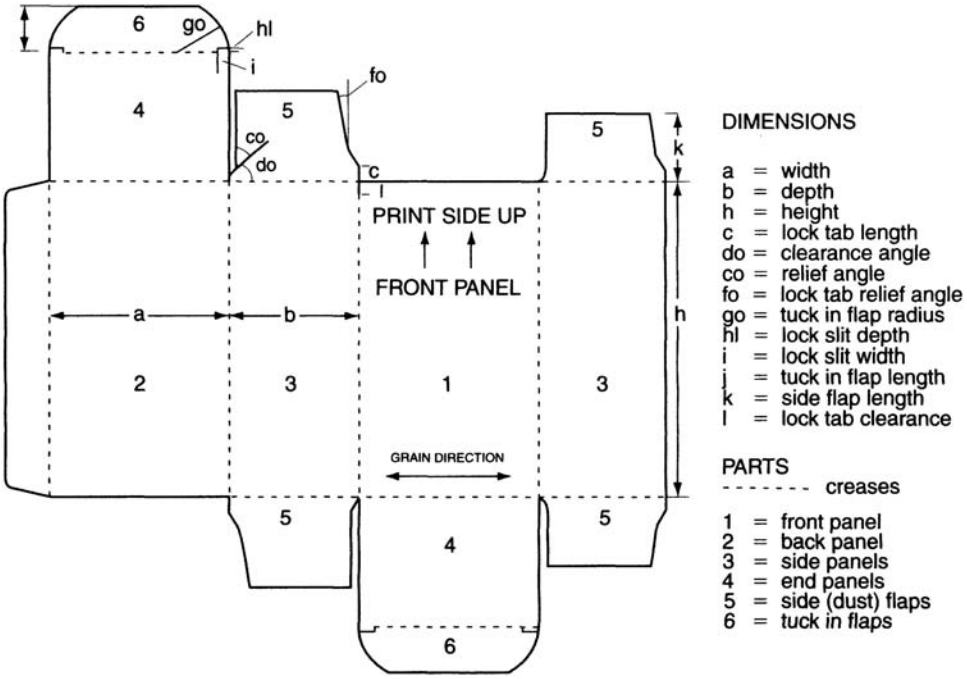

Figure 5.13 ECMA 2120 style carton with twin lock slit flaps

The other point to take into account is the 'conditioning' of the lightweight papers prior to printing and folding. This just means that the paper should be kept, as far as practical, in optimum storage conditions.

All leaflets, though folded tightly for insertion, have inherent problems of ink 'show through', particularly with ink colour solid blocks, e.g. photos or pictures. Security bar code reading can be a severe problem on the thinner papers. The amount of copy required on all types of leaflets has increased dramatically over the past ten years, so much so that packs have had to be devised to accommodate very large leaflets (A3); this has created its own cartoning machine design problems.

Folding or collapsible cartons

These difficult to handle, temperamental objects in white lined folding boxboard are popular in the industry because they are good at their job, which is to contain, protect and distinguish the product from *all* others in an economical manner. They are sometimes known as 'secondary' packaging.

Ethical products should either have a print free area or a printed area which does not contain vital or legally required information which would be covered or obliterated when the pharmacist's label giving information for the patient is applied. The standard size for this label is 70 mm×40 mm, or 70 mm×35 mm.

Choice of design

When choosing a carton design the following points should be noted and fully discussed with a printer used to dealing with pharmaceutical products and with the necessary levels of hygiene control, QC, and inspection.

1 *Style*—This could be from a catalogue of carton designs, e.g. that of the European Carton Makers Association (ECMA). This includes the method of flap retention in its style parameters, e.g. lock slit, friction fit, claw lock, crash lock, envelope lock. Are dust flaps required? Is reverse tuck or aeroplane tuck wanted? Figure 5.13 shows a typical reverse tuck twin lock slit carton.
2 *Type of board*—This has been discussed above. Each of the types of board mentioned comes in various calipers ranging from about 200 µm up to around 700 µm. This will depend to a large extent on what is going to be put into the carton, allied with the size. Board surface facing materials need to be decided, as these will affect the type of printing chosen and may affect the creasing and subsequent carton erection.
3 *Layout*—It is usual to have the top opening flap opening away from the opener, with the 'glue flap' around the back of the carton, placed so that it interferes as little as possible with the overprinting operation.

4 *Size*—This has been mentioned above. Only make the carton big enough to contain the contents and allow enough clearance for machine operation.
5 *Graphics*—Understand what graphics are needed and the limitations of each of the printing processes you are likely to use. One colour is easier and cheaper to print than four colour process.
6 *Quantity to be produced*—If only running a few hundred cartons of one particular type, then choose the process with the cheapest plates and shortest make ready: that will be the cheapest, e.g. one colour flexographic or letterpress printing. At the other end of the scale, if you wish to produce four colour process printing with screens and tones and produce them by the tens of millions then either offset litho or gravure printing is the choice.
7 *Method of printing*—Usually using offset litho, flexography, letterpress or gravure. May include hot die, stamping, foil blocking, embossing, debossing.

Origination

1 *Plates*—Need to be made from the artwork, one per colour specifically designed for the machine on which it is going to be used.
2 *Cutting and creasing formes*—These are the cutting (sharp) and creasing (blunt) knives fitted into a sheet of thick plywood so as to cut the flat printed sheet of board and press in the creases needed to form up the carton. Each sheet of plywood that carries the knives is called a forme. The knives are surrounded by strips of foam rubber, to prevent them from tearing the board. Opposite to this sheet is a 'negative' sheet of plywood called the 'counter'. On this there is a mandrel of hard material for the sharp knives to cut against.
3 *Cost of origination*—This entails looking to the best way of minimising the costs of artwork, plates, printing processes, sheet, sizes, formes and counters, etc.

Make ready

This is 'simply' the preparation of the printing machine to make it ready for production, including the selection of the board sheet size and which way the grain of the board in the finished carton will run. The figures, drawings of cartons and artwork should all indicate in which direction the grain is to run.

Printing

May be printed on flat sheet or from reels. May use either a four colour process system (cyan, magenta, yellow and black), or a multi-colour system. As indicated above, almost any printing process can be (and is) used. The most common methods of printing today are all sheet fed, mainly using letterpress and offset litho.

Cutting and creasing

The basic purpose is to stamp in the crease lines, at the same time cutting out the outline of the carton. The prime reason for creasing the carton blank is to define the shape of the carton panels and allow it to fold without distortion. This is achieved by using sharp cutting and blunt creasing 'rules' (either flat bed or rotary). The sheets of preprinted board are fed into what looks like an ordinary small printing press, located over the counter and the forme comes down with some force, cutting and creasing that single sheet.

Stripping

This is the removal of unrequired waste surrounding the printed cut and creased flat carton blanks on the sheet. It is still quite often a hand-based operation.

Pre-folding and gluing

Cartons are usually supplied in a collapsed state, with a glued side seam and two of the folds already made. Folding/gluing is done at high speed and it is necessary for the adhesives used to have a high tack, since freshly folded creases are quite resilient. At this stage, crease quality is very important, since unduly stiff creases will resist gluing.

Following gluing the carton is usually compressed to a flat state where it already exhibits some degree of 'crease set'. To minimise this it is frequently advisable to open the carton through 90° to 180° momentarily to literally break the crease,

reduce possible crease set and generally assist final erection. This process is termed pre-folding. (Tests that it is sensible to know about and use during a carton design sequence are covered below.)

Packaging and identification

The cartons should be loosely bundled together, stacked on their edges into strong corrugated box. It is detrimental to stack them 'flat' as the weight of cartons above will inhibit the pre-break (or natural springiness of the carton), making automatic handling an impossibility. The looseness is for similar reasons to prevent having problems with cartons. The case should be securely sealed and identified in the manner prescribed by the specification, with at least the security code (item code, part number), customer, batch/lot, a QC pass stamp/mark and a description.

Carton erection and filling

The action of mechanically erecting, inserting primary pack, insertion of leaflet, then the closing of the carton is another world in which technical expertise may be required. The criteria on which the form of carton filling will be decided include, quantity per batch/lot/order, size and weight of the goods to be cartoned, cartonboard caliper, design of closure flaps, and what else, apart from the primary container, has to be inserted.

Hand cartoning

Basically any carton style, with any form of goods, of any caliper board, with any of the closure flap designs (lock slit, friction fit, claw lock, crash lock, envelope lock), with any number of leaflets or measures or droppers etc. can be used in hand cartoning.

Semi-automatic

This is usually a machine where the carton is erected, the bottom closed and the top opening presented to the operator who drops in the goods and any accessories. It would be expected for this type of machine to have an overprinting unit of some type built into the cartoning machine.

Quantity per batch/lot/order needs to be greater than the time needed to change the machine from one size of pack to another, which could be from 30 min to 3 h. Works at a speed of 40–60 items per minute with two to four operators. The size and weight of the goods to be cartoned have some relevance, as large heavy objects (2 1 Winchesters of liquid) will need to run more slowly than, say, 5 ml bottles.

The cartonboard caliper, particularly the consistency, is more critical than for hand cartoning as it affects the 'pre-break' of the carton and once a machine is set to open pre-break there is little tolerance for variation. The faster and more sophisticated machines need tight tolerances.

The following designs of closure flaps, lock slit, friction fit, claw lock, envelope lock and glued flaps can be made to work on an appropriate semi-automatic machine. One would recommend for simplicity that attention be paid when using claw locks and envelope locks, ensuring that they are really necessary before introducing them, as they are not the easiest carton closures to handle.

Note that cartons can have different locks on each end, e.g. lock slit at the bottom and friction fit at the top, or (more usually) envelope lock base seal with friction, lock slit, claw or glued flaps at the top.

Automatic

There are two basic types of machine—intermittent motion and continuous motion. The intermittent is the smaller, slower and cheaper, usually with a blade opening action for the carton pre-break, so that it is likely to accept a lower quality of carton than the really high-speed machines. The continuous motion machines tend to be much larger, faster and more expensive and, being much faster with vacuum pick-up of the carton for a 'knock' pre-break, are much more sensitive to the quality of the carton presented.

Automatic cartoning should only be used when the quantity per batch/lot/order is large enough to keep the machine running for more time than it is down on change-over.

The size and weight of the goods to be cartoned is something of a limiting factor, as our 2 l Winchester would probably not be candidate, but a 300 ml bottle certainly would be run automatically. Speeds range from 60 to 350 per minute, with machine prices rising to match the speed. The design of closure flaps is probably practically limited to lock slit, friction fit and glued flaps. This again is in the interests of speed. What else, apart from the goods, has to be inserted may create a problem. Leaflets

can be inserted, as can probably one other accessory, but for more than this specialist machines have to be designed to do the job.

Rigid boxes

These are still occasionally used e.g. rigid nested fibreboard boxes for ampoules, but nowadays any paper-board near parenteral products is viewed critically, due to the fibre load from the board itself contaminating the local atmosphere.

Rigid boxes need similar stages to folding cartons see 'Choice of design', 'Origination' and 'Make Ready' above. Printing, if necessary (but usually labelled with a pregummed label, which might act as a tamper-evident seal as well), is usually applied as a pre-printed liner after the rigid box has been formed. Hence the further stages are:

1 selection of board, board size and cutting to size on a cutter/scorer machine, e.g. one of the chipboards
2 corner cutting—removing the corners so that the box can be erected
3 corner staying—adding gummed paper to each corner to make the erected box rigid
4 quad staying—an alternative to (3)
5 paper slotting—printed or plain covering
6 QC to specification
7 packaging and identification.

Rigid boxes are normally hand packed.

Overprinting

This is sometimes known as 'batch coding' as well as the more popular term, overprinting. This has become a necessary evil in the modern world. All overprinting (this may include off-line methods as well) is used to add variable data as late in the production cycle as possible, i.e. batch/lot numbers, manufacture and expiry dates, price blocks for the Middle East in particular and registration numbers for many other places. If these problems are approached by the method of using fixed copy for a large area of the world allied with a fairly sophisticated overprinting system, one can save the cost of the system in inventory savings alone.

The overprinting of 'variable' information as late as possible in the label application and carton closing processes gives the production company a high degree of flexibility to allow for unforecasted emergency information to be added. This copy is normally added to the printed label or carton either just prior to the packaging operation or during the operation itself. As with all printed copy, the print must be indelible, legible and not fade during the shelf life of the product under normal usage conditions. It is usual to overprint in black and occasionally red. *Note* that red is traditionally used for warnings or poison markings, so check carefully before using.

Overprinting is usually carried out with one or other of the following printing processes: hot foil stamping, flexographic, letterpress, tampon, thermal printing, and stamp debossing.

Some of the information required may be in the form of bar codes. This has stimulated the European Pressure Sensitive Manufacturers Association (EPMSA) in line with the Article Numbering Association (ANA) EAN guidelines, to produce a standard for bar code overprinting on pressure sensitive labels. EAN bar codes can now be successfully printed onto labels using flexographics, or thermal transfer printing.

Contact printing techniques

Contact printing is the more traditional type of printing in the industry.

1 *Letterpress*—the traditional slugs of type in either lead/antimony alloy or hardened steel letters. Usually locked up (set) in a chase (holder), or using a 'baselock' type of system where the type has a foot which slips into a holder and can be locked by a spring clip, being inked each pass and 'kissing' the substrate to deposit the ink. Can be used on most substrates, but is best on paper and board which is not too shiny. Cast coated papers and boards give problems.
2 *Debossing*—the same as letterpress except that no ink is involved and the characters are pressed quite hard into the substrate. Used occasionally for paper, but more normally for blister and strip packs. This method is likely to generate complaints, due to the difficulty of reading it clearly.
3 *Hot foil*—again similar to letterpress, but the ink is carried as a solid on a PET carrier and is stuck to the substrate by the type face using a combination of heat, pressure and time. This means that it is probably not as quick as letterpress or

debossing. This system can now be operated by a clip-in rotary flickwheel type-holder, which means that information can be changed very quickly.

4 *Thermal transfer* printing is the selective heating (computer-controlled) and cooling of small elements in a print-head which can be used to impress a one-use thermal ribbon onto the substrate surface. Resolutions of up to 12 dots per mm can be achieved.
5 *Flexographic*—here the characters are formed on a flexible 'plate' of rubber or plastic. The characters pick up ink (probably thinner than letterpress ink) and transfer it to the surface of the label or carton. Can be made to run quite quickly. There is today a cheap rubber-type 'baselock' system on offer, primarily designed for the Third World.
6 *Offset litho*—this technique has occasionally been used in the past by using a special paper plate that can be photocopied and uses the properties of oil and water separation. Usually used only for fairly large labels.
7 *Impact dot matrix*—where a block of 'needles', usually nine but sometimes more, are electronically selected to strike forward onto a typewriter type of ribbon, thereby placing the ink from the ribbon onto the substrate.

Non-contact printing techniques

These are more modern types such as ink jet (solvent-based and hot plastic based) and laser.

Ink jet

These printers come in two types:

1 Drop-on-demand printers have an array of nozzles which fire a drop of ink when commanded by their computer control. Can use either a solvent-based ink or a solid base which is melted and ejected by the print-head.
2 Continuous flow works by using piezo electric crystal to generate an ultrasonic beam to disturb the flow of ink by producing uniform sized droplets. These are then electrostatically charged under computer control. The charged droplets are deflected to a catching mechanism and the neutral ones pass onto the substrate forming the image.

Toner-based laser

A computer-controlled laser beam forms an image on a charged photosensitive drum. A carbon toner is applied and adheres to the charged areas, developing the image which is then transferred to the substrate and fixed with heat and pressure. Text, graphics and bar codes can all be produced this way.

Ion deposition printers are used in similar circumstances, but their method of operation is different. A latent image is formed on a dielectric cylinder which is directly imaged by a projection of ions. Development is by a toner adhering to the charged areas and simultaneously transferred and fixed to the substrate under pressure.

It is predicted that on short-run label production/overprinting there will be increases in use of non-impact printing, especially thermal, thermal transfer and laser technologies. Ink jet coding design with small characters is also expanding into pharmaceuticals.

On-line or off-line printing?

In all overprinting operations the economics of the situation must be addressed, e.g. on-line or off-line.

On-line overprinting has the advantage of being directly under the control of the person in charge of the operation, but has the disadvantage that if there is a problem with the overprinting operation the production line halts. Off-line overprinting has the advantages of not directly holding up production if it has problems, and having staff that are usually better trained and specialist in printing. The disadvantages are that generally extra overprinted components have to be supplied to compensate for potential packaging line problems, and the overprinting operation can sometimes become a bottleneck.

A capability for in-house design in overprinting and printing in production is discussed referring to EPiSYS or the MAP80 systems of in-house label design and printing (as often currently used in clinical trials packaging).

Reel-to-reel laser printers are seen as part of the answer to low-volume orders needing variable information, along with the success of the EPiSYS technology. These laser printers will probably have an expanded use in the not too distant future to encompass primary pack labels, when the development of better and more light-fast colour printing is achieved. More recently both Indigo and Xeikon have introduced 'digital' in-house printing systems.

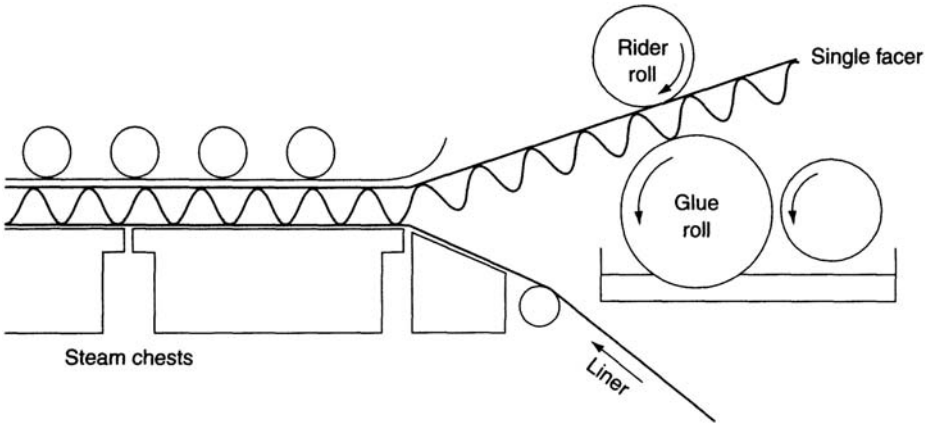

Figure 5.14 A corrugator

Solid and corrugated boards for casing

Too little attention is usually paid to this important area of packaging. If the transit packaging is poorly designed then the product will not reach the market in usable condition. This automatically puts up costs and leads to intense customer dissatisfaction. There are several types and structures of boards for casing.

Solid fibreboard

This is two to six layers of recycled paperboard which is treated with an adhesive between the layers and press-laminated together. The outside layer can be of 'Kraft' paper to improve the strength and help better resist water and water vapour. It has good crush-resistant and anti-puncture properties.

It is usually specified as just the thickness of the board, 0.95 to 2.9 mm (340 to 700 g/m^2 with 60 to 125 g/m^2 of Kraft). It may be printed by flexography or letterpress or ink jet.

Corrugated fibreboard

Popularly known as just 'corrugated', this is the most popular form of outer protection used in the industry today. It comprises one or more sheets of fluted (corrugated) paper secured by an adhesive to two or more liners. The paper used for the 'corrugations' is made up of recycled paper, e.g. semi-chem chipboard or 'strawboard', 25–75% straw with various quantities of waste-based pulp added. As the corrugated layer is impregnated with a stiffening agent (usually starch or synthetic vinyls) during the corrugating process, the relative strengths of the three types of recycled paper are not too different. Usually printed by flexography or ink jet, which can weaken the board.

Note that pre-printed sheets may also be employed using offset or gravure printing techniques. With a pre-printed outer liner, care has to be taken in the print design and layout so that when a case is made the print corresponds to the case shape, i.e. is kept in register on the cutters. Figure 5.14 shows a corrugator. There are various types of corrugated fibreboard:

1 single wall, i.e. one sheet of fluted paper between two liners (Figure 5.15 shows single wall corrugated)
2 double wall, i.e. two sheets of corrugated paper between three liners (Figure 5.16 shows double wall corrugated)
3 triple wall, sometimes known as Triwall (trade name), i.e. three sheets of fluted paper between four liners (Figure 5.17 shows triple wall corrugated).

Flutings are described as A, B, C, E and micro flutes. This describes the depth of the fluting (see Table 5.3).

Abbreviations commonly used for describing the structure of boards are:

- K, Kraft liner
- BK, bleached Kraft liner
- T, test liner

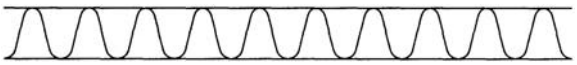

Figure 5.15 Single wall corrugated fibreboard

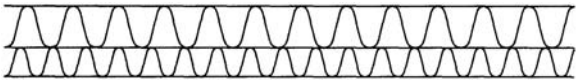

Figure 5.16 Double wall corrugated fibreboard

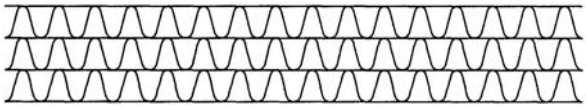

Figure 5.17 Triple wall corrugated fibreboard

Table 5.3 Flutings in corrugated fibreboard

Flute form	*Approx. height of corrugations (mm)*	*Approx. corrugations/m*	*Case wall corrugations*
A flute	4.5–4.7	105–125	Triple
B flute	2.1–2.9	150–185	Single and double
C flute	3.5–3.7	120–145	Single, double and triple
E flute	1.1–1.4	290–320	Single
F flute	1.0–1.2	340–390	Single
Micro flute	0.9–1.0	400–440	Single

- C, chipboard liner
- MK, mottled Kraft liner
- WTK, white-topped Kraft liner
- SC, semi-chemically prepared board.

The grammage (substance) of the corrugated fluting would normally be expected to be 112g/m^2 , but 125, 150 and 175 g/m^2 can be found in use. The liners should be of approximately equal grammage so that the corrugated board is balanced; anything from 115 g/m^2 right up to 400 g/m^2 has been used. It is usual to use Kraft liner, with its better water resistance and smoother surface, as the outside liner. To print (usually flexographically) the corrugated board, the smoother the liner, the better the quality of printing that results.

'Test' liner (pulped waste-based paper) is usually used both as the inner liner and for fitments. The centre liner(s) in double or triple walled containers could be semi-chem, chipboard or test liner according to the properties required.

There is no single industry-wide way of describing a corrugated case wall, but below are examples of those recommended in BS 1133 section 7.5.

- 150K/C/150T—single wall case with C flute 112 g/m^2 with an outer liner of 150 g/m^2 Kraft paper and an inner liner of 150 g/m^2 test paper.
- 150K/B/150SC/C/150T—double wall case with B flute outside C flute, both with substance of 112 g/m^2, with 150 g/m^2 Kraft outer liner, 150 g/m^2 semi-chem middle liner and 150 g/m^2 test inner liner. Note that this system assumes a 112 g/m^2 corrugated layer, so that if a 150 g/m^2 corrugated layer is really needed then this must be specified to the supplier.

Use of corrugated boards in distribution

Manufacture of corrugated and solid-board cases

The flat sheets of board (solid or corrugated) are fed into machines which produce the cases. These may consist of:

1 a slotter creaser
2 a printer slotter
3 folder/gluer (or stitcher or stapler)
4 rotary or flat bed die cutters (including waste stripping).

Any decoration is usually done flexographically and currently uses solvent-based inks to improve drying. Delivery is usually of made-up cases in the flat, stacked onto pallets and either stretchwrapped or banded.

Collation and casing of packs

In packaging, a carton may or may not be chosen as the prime container. If it is not chosen then a number of containers may be held together in a tray, or containers on their own, both held together with some form of film wrap, e.g. shrinkwrap. Product in a carton must be arranged so that the longest side of the carton is vertical, as this is the way to use the maximum strength of the carton.

Structure of cases and design parameters

Cases should be designed to the FEFCO, sometimes called the International Fibreboard Case Code (IFFC), system. This is an international system which has codified the various designs of cases into a simple book of basic designs. Figure 5.18 shows FEFCO case designs.

At this point it is sensible to include fitments, either solid or corrugated, into the equation. Fitments are also described in the FEFCO book, and are used to provide added strength and protection to the casing system by:

1 thickening the walls of the case
2 thickening the top and base of the case
3 being added as nests to prevent collisions between products in the case
4 preventing movement of the product
5 increasing the puncture resistance of the case.

Fitments are usually made of entirely waste-based materials.

In order to optimise the strength/cost balance an understanding of the way cases behave under load is vital. In helping to determine this optimisation, tests and estimates of the various parameters surrounding cases must be considered. Probably one of the most useful tests performed is the edge crush test.

Edge crush test (ECT)

This is defined in ASTM 2808 and BS6036 and TAPPI 811 and is a useful way of estimating the way a particular board will react under standard conditions. From the ECT, box compression ratios (BCRs) can be calculated for any case, thus:

$$\mathrm{BCR} = 17.7 \times \mathrm{ECT}1.06 \times d0.85 \times (L + B)0.31$$

where ECT is in kN/m, d is the board thickness (mm), L is the length of the case (mm) and B is the breadth of the case (mm).

When one is designing a case, a useful piece of knowledge is that in general each 1 g substance of fluting is as strong as 2 g substance of liner. Cases may be held together at the ‘manufacturer’s join’ by:

- stitching the join together—abbreviation ‘S’
- gluing the joint together—abbreviation ‘G’
- taping the joint together—abbreviation ‘T’.

Factors affecting design

Determine whether the product is going to be single, double or higher stacked on pallets, as this will create the need to increase the strength of the board accordingly.

Note the design of pallet being used, as the gaps between the deck boards may be too wide for the case size, letting case edges ‘dive’ down between the boards. Note also the pallet ‘footprint’ in any option used for multi-stacking pallets. Ensure that cases are stacked with their vertical walls directly above each other as this is the best way to carry load from above. Know the weight of the product to be carried per case. There are weight limits in various parts of the world. The author’s personal experience suggests about 12 kg as the maximum case weight.

Closing of cases

This is carried out by one of five methods.

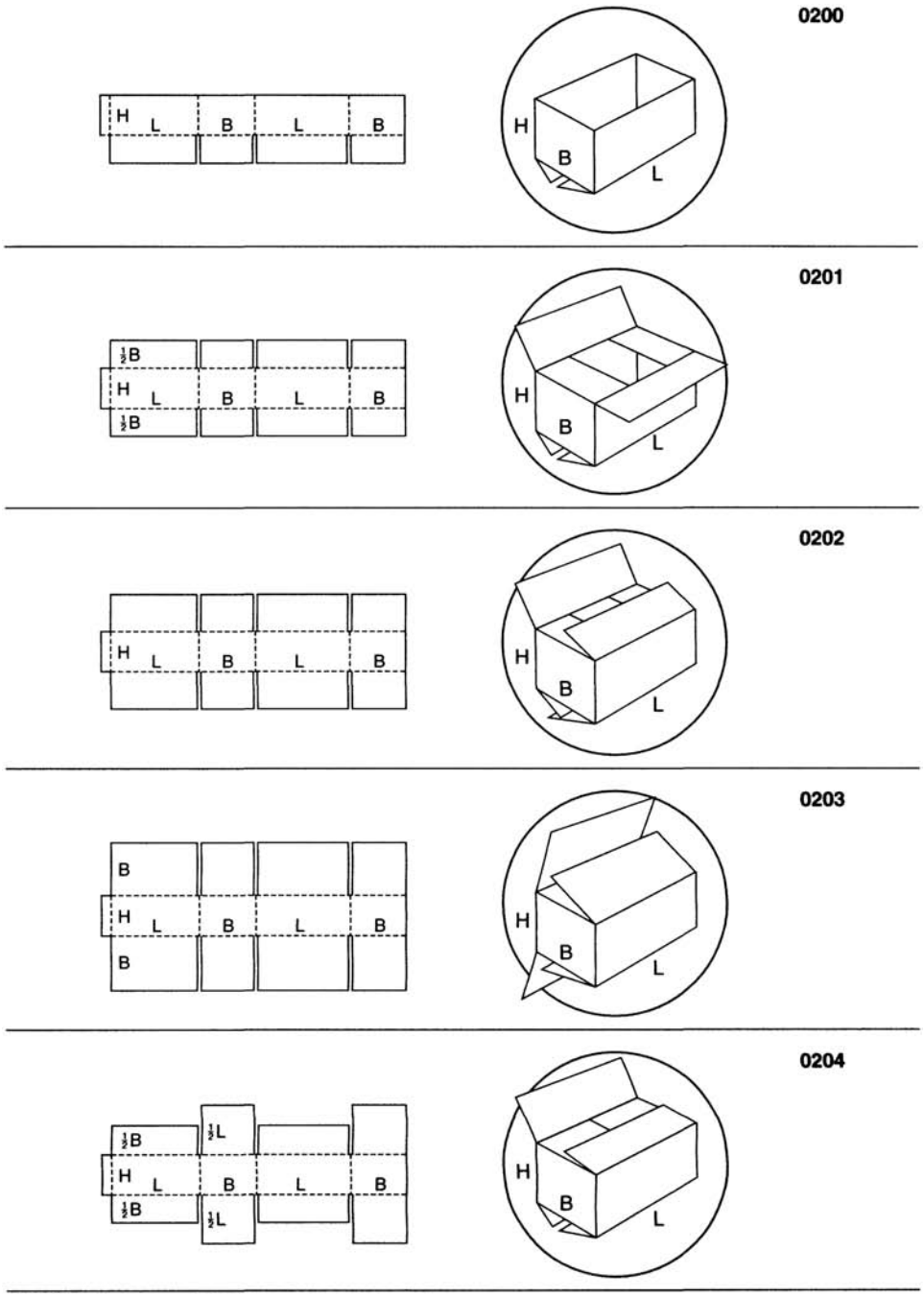

Figure 5.18 FEFCO case designs

1 Gluing, either hot melt or cold adhesive. This would only be used on cases where the inner flaps of the case protected the product, e.g. FEFCO 0204 design.
2 Large staples can be used, but they puncture the liners of the outside corrugation and can let in water to the corrugations; nevertheless they form a secure closure and are widely used.
3 Water-based adhesive tape, where the adhesive is activated by wetting and this soaks into the outer liner of the case forming a strong closure, provided the relative humidity remains reasonably low. Not recommended for tropical markets where the high humidity makes paper taping a security risk.
4 Pressure sensitive adhesive tape, probably the most used today. At least 50 mm down leg of tape is needed to form a positive bond with the surface of the liner and there needs to be a substantial overlap of tape over the join of the outer flaps. For this reason 50 mm or 2 inch tape is the most popular. Clear tape pressure sensitive adhesives are susceptible to

UV light degradation. It therefore makes sense to incorporate UV blocking agent either into the plastic material or into the adhesive itself.

5 Interlocking flaps may be used, but they are not considered to be a secure form of case closing.

6 Specific hot melts are used for very hot and very cold climates.

Environmental issues

All vegetative materials undergo respiration and transpiration, thereby making a major contribution to the atmospheric balance in which we live. Since trees are a major landbased part of this balance, forest destruction is a concern. There is also a linkage to global warming.

In addition to the management of the forest, great strides have been taken to salvage *all* waste wood, bark, chippings, sawdust and waste pulp so that it can be turned into fuel for the upkeep of the paper mill itself. Rain forest hardwoods make very weak, poor paper or board and are not used. The use of chlorine-based products for the bleaching process has virtually died out in Scandinavia, but remains in some other parts of the world.

Some questions are posed in the next few paragraphs. There are probably no right answers, but many opinions and certainly many more questions.

The impact of the use of paper and board has to be seen in the context of what we would do without it. One could print directly onto containers all the information dis cussed above for labels and leaflets. One might suspect that massive warehouses would need to be built in order to contain all the printed variables on the prime containers, and this would be a doubtful benefit to the environment.

The prime containers in warehousing and distribution could be protected with plastic boxes or in wooden crates, which could be made returnable and therefore reusable. This would entail the problem of retrieving the containers, cleaning (thereby creating effluent), re-marking them and putting them into the cycle.

The trite answer is to do a life cycle analysis for each material used, theoretically from ‘the cradle to the grave’. That is all very well, but where is the cradle and where is the grave? It has been suggested that with materials tied into the ‘carbon cycle’ there is no cradle and there is no grave. What has to be done is to make the best analysis possible taking account of as many factors as are known!

Paper- and board-based containers

Fibreboard kegs and drums

Fibreboard kegs can be used for solid bulk drug, bulk tablet, or bulk excipient containment and transport. These are made up of multiple plies of test or Kraft liner board, convolutedly wound on a mandrel and bonded with sodium silicate adhesive between the plies. There may be an LDPE or other inside liner and the exterior may also be varnished. The base could be of either metal or plain thick board, the latter waterproofed by dipping into paraffin wax.

There may also be a galvanised mild steel base chimb bonding a board base to the wall. The lid may be of the slip-over type, in which case there is no need to protect the top of the keg, or of the push-in type, where a top mild steel chimb is added to the wall of the keg to carry the lid. This latter type of lid, made of either metal or plastic, will usually have some more sophisticated closure, e.g. lever lock.

Paper and composite open mouth sacks

These may be used for bulk excipients where there is no risk to or from the environment, e.g. chalk. They comprise two to six plies of sack Kraft types of paper, with possibly LDPE coated or metallised paper or one ply of LDPE in the case of composite sacks. The sacks may or may not have a gusset. They will all be either stitched or glued at the base and usually stitched to close the open mouth.

Composite containers

These can be used as tubes for protection or for small powder drums of 100–200 g. They are made by spirally or convolutedly winding the various plies in turn around a mandrel (similar to kegs), bound together with suitable adhesives. The materials are basically grades of paper or light board but may contain PE, aluminium and fine calendered coated decorated paper as an outside layer.

They are usually closed with metal (tinplate) or plastic bases, with closures of similar materials which may also contain dosing devices.

Paper liners, linings and laminations containing paper

Papers of various grades are used as liners inside bags made of another material. Glassine has been used as linings for the inside of plastic, metal or fibreboard kegs, where there has been a suspected problem with the compatibility of the drug and bulk container.

Paper is used extensively in laminations where it is bonded, usually by heat and/or adhesive, to other films, notably plastics and aluminium, e.g. LDPE/adhesive/aluminium/adhesive/calendered paper. This type of lamination can be used for form fill and seal work, e.g. sachet packs of deliquescent powders.

Cellulose films

The coated film is usually used as an overwrap, has been used for strip packaging when metallised, but has lost popularity in recent years with the better barrier and stronger olefin-based films becoming more available, cheaper and with 'tailored' properties. Cellulose acetate (CA), cellulose nitrate (CN), cellulose acetate propionate (CAP) and cellulose acetate butyrate (CAB) may all be found in use. The poor tear resistance, once the tear has started, does not help their case. Also, the most popular method of using cellulose films is deadfold wrapping holding down the envelope corners by heat dabbing which bonds the coating. This method has proved not to be tamper-evident.

Paper and board testing

All uses are related to the function requirements which are necessarily linked to the material properties and characteristics. Details of material tests for paper, board, cartons and corrugated are given in Appendices 5.1–5.4.

Pharmaceutical product and pack security

To cover this subject fully product issues are reviewed independently and in the context of their contribution to overall security made by 'paper'-based materials and printing.

Paper and board as security features may seem a little far from reality to the uninitiated, but seals, tapes, labels and cartons can all be utilised as devices to ensure the security of your product. The security issues will be dealt with in two ways: first the really criminal issues, i.e. tampering and counterfeiting in particular; second the security of ensuring that the correct copy gets onto the correct paper material, onto the correct substrate containing the correct pharmaceutical product.

The security environment in pharmaceuticals

There is massive fraud or illegal activity in the sale of all goods worldwide. Figures quoted in 1993 indicate that up to 5% of world trade or $80 bn per annum is involved, and this is rising each time fresh estimates are released. Pharmaceuticals are not exempt from these problems ($200 m per annum estimated), despite having theoretically tighter systems of manufacture, storage and distribution due to governmental licensing of products, storage, and distribution, thereby authorising sale by wholesalers and dispensing by pharmacists. Here it must be pointed out that this refers largely to Europe, the USA and Japan. Procedures may not be as tight in developing countries, despite government controls and licences.

The illegal, fraudulent and unauthorised practices can be placed into eight broad categories:

1 product copying
2 product substitution
3 'pass off' or counterfeit packaging to support (1), (2) and (7)
4 adulteration or tampering
5 'shrinkage'
6 illegal parallel trading
7 'poaching' of territories by agents
8 invention of 'new' products.

Some of the examples which follow will fall into more than one category, e.g. how does one substitute something in a pack without tampering with it? Two further points should be considered that will affect the way in which companies react:

- producer liability legislation
- the legal need to track hazardous materials comprehensively

Product copying

This category of illegal activity attempts to copy the physical appearance of the pharmaceutical formulation without going to the massive expense of setting up all the legally necessary control systems, thereby producing something similar but cheaper and probably of much lower quality. The copy could be in either original packaging or 'pass off' packaging. Copies that have been seen have either contained impure amounts of drug substance or no active ingredient whatsoever.

The dangers of these copies are:

- impure active ingredient—uncontrolled effects on patient
- no active ingredient—no therapeutic effect for the patient and overall loss of confidence by patients and the medical profession
- impure or incorrect excipient substances—as above (note that deaths have been recorded where, in the Third World, 'glycol' was added to a product to extend the volume).

Product substitution

The substitution of one product by another, 'dressed up' to look like a more expensive product, e.g.

1 the labelling of a low-cost antibiotic as a much more modern and potent antibiotic
2 refilling or recycling vials using even non-sterile products
3 one company's counterfeit product in a second company's reused packaging.

The great danger inherent in this type of activity is that the substitute is probably cheaper, older and a lot less potent than the original, consequently the patient may not react in the way the health professional intended. The result here may not be fatal, but at the minimum a loss of confidence in the original product by the health professionals.

'Pass off' or conterfeit packaging

The term 'pass off' is the correct one in English law, since 'counterfeiting' is theoretically used only for offences concerned with currencies. However, 'counterfeiting' is the term usually used.

In the past few years some remarkable copies of packaging materials have temporarily fooled packaging experts. At the other end of the scale there have been many poor copies that would cause one to wonder how anyone could be so easily fooled.

Any of the examples quoted in 'Product copying' and 'Product substitution' above can be taken, plus out-of-date material or factory rejects 'obtained' and recycled with fresh packaging and different manufacture and expiry dates.

The danger in date-expired materials is that pharmaceutical products are given very strictly controlled shelf lives. Past the end of the shelf life there is *no* guarantee that the degeneration products produced will not be harmful to a patient. If the 'obtained' materials were factory rejects, then they had been considered by the factory QC system as not within the specification necessary for administration to patients.

Adulteration or tampering

Adulteration is the deliberate contamination of a product for extortion or for some other malicious intent, e.g. personal revenge. The two best known examples in the pharmaceutical industry are the 'Tylenol' affair in 1982 and the 'Sudafed' affair in 1991, both in the USA.

In both of these cases OTC pharmaceutical preparations, analgesics contained in capsules, were contaminated with a cyanide salt and deaths resulted. In the author's opinion, making packs fully tamper-evident is one of the hurdles that the industry has to tackle. Many companies have decided to add additional tamper-evidence, but it can be argued that there is still a long way to go. Experience to date suggests that adulteration appears to be more prevalent in the more sophisticated markets whereas tampering, in its widest sense, is worldwide.

Shrinkage

This describes the loss of goods through pilferage in production, storage, distribution or even disappearance from hospital and pharmacy stores. This is more prevalent than might be thought. Even lorry-loads of goods have been known to disappear.

The only real answer, at present, is the rigorous 'policing' of all parts of the manufacturing, storage and distribution areas. The pharmaceutical industry tries very hard to reconcile all input materials, be they drug substances, excipients, drug delivery systems or packaging materials. Some companies and countries claim that their control systems are so good that 'it cannot happen here'. Despite very rigorous systems and controls, materials still 'disappear', especially if there is money to be made! Human ingenuity knows no bounds.

Illegal parallel trading

All parallel trading of pharmaceuticals inside the European Union is legal, provided that the following three conditions are fulfilled:

1 the product is registered and approved in the receiving market
2 the manufacturer is fully licensed to manufacture the drug in the country of origin
3 the importer in the country of sale is registered and licensed to handle pharmaceuticals.

The reasoning behind parallel trading is that of the 'free market' and that the best (i.e. lowest) prices can be obtained for any particular pharmaceutical presentation. Having worked in the industry for 36 years, there is one point the author has learnt—Ministries of Health actually control all the prices.

Over the past several years parallel trading has increased into the highpriced countries (e.g. Holland, Germany) from countries where the prices are lower (e.g. Greece, Belgium and Spain). Included in this trading have been products that are pass offs.

There is also the problem of illegal imports from both within the EU and non-EU areas. Illegal imports from within the EU usually do not comply with the three conditions above. In the UK the levels of control exercised by the DoH inspectorate have recently been revised, to try to combat illegal parallel imports.

Poaching of territories by agents

This is what might be termed a contractual offence between a manufacturer, an agent (who is contracted for specific markets) and the regulatory authorities in those markets. In many ways it is similar (if not identical) to the illegal parallel trading mentioned previously.

Inventing 'new' products

Human ingenuity in making money is nowhere more evident than where illegal operators have 'invented' a new product for the company, e.g. a well-known dermatological product name from an international company was used for a soap in certain markets and allegedly sold quite well.

There are two dangers here. First, the patient is paying good money for a product that has little or no therapeutic effect, and in certain cases might be exactly the wrong thing for the consumer's complaint. Second, the reputation of the company involved can suffer.

Two major factors which influence the reactions of pharmaceutical companies to the eight problems discussed above will now be considered.

Producer liability

There is a growing need for companies to be able to trace and authenticate their products so that claims arising from customer complaints and product performance liabilities, in particular, are proved. The probable nightmare scenario to a pharmaceutical company is where deaths are reported in the international media and attributed to its product—and it cannot 'prove' conclusively that the product was not its own but a 'pass off'. To the best of the author's knowledge this has not happened yet.

Most pharmaceutical companies are taking responsible counter-measures to avoid this dramatic situation.

Tracking of hazardous materials

There is a legal obligation to be capable of tracing hazardous goods, i.e. those classified under the UN hazardous goods scheme. It may not be appreciated that a number of pharmaceutical products are UN certified. Pharmaceutical companies can trace any 'batch or lot' of product up to the time it leaves their immediate control. There are techniques of 'trace back' used to investigate product complaints. Each company tries to reconcile 100% all materials, e.g. raw materials, drug substances, excipients and packaging materials, during all stages of progress through the company. It also holds records of the sources of all those materials, and today most of these sources are regularly audited.

Parameters needed for the design of a pharmaceutical security package

In this section only the solutions that encompass the use of cellulose-based materials in their make-up will be covered.

Project objectives

First, project objectives must be clear through an analysis of the problem(s) appertaining to the product(s). Do not proceed blindly into a strategy which does not suit the situation. The final objective will be to prevent, or at least minimise, product copying, substitution, etc. at a realistic cost. There are only two options:

1 do nothing and hope that the problem is solved by the forces of law and order
2 protect the product with the most cost-effective systems to minimise the problem. The totally criminal-resistant pack may never be achieved, but building in a number of layers of protection increases the chances of the criminal making a detectable error, or giving up the attempt and going to try it out on someone else's pack.

As stated earlier, one should carefully analyse the problem before deciding which of the above eight problem categories one intends to protect against.

1 Is more than one protective system needed?
2 Are the correct reasons for introduction being considered?
3 Is protection against more than one type of activity being considered?

Some of the issues—the vulnerability of packs and the concerns of the industry—are discussed below.

The issues involved in the initial evaluation of what, if any, actions should be taken are probably the most demanding. They must not be taken in isolation but supported by the company management. An approach to consider is the effects of an illegal action and the follow-up company action, e.g. is the incident fully understood? Have the reasons for the illegal incident really been analysed? Has the company the expertise to examine the problem and think the way the criminal thought?

Probably the hardest decision that has to be made is the need for public announcement. Is it worth taking the risk of losing public and professional confidence in the product, or is it better to rely on their understanding that what is happening is not the fault of the company and that the company is making considerable efforts to rectify the situation?

Which systems are considered to protect the goods? This will largely rest on what illegal activities have happened to the goods, the markets involved, and the type of packaging. Is an overt or covert feature to be used to protect the goods? Whatever overt measures are taken, an eye must be kept on public education because without it, vast numbers of inspectors might have to be employed to achieve the same level of inspection and coverage.

Have all the avenues of supply with reference to security considerations been examined, for example, security of printed materials supplies and suppliers and the movement of security packaging (and indeed ordinary genuine packaging) materials between the supplier and the final assembly workplace?

Vulnerability of the packaging system could include the following.

1 Product 'look alikes' can be easy to produce using conventional printing processes. The average label and carton used in pharmaceuticals are quite easy to reproduce well enough to fool both the pharmacist and the patient, even though they may not mislead the expert.
2 There is a very long period between drug patent and market approval, during which information and graphics can leak from a company. It is not unknown for the illegal route of pharmaceutical supply to outstrip the legal route into certain markets.
3 There are different prices in different markets, with more likelihood of illegal parallel trading and the introduction of 'pass offs'.

4 The multiple supply chains used by pharmaceutical companies can be bewildering, sometimes leading to the genuine product landing up in a market for which it is not intended.
5 No tamper-evident systems are employed on packs. This omission is gross negligence on the part of the company, since a degree of tamper-evidence can be provided very easily and cheaply, e.g. tamper-evident fragile paper labels. Anti-counterfeiting systems should, as has already been said, only be used after long, detailed and very careful consideration of the problems.

The concerns of the pharmaceutical manufacturer could include the following.

1 That patient safety is of paramount importance. The biggest risk is to the patient and all else should be a secondary consideration. The pharmaceutical company exists to supply safe, secure, therapeutic treatments to its customers. Any break or interference in the chain can only result in the final consumer, the patient, receiving inferior product with results ranging from loss of money for a placebo product look alike to serious health complications if a patenteral product is compromised.
2 Either of the above could cause a loss of confidence to the health professionals and the public, with the most serious effect on the economics of a company. Loss of confidence by anybody means loss of prescriptions, therefore loss of business. This could feasibly occur even though the product itself was OK, if the mass media were given a story of a drug being substituted. This does not have to be true, and the company can probably prove to the authorities that the product is not affected, but the medical professionals and the general public will be difficult to convince that the product is safe if anti-tampering and anti-counterfeiting measures have not been taken.
3 The product liability laws are such that if the company cannot prove that the goods that were bought/prescribed/taken by a patient are not its own, then the company is liable. How much easier to prove that the goods were not the company's if there are security features which are not to be encountered on an illegal pack.
4 There is a great fear of going public when one of these types of problem arises in the industry. When faced with this problem certain companies have introduced packaging measures, gone public and advertised the overt counter-measures to the health professionals. The net result was a rise in sales for 8–10 months after the event.
5 The fear of loss of revenue is always present in these cases. Facing up to the security problem and being proactive might in the short term cost money, but in the long term will protect the company revenue—look on it as insurance!

Key features

1 It is suggested that a 'horses for courses' approach be adopted, i.e. look at each problem individually and decide on the best answer. With cellulose-based materials the following might be considered: specialist inks (UV, photochromic, thermochromic), holograms, special prints, clever multicolour designs, watermarks, chemically marked paper and board, etc. Any of them could be appropriate, depending on the circumstances of the problem.
2 This is why clearly defining the problems and what is to be achieved is critical, so that any counter-measure designer is in a better position to defend the product. If the company doesn't have an expert in this field, there are consultants who will help identify problems.
3 What is wanted: authentication or deterrent, or both? This decision will change the way to approach the design.
4 This goes back to covert or overt features, depending on the answer to (3) above.
5 Assess whether there should be a single feature on one product pack or continuous throughout the product range, even though it may only be one or two product presentations that are being targeted.

The produced anti-criminal device must then have the following characteristics.

- Very difficult to counterfeit. While this may be obvious, some pharmaceutical products are like currency in some parts of the features world. Hence consider if currency without anti-criminal features built in would be accepted. The answer will be *no*!
- A device which needs no specific marketing monitoring i.e. self-policing after public education.
- An obvious deterrent to put off the criminal.
- The ability to maintain public confidence, through a form of label/seal with a distinctive secure print on it, advertised wherever advertising is allowed in order to get the public to check the goods on receipt.
- Relatively easy to introduce, for speed is of the essence. If the company is seen to be taking steps to protect its customers, then those customers will probably react favourably.

Which deterrent?

1 It is important to treat security as security features and not to be drawn into treating them as promotional. There may be a promotional angle that the marketing department can employ, but security of the system is paramount.
2 Simple design can be easily reproduced particularly with the advent of the colour photocopier. Review the design and include features that change when photocopied.
3 All markets will need consideration for both literate and illiterate patients, i.e. a company logo may not be a good idea as it might mean little to the end user.
4 Ensure that a secure supplier is chosen for the designs that are being considered. Although obvious it is often missed.
5 The format must be carefully chosen as it must fit in or onto production lines efficiently and securely. All staff must understand what is happening and how important is the (particularly) overt device. It may not be necessary to tell them about covert devices, as the less said about them outside the security circle the better.

Other considerations

1 The issue of public education will only apply to overt devices. Educate the health professionals first and rely on them and legitimate publicity to ensure that if the security device is not on the pack then questions are raised immediately. Speed is important, as the trail of the criminal will go cold very quickly.
2 The total security throughout all the supply, manufacture, and distribution chain has been mentioned before. It has been known for a counterfeit supply of goods to be sold in original packaging material. If the counterfeiter can counterfeit goods he can do the same with individual company's purchase orders. Build in checks throughout the system, particularly the habit of making personal contact with people in the supply chain to check that orders received are genuine.
3 There are other controls, e.g. governments, patents, discarded production equipment. Ensure that the government being dealt with doesn't 'leak' any security secrets. Use patents whenever possible to protect packs. Ensure that on disposal of production or packaging equipment there are no tools, change parts or packaging materials belonging to the company that go with the old machines. It has been known for the criminals to get hold of them and reproduce counterfeit packs.
4 It is essential that a series of controlled changes of security feature be devised to keep ahead of the criminal. Change small features of the design, keeping accurate records of when and what was changed. This means that the company can take account of the latest in technology and keep the criminal guessing as to what might be done next.

Deterrent design and use

The type of deterrent

Is it to be label, a specially designed sealed carton or perhaps watermarked paper or board, chemically marked paper or board security inks, holograms etc.? In a large proportion of the potential methods of protection you will need to ensure that the device, print, etc. actually 'permanently adheres' to the substrate.

The substrates

The substrates could be any of the following:

1 cartonboard—what surface is to be used (cast coated, clay coated, uncoated)?
2 label materials—what paper surface (cast coated, clay coated, uncoated)?
3 cellulose films—with or without surface coatings?

The primary pack could also be glass, metal or plastic needing a security label, carton or overwrap.

The adhesion system

It is vitally important that the adhesion between the security system and the final substrate cannot be breached by any means without leaving conclusive 'easy to see' evidence. It is no use using a hot melt adhesive, which can be reheated and allows either a label to be removed and a 'pass off' put on or a sealed carton to be opened. More harm than good may be done with such a system.

Tests must be performed so that one can be satisfied that the above criterion is fulfilled all the time, throughout the distribution and storage chain, worldwide if necessary.

Additional items to be considered when designing security systems

1 The surface exposed to the public: This must be robust enough to withstand the scuffing and vibration of a normal pack in transit and use by the medical service. If overt it must have a bright clear image to attract the public.
2 Production systems of transferring the system to the final pack: Again this may seem obvious, but check carefully the feasibility of the laydown of final design onto the final pack. Also make sure that there is equipment to do the job economically and accurately. The design must have a high degree of accuracy and design procedures which cover the entire system of design production, including all aspects of producing and applying the design to the final pack.

The evaluation for end use must be thorough and realistic, e.g. fragile papers for seals might not apply well on machines and fracture in transit, yet be easy to open. The postaddition of additional security system packaging processes, e.g. overwrapping with securely marked or designed cellophane incorporating a tear band, can also be practical.

Costs

1 There are project and evaluation costs (non-recoverable).
2 Possible research costs into an adhesive, carriers and substrates to be considered.
3 The implementation and education costs to introduce a total security system (setting up and training everyone from designer to supplier and company staff).
4 The cost of educating health professionals and the public if the system is to be monitored effectively.
5 Audits of supply distribution system are needed to check system integrity.
6 Costs of additional material needed for the job.
7 Additional capital needed for machines.
8 Possibly additional staff to monitor and work in key areas.

What the project must achieve is total security of production, public education (particularly health professionals), security of supply chain, effective monitoring and keeping features updated.

Security in the packaging operations

The second form of security to be addressed is the one of ensuring that the printed word, as laid down by the competent authority, is securely translated onto label, leaflet or carton by whatever means, and affixed/placed on or around the correct drug container.

Although simple in principle, the industry gets it wrong time after time. Both the FDA and the MCA state that the single most common cause of a product recall is a mistake in ‘labelling’ or identification, commonly known as a ‘mix-up’. A breach of internal security has been devised to prevent such a mix-up happening. Detailed below are some recommendations on the best way to approach the problem when handling labels, leaflets and cartons.

There must be an integrated approach to the problem. Putting a bar code reader on a packaging line doesn’t address the problem: it is an important addition to the system, but not the whole answer. Some additional points that might assist in the discrimination of one piece of printed material from another are as follows.

1 Distinction in colour layout and shape, especially when manual inspections are the norm.
2 Critical information should be in one colour, to minimise problems should one plate in the printing process cease to function.
3 Use ISO 9000 registered suppliers especially those used to dealing with pharmaceutical printing. Codes of practice are issued by the Pharmaceutical Quality Group of the Institute of Quality Assurance and linked to ISO 9002, specifically aimed at printing suppliers to the industry.
4 In-house systems, e.g. warehousing, should be set up in such a way as to minimise the risk of mix-ups, e.g. using discrete lidded storage bins.
5 All machines, packaging areas, printed material transport systems, etc. should be specifically designed to facilitate clearance of all the ‘current’ set of printed material.

6 Formally document all the checks that are carried out, ensure that the person checking has been trained and knows what to look for, knows what to do when a mix-up occurs and knows that the success of the system depends on their ability. Note: The results of checks must be recorded.
7 Increase the number of security safe positive accepting electronic/mechanical machines. Be careful in choice of systems and never forget that an integrated system that cannot be bypassed ensures the best security for your company.

The next few paragraphs work through the procedures for designing, approving, printing, supplying and using a label (but the same principles apply to all printed materials).

First, the copy must be written by a competent person, fulfilling copy guidelines laid down by the various regulatory authorities. This approved copy is then laid down as artwork which meet the demands of the pharmacy label/leaflet regulations, regulatory authority, company corporate identity and the container label design (size) which is best suited to the container and application system.

Note that the adhesive performance requires validation on the substrate being used, beyond the shelf life of the product and in the extremes of storage and use conditions predicted for the markets that are to be supplied with that particular label/adhesive/container application. A label that does not remain on its container is a security risk! The problem of adhesion failure occurs in cartons with the 'glue flap' being a vulnerable point, due to inefficient gluing on the folder/gluer, or the wrong adhesive being used.

When the artwork is completed it must be authorised for use by the originator, regulatory affairs, marketing, quality assurance and packaging to ensure that all the parameters are in accordance with requirements. The completed colour separated artwork should be sent, by the purchasing department, along with the remainder of the label specification, to an audited authorised printer.

The printer should be used to dealing with pharmaceuticals and have been audited to ISO 9002. This will ensure that all the correct procedures for line checking, physical separation, printing plate separation, line, make-ready, records, absence of gang printing etc. are in place and followed. Some companies call this GMP at suppliers. Colour proofs of each colour to be used should be returned for checking prior to the actual print run.

The artwork must include a unique part number (or item code) as the basis of identification, security and reference, which will change for every change to the printed component (however small). This identification is the key to all security traceability. This code may be represented by either alpha-numeric human readable characters or an associated bar code. This requires the capability for automatically reading either the bar code or the part number using suitable equipment on the printer's press and on packaging lines. The printed part number and/or the bar code should be unique and verified on the printed component artwork, in as many colours as the reading system is capable of reading to ensure that all the printing is there on the label.

If the printer is equipped to read either type of code then ensure that all labels are read, not just one line of codes on an unslit label reel, for example. This last reading should take place as the final act of inspection just prior to the labels being securely wrapped and sealed into their transit packaging ready for dispatch.

There are options to sample and test each delivery of labels or, through confidence in the printer, accept a 'certificate of conformance' and only randomly sample occasional deliveries. Labels, once delivered and accepted, should be stored in individual, segregated and secure closed bins, one bin per part number. They should be issued on a 'first in first out' (FIFO) system.

When quantities of the label are requisitioned against the packaging documentation, (based on the packaging specification) they should first be visually identified, counted and code checked (preferably by machine reading) and then signed off by the authorised store issuer. The materials are then securely held away from the packaging line area, awaiting use.

If the overprinting of LOT, BATCH, or EXP, etc. is to be carried out away from the packaging line then a similar separate loop of the checking procedure must be written and used.

When the order is ready to be packaged on a production line it must be preceded by a formal line clearance procedure and the material then carefully visually checked for accuracy of part numbers and accuracy of quantity.

The printed packaging material should be kept away from the packaging line machinery while the bar code reader or vision system code is set from an independent source of information, e.g. the pack specification or the works order document. The printed packaging material itself must not be used to set the checking equipment as this is a known GMP risk. With the advent of computer integrated lines it is possible to download the bar codes or number directly to the reading system, leaving the packaging line personnel the task of only aligning the reading heads.

The system of code reading must be challenged at regular intervals by feeding slightly wrong codes to it and confirming that they are not accepted. It is advisable for automatic systems on packaging lines to be 'positive accept'. This means that the line/machine will reject everything unless a positive accept signal is received from the sensor, which then 'opens' to 'pass' the package.

The parts of the packaging line between stations (open conveyer) should be covered so that the goods once passed through the automatic checks cannot, as far as is practical, be handled by operators again. This is because it has been reported that up to 70% of product mix-ups and adulteration in the whole British industry are caused with the supply company deliberately bypassing systems.

A mix-up leading to a recall means at least a loss of reputation through adverse publicity in pharmaceutical journals, loss of revenue, cost of collecting the recall and stock replacement and loss of confidence in the company.

Bar coding

This is an essential form of printing nowadays, usually in two forms for two totally different reasons as detailed below.

Non-security bar codes

These codes are used every day in the UK on the supermarket checkouts, and an extended version of them is used to control movements of goods in warehouses. They are being applied in the pharmaceutical industry, both on OTCs and, less obviously, on POM classified medicines. The OTCs are sometimes sold by the large supermarket chains, and therefore have been brought under the same rules and regulations as all other fast-moving consumer goods.

EAN (UPC) codes

These codes are 'market' codes designed to be used at point of sale, so that the inventory can be kept up to date to the minute. They are made up of thirteen numeric characters all with a meaning. Note that there are some eight character codes, discussed below.

The first two EAN codes denote the country of issue of the number, e.g. UK for the number 50. The last or thirteenth number is a 'check character' calculated to modulo 10, which completes the code, confirming that the code is genuine and has conformed to the number structure. The remaining ten are split into two groups of five. The first five is the number assigned by the Article Numbering Association (ANA) to the purchaser of the sequence of numbers, e.g. 50 99999 00001?. The 99999 is specific to company 'X' and no other company or supplier can use it without permission of the owner. The next group of five is the number that the owner assigns to the specific product name and size, e.g. in 50 99999 00001? the 00001 could describe a bottle of 50 Cureall tablets, 100 mg.

So the code tells us that it is UK issued, the code is owned by company 'X', the product is a bottle of 50 Cureall tablets, 100 mg.

To return to the last character, i.e. the check character, at modulo 10 it would work out as 9 so the full code reads 50 99999 00001 9, and thirteen meaningful characters.

Difficulties in printing these codes in a readable form resulted in a complicated series of specifications written by the ANA. These specifications have been somewhat modified in the light of improved readers, but if codes are to be read efficiently, follow the ANA guidelines.

To optimise the contrasts between the bars and spaces, it is preferable to print black onto a white surface. Print gain is a term used by printers to quantify the amount by which the printed bar is bigger than the plate used. Different printing processes and machines have different gains, so leave control to the professional printer to obtain the code films to the correct gain.

A normal 100% magnification EAN 13 code is exactly 37.29 mm long and 26.26 mm high. These dimensions include the quiet zones around the bars themselves. The magnification has been reduced successfully to 80%, and the height can be reduced or 'truncated' 16 mm overall.

There is an EAN 8 code. These are certain numbers in the code sequence in which the zeros can be ignored, giving only eight digits, thereby reducing the code width to 26.73 mm overall. The same rules on reduction and truncation apply.

Warehousing codes, e.g. EAN 128 or traded unit outer codes

This is a system of extending the basic EAN code to 'add on' data to the basic code, e.g. bar coded batch code and/or expiry date. In order to achieve this, 'addition identifiers' (AIs) are used to delineate where the additional part of the code begins and ends. This code is much larger than the primary EAN code, e.g. 123 mm long by a minimum of 27 mm high. As it would usually be printed onto cases or trays or tray or case labels, there is more space in which to accommodate the code. Figure 5.19 shows an EAN 128 code.

Figure 5.19 An EAN bar code (not to size)

Figure 5.20 An ITF bar code (not to size)

Interleaf two of five (ITF) codes

An alternative to the EAN 128 is an ITF code. This is a bar symbology which allows numeric characters only (i.e. 0–9 inclusive) to be portrayed as a series of thick and thin bars and spaces. Using our EAN number we have to add a zero to the front of it, making it a fourteen numeric code. The overall size of this code is 159.828 mm across (remember this is totally inclusive of all the margins) and 48.1 mm high. Figure 5.20 shows an ITF codes. Again, supplementary information can be added to this code.

Other codes

Interleaf 3 of 9 or code 39 has been used, particularly in some European markets, as a means of helping to control the reimbursement of drug costs, by electronic reading means, to the patient. It is similar in structure to ITF, but allows the full alphanumeric range of characters to be used.

The Health Industry Business Communications Council (HIBCC) code was originally developed in the USA to establish its own codification structure for the full range of health sectors, but has come to be used mainly within the US hospital system. In the UK, HIBCC is also called the Health Industry Bar Code Convention by the Article Numbering Association (ANA), and also the Health Industry Business Code Council. In the Netherlands it is known as the Health Industry Bar Code (HIBC). The code is composed of five elements:

1 1st character '+' denotes HIBCC
2 2nd to 5th characters denote the manufacturer or proprietor of the product at international level—'E' as the second character denotes Europe
3 6th to 18th characters (variable in number) identify the product (could contain an EAN code)
4 19th character denotes the level of packaging, e.g. unit of sale, pallet, case
5 check character in a maximum of the 20th position calculated at modulo 43.

The code can be represented in any of the following standard bar formats: code 39, code 16K, code 49, and code 128.

Other codes coming onto the market are answering the problem of more and more information being required by the warehousing, wholesale and retail pharmaceuticals trade. It may soon be possible by using an individual bar code to be able to trace at least every batch of product right down the chain to individual patients.

Security codes

These are usually called 'Pharmacodes'. This is a misnomer, as the term 'Pharmacode' belongs as a trade mark to one company only. They are in the form of thick and thin bars of dark print on a light background. The thick and thin bars are of specified dimensions and give the effective signal of '1' and '0' respectively when moved past a scanning head. The 1s and 0s are then compared with a pre-loaded code and the result passes or fails.

The pre-loaded code can be entered in one of two ways. It can be loaded as a number, e.g. 112. This is then set by the decoder as 110001, i.e. to read thick, thick, thin, thin, thin, thick. The other method is to set the code directly by pressing usually the thick bars on one side of a decoder and the thin on the other side. Whichever method is used, the information for the code reader must be obtained from a controlled source, e.g. pack specification or works order.

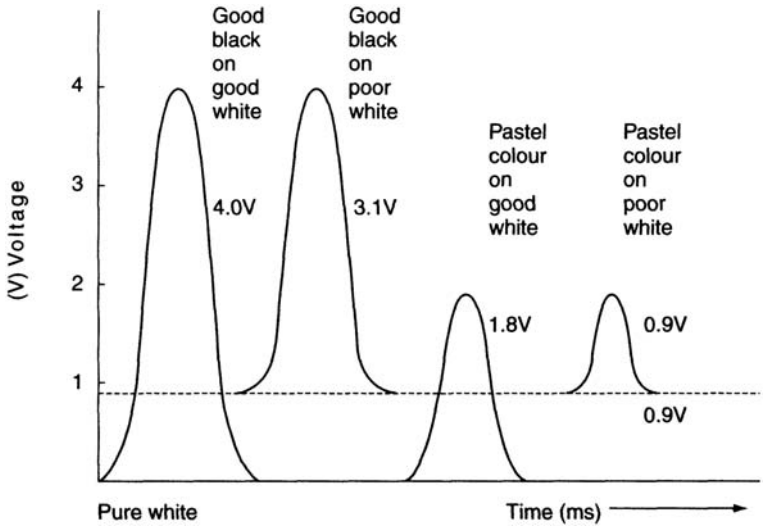

Figure 5.21 High ground voltage

The purpose of the code is to provide an affordable easy machine-readable form of the item code (part number) and prevent mix-ups at any point in the system. The mechanism by which this is achieved is by the code moving past a combined light source and sensor. The reflected light generates a peak voltage over a short time for a thin bar and about times three for a thick bar. In order to prevent mis-rejects the contrast between the background and the bars must be as great as possible. The background should always be white, but there are many problems with white: shine, uncoated paper, print show-through, etc. This means that the ground voltage (that voltage from which the spike is measured) might *not* be zero volts. Figure 5.21 shows high ground voltage.

Ground voltages up to as high as 0.9 V have been experienced. The reason for this is that the light source is constant (over a short period, even though it might decay in value over months). If it is calibrated to zero volts on the whitest source available, e.g. standard white tile, calcium carbonate block, any white darker or less reflective will not register zero volts but a positive value as the conditions controlling the detector must remain the same for the duration of the testing period, i.e. the production run. Again if the contrast between the bars and the background is poor, there is a greater chance of a misread.

There are a number of competing systems on the market, all doing approximately the same job and being successful provided all the systems governing the running of these bar codes are themselves secure.

The advent of vision verification systems is now competing with bar codes in the security field. These systems read the preprinted part number and either compare it with a pre-loaded independently obtained code or the whole system can be fully computerised and the reader told what component to expect and read as it passes.

Conclusions

This chapter has covered one of the oldest yet most useful of pharmaceutical packaging materials which has survived the onslaught of plastics and, being biodegradable, has considerably contributed to the store of natural materials that can be used for product protection. The chapter has also included sections on security, since papers (in particular) are frequently involved to assist security, a key example being the printing of bar codes—both for security and for efficient stock control and movement tracing.

The objective of the chapter is to provide a reasonably detailed amount of information on this very important and varied group of packaging materials, widely used in the pharmaceutical industry.

The best known applications of paper and board are labels, leaflets, folding boxboard cartons and corrugated cases. Without these, packaging or products would be more expensive and difficult. Please also note some of the ‘rarer’ or more hidden uses of cellulose, e.g. cellulose film, layers in laminates.

The major problem discussed in this chapter is not in the technologies of cellulose materials but in the question of security. Companies can be made less competitive by non-adherence to security rules. The two major areas are mix-ups in the production, delivery and use of labels, leaflets and cartons and the more modern phenomenon of passing off counterfeit drugs.

The future is bright for cellulosic materials, due to the more detailed requirements needed for information—particularly the expanded EU leaflet requirements.

On the environmental front, the success of Scandinavia (in particular) in managing its forests in an eco-friendly manner and cutting pollution of the environment during the manufacture of paper and board has countered many of the environmental

objections to the paper- and board-making industries. Trees, grasses, etc. are renewable and as such preferable, where they are an economic alternative to petroleum-based materials.

In short, paper board and other cellulosic materials have a major future in this industry.

Appendix 5.1: Testing of paper and board

It is fundamental to a good understanding of paper and board that the testing regimes that can be used and the specific tests and the reasons for using those tests are appreciated.

The reason for testing is to gain information, thereby ascertaining the acceptability of the test piece in comparison with a specification. That specification should be drawn up so that if all results pass, the material is fit for the purpose that it is intended to fulfil. All tests must be relevant to the use of the material, and must be understood by all the parties involved. This need has led to a series of standard tests: British BSI, ASTM, etc.

Testing conditions have also to be defined, as paper and board are very susceptible to humidity and temperature changes. It is therefore essential that the test pieces for paper and board are in fact 'conditioned' so that the tests can be carried out under 'standard' conditions, thereby giving fair comparisons. Those conditions usually quoted are:

- temperature—23°C 1°C (BS 3431 and ±ISO 187)
- relative humidity—50% 2% (BS ±3431 and ISO 187).

Note that there is one major exception to this rule—moisture content of the material. How to test is simple. Just follow carefully and accurately the standard test methods. Note also that test pieces should be cut accurately for tests where dimensions are criti cal. If one is using specific test instruments it must be ensured that the instrument is properly set and calibrated (if necessary) prior to the commencement of a test.

The reporting of results should include at least the following data:

1 The test method used, e.g. Grammage BS 3432:1980 (always specify the date of the method, as the BS and all the other standards are routinely updated)
2 the instrument used (its reference no.)
3 the test conditions
4 the size of the test piece, where relevant
5 the number of replicate tests per sample
6 the units used—this is very important, as a number of different units are used in reporting (both the SI and Imperial systems are in use together)
7 any other facts relevant to the test piece, e.g. discoloration of a white test piece on moisture content testing.

Appendix 5.2: General tests for paper and board

1 Sample conditioning of paper and board: BS EN 20187; 1993, ISO/R187 1990. This is the way to condition any test piece prior to testing by the appropriate BS method.
2 Pre-test procedures for paper and board. BS 3430:1986 (91) ISO 186 (1985) sets out the methods of obtaining a representative sample of the paper or board for testing in order to ensure that an average can be taken and compared with the original specification.
3 Moisture content of paper and board is measured according to BS 343:1986 (91) ISO 287 (1985). All papers and boards can be covered, i.e. all calipers of paper, chipboard, pasteboard, folding boxboard, solid and corrugated fibreboards provided there are no substances that will escape at the temperature specified for the test.
4 Folding endurance: ISO 5626:1993 describes four methods, i.e. Köhler Molin, Lhomary, MIT and Schopper. These various instruments fold the test piece back and forth through a specified angle until rupture occurs. Applies to all forms of paper and board, but there may be different instruments for different boards.
5 Density of paper and board: BS 4370:1973–1991. These are methods of test for rigid cellular materials. There are fourteen different test methods for aspects of the physical properties—dimensions, apparent density, compression strength, dimensional stability, cross-breaking strength, shear strength, shear modulus, thermal conditioning, water vapour transmission, tensile strength, friability and coefficient of linear thermal expansion.

6 Methods for determining air permeability: BS 6538:1985 (95) ISO 5636 (1984). Permeability is the mean airflow through unit area under unit pressure difference in unit time, under specified conditions, expressed in $\mu m\ Pa^{-1}\ s^{-1}$. Beware as there are several types of instruments that can be used and the results may be quoted as, for example Bendtsen. Note that this is only a valid test in what is termed the 'medium air permeance range'. This is important when you are using lightweight uncoated papers on machines that have a vacuum pick-up system.

7 Methods of test for the assessment of odour for packaging materials used for foodstuffs: BS 3755:1964 (71) This particular test has been deleted from the latest lists of the BSI.

8 Grammage or substance: BS 3432:1980 (90) ISO 536. The weight of material per unit area of the sample, usually confined to papers and boards, excluding the manufactured corrugated sheet but including the component parts of the corrugated sheet. Units are usually g/m^2.

9 Paper caliper BS EN 20534 1993 ISO 534 1988. Single sheet thickness between one surface and the other. Measure over a specified area and under a specific static load by means of a high precision dead-weight micrometer.

10 Tensile strength, both wet and dry: BS 4415:1992 ISO 1924 (1992). The maximum tensile force per unit width that a paper or board will withstand before breaking. The stretch at break is the measured elongation at the moment of rupture of a test piece, when tested under specific conditions.

11 Tear strength either across or along the grain: BS EN 21974 1994 ISO 1974, 1990. The mean force required to continue the tearing of an initial cut in a single sheet of paper and four torn together through a fixed distance using a pendulum to apply the tearing force. The work done in tearing the test piece is measured by the loss of potential energy of the pendulum. This obviously can be done either across or along the grain. The scale is calibrated to indicate the average force.

12 Burst strength, both wet and dry: BS 3137:1972 (95) ISO 2758, 2754, 3689. The maximum uniformly distributed pressure, applied at right angles to the surface, that a test piece of paper and board will stand under the conditions of the test. The test piece is placed into contact with a circular diaphragm, the test piece being clamped around the periphery, but free in the centre to bulge with the diaphragm. Hydraulic pressure is applied to the diaphragm, bulging it until the test piece bursts. This denotes the general strength of the test piece.

13 Puncture resistance: BS 4812:1972 (93) ISO 3036. A triangular pyramid puncture head is attached to a pendulum. It is released to swing onto a test piece. The energy required to force the puncture head right through the piece, i.e. to make the initial puncture and to tear and bend open the test piece, is measured.

14 Stiffness of thick papers and boards: BS 3748:1992 ISO 2493 1992. This is the degree of resistance offered by a paper or board when it is bent under specified conditions.

15 Ply bond of boards: TAPPI 403. This test ensures that the various plies of a multiply board have bonded together enough to ensure that they will perform satisfactorily in service. This test applies not to boards that use an adhesive as the bonding agent, e.g. pasteboard, but to those in which the plies are joined by heat and pressure only.

16 Creasability of boards: BS 4818:1993 described the method of determining the creasing quality of cartonboard within the range of 300–1000 μm. This is important to the packaging line, since if the creases are not correct and do not assist the carton erection, the cartoning machine will not function correctly.

17 Cobb test: BS EN 20535 1991 ISO 535 1991 for water absorbency. This measures the mass of water absorbed by 1 m^2 of the test piece in a specified time under a head of 1 cm of water. It is determined by weighing before and after exposure to the water, and usually quoted in g/m^2

18 Rub resistance: BS 3110:1959 (94). This is the resistance of a printed test piece to withstand rubbing against either another similar printed test piece or against a plain test specimen. The objective is to see that the ink/print has cured and will not scuff or smear in service.

19 Pick test: BS 6225:1982 (95) ISO 3782, 3783; also called the IGT test (Instituut Voor-Grafische Technical TNO Amsterdam). It is a small printing unit which allows one to print a small strip of paper under controlled conditions. A specified amount of a special oil is added to the printing system and printed onto the test piece. The surface is then examined for signs of disruption (otherwise known as 'pick' in the trade). Results are correlated from a time calibration table. It is essential that the paper surface does not pick when printed, as pick means that some of the deposited ink may be lost from the surface, and in extreme cases the paper surface may start 'dusting'. This means that the sizes and binding agents are not working and the fines of the fillers and opacifiers are loose on the paper surface.

20 pH, chloride or sulphate by BS 2924:1992 Parts 1–4, ISO 6588, 6587, 9898, 9197 or DEF STD 81–1. These factors are tested on a aqueous extract of the test piece. The acidity or alkalinity (pH) can help the life of the paper or board, as the natural pulp is slightly acidic and goes dusty and powdery in 50–70 years. Most papers today are neutral. Sulphates should be >20 mg/kg of sample and chlorides can vary with the cleaning processes of the pulp. The conductivity of the test piece can be also be determined in the aqueous extracts.

21 Roughness/smoothness: BS 4420:1990 (95) ISO 8791 (Bendtsen) or BS 6563:1985 (90) (Parker Printsurf). This is a measure of the extent to which a paper or board surface deviates from a plane and involves the depth, width and number of departures from that plane. This is very important for the 'printability' of the paper.
22 Brightness to BS 4432:1980 Parts 1–4 (95) ISO 2469, 2470, 2471. This is the reflectance factor measured at the effective wavelength of 457 nm with a reflectometer having specified BS characteristics. Note again that this might be quoted with a manufacturers name behind it, e.g. Technibrit.
23 Opacity to BS 4432:1980 Parts 1 and 2 (95) ISO 3688. This is the ratio, expressed as a percentage, of the luminous reflectance factor of a single sheet of the paper with a black backing to the intrinsic luminous reflectance factor of a layer, or pad, of the same paper which is thick enough to be opaque.
24 Dennison wax test. This is an older test that was largely replaced by the IGT test, but is still used by some older paper and board mills. It consists of a series of specialised waxes, which are heated to a specified temperature, placed on the paper surface, left to cool, then removed. The wax formula 'picks' dust and debris from the surface, and the wax formula number that shows the picking indicates the degree of ink viscosity (or stickiness) that the particular paper will tolerate without risk to the print.
25 Wet burst strength: BS 2922 (PT1):1985 (95) ISO 3689. This is used for determining the wet bursting strength of any paper or board following immersion in water.
26 Wet tensile strength: BS 2922 (PT2):1984 (95) ISO 3781. This is a method of determining the wet tensile strength of any paper or board after immersion in water.
27 Ash in paper and board: BS 3631:1984 (94) ISO 2144. This is a method of determining the ash content (i.e. the inorganic matter left after controlled combustion) in paper and board. The method is suitable for most loading materials and coating pigments.
28 Detection and estimation of nitrogenous agents in paper: BS 4497:1969 (93). This standard describes the problems involved with the nitrogenous treating agents for paper and gives qualitative and quantitative methods for use with certain agents used in paper treatment. It applies only to substances that have a strong affinity for acid dyes.
29 Ink absorbency: BS 4574:1970 (91). This gives recommendations for the determination of the ink absorbency of paper and board by K & N ink. Applies to both paper and boards to be printed by the litho gravure or letterpress process.

Appendix 5.3:
Specific tests for cartons

1 Compression to BS 4826 (PT3):1986 ISO 2234. This standard lists three methods which can be used to assess the strength of the erected package, thereby estimating the degree of protection that it confers on the contents. This is particularly useful for products with no inherent strength in one plane or another, e.g. strip packs.
2 Carton opening force. The method that is often used is to hold the flat carton, as delivered, by its creases between thumb and first finger and press. The carton should spring open into the 'square' position without a need for unreasonable force. If the carton does not spring open, or buckles in on itself, then it is reasonable to assume that those particular cartons will cause problems on any cartoning machine. This can be measured by instrumentation.
3 Coefficient of friction: BS 2782 (PT2):1983 method 824A or ASTM D1894. Both the static and kinetic coefficients of friction are determined by sliding the specimen over itself under specific test conditions. As discussed earlier, the finish of board can differ dramatically. Compare a corrugated case with a test liner and with a Kraft liner, or a cast coated or varnished carton with an uncoated carton. Where machines are involved there could be problems with different coefficients of friction, since friction is used as part of the control on carton and corrugated case erecting machines.
4 Crease stiffness: BS 6965:1988 (94). Also called the crease recovery test. This involves testing a carton board piece and folding it through 90°. It will then try to recover its former position when the bending force is removed. The increase or decrease in the inherent board stiffness after folding is measured. As with all tests involving forces, the test should be performed both along and across the grain.
5 Joint shear strength: BS 5350 Part C5 1990. This is a method of testing the glued lap seam on the side of a carton for strength of the adhesive, using a tensile testing machine. This quantity is important in ensuring that the correct adhesive for the cartonboard finish has been used, and in the right quantity. Another problem that frequently occurs is skewed lap seams. This means that the carton is out of true, and will not erect on a machine.

Appendix 5.4: Specific tests for corrugated

1 Flat crush resistance test for corrugated board: BS EN23035:1994 ISO 3055 1982. This only applies to single wall and single faced corrugated. Test pieces are placed perpendicular to the paper surface between two platens, which move together until the fluting collapses. Measure the maximum force obtained.
2 Edge crush test for corrugated board: BS 6063:1992 ISO 4097. A rectangular test piece of corrugated FBB is placed between the platens of a crush tester with the fluting perpendicular to the platens. Compress until failure, measuring the maximum force. Useful in assessing stacking strength
3 Ring crush test (corrugated): TAPPI T818 1987. A compressive force is exerted on a specimen, held in a ring form in a special jig and placed between two platens of a compression machine. The upper platen approaches the lower platen at a uniform speed, until the specimen collapses. This correlates with the edgewise compression strength of the paperboard or fluted medium.
4 Flat crush of corrugating medium (Concora test): BS EN:ISO 7263 1995. Paper is fluted by passing between heated rollers and then formed as a single faced corrugated board using a pressure sensitive tape as the liner. A crushing force, perpendicular to plane of the paper, is applied and measured at the point in time the paper crushes.
5 The specific apparatus and detailed procedures for the measurement of corrugated board caliper are contained in BS 4817: 1972 (93) ISO 3034. This obviously differs from the other methods already described in that the corrugations could be crushed when using calipers or any other form of measuring equipment.