FFPI
FORSCHUNGSGEMEINSCHAFT FALTSCHACHTELN FÜR DIE PHARMAINDUSTRIE

Research Group Folding Boxes for the Pharmaceutical Industry

Cardboard for Pharmaceutical Folding boxes

Specification
Technical Bulletin FFPI-SP 08/2019

1 Scope

This specification describes technical requirements for cardboard intended to manufacture folding boxes to package pharmaceutical products.

2 Technical requirements

2.1 Cardboard grades

The cardboard grade must be agreed upon. Preferred grades for folding boxes for pharmaceutical purposes are GC and GD (designations in accordance with DIN 19 303). The front side of the cardboard must be coated.

2.2 Bending stiffness and thickness

The combination of bending stiffness and thickness is essential for designating the technical properties of cardboard. It is recommended to specify an upper limit for thickness and simultaneously a lower limit for bending stiffness in cross direction (CD)[1].

2.2.1 Bending stiffness

Required bending stiffness in cross direction (CD) must be agreed upon. The value depends on dimensions of folding box and details of application.

Bending stiffness must be determined in accordance with DIN 53 121[2] (2-point method, bending angle 5°).

2.2.2 Thickness

Thickness must be determined in accordance with DIN EN ISO 534. Thickness tolerance must be agreed upon to ensure proper paperboard performance[3].

2.3 Creasability

Creasibility is assessed in accordance to Technical Guidelines "Good Creasibilty" of Association of Folding Box Manufacturers (FFI). A cardboard is good creasable, if creasing lines made in accordance to the technical guidelines passed (a) optical and (b) technical assessments

(a) Optical assessment: After folding the creasing lines through 180° the crease must not burst open on the outside; the crease fold on the inside must be even.
(b) Technical assessment: Assessment by means of folding factors[4]. There values must be agreed upon.

[1] Often cardboard is specified using grammage. In contrast to bending stiffness and thickness grammage does not designate a technical property of cardboard

[2] Sometimes instead of bending stiffness the resistance to bending in accordance with ISO 2493 with bending angles 7.5° or 15° is specified. The measurement readings of bending stiffness and resistance to bending cannot be compared to each other. Bending stiffness of corrugated board in accordance with DIN 53121 must be determined by using 4-point method.

[3] To maintain sufficient ability to die cut and crease the cardboard, the tolerances of thickness should be as low as possible. High quality creasing lines are a pre-condition for good runnability of folding boxes in cartoners. Specified thickness tolerances must not be exceeded.

[4] Folding factors are measured in accordance to FFI-Technical Guidelines. They are defined as

$$folding\ factor = 100\% - \frac{B}{A} \cdot 100\%$$

A is the folding work of creased and B the folding work of uncreased cardboard

2.4 Whiteness

The whiteness[5] must exceed 82 %.

Whiteness is determined in accordance with ISO 2470-2 with illuminant D65.

2.5 Moisture content

The relative equilibrium moisture content of cardboard at 23°C must be:

- Grammage up to 400 g/m²:
  45 to 60 % relative humidity
- Grammage above 400 g/m²:
  50 to 65 % relative humidity

Moisture content must be determined in accordance with DIN 53 118.

2.6 Supplementary markability

2.6.1 General requirements

If folding boxes must be subsequently marked (serial numbers, codes, or other individual markings etc.) the cardboard must meet the specific requirements of the marking system. Special requirements regarding printing and varnishing in the area intended to be marked must be specified and agreed upon[6].

Datamatrix-codes must be tested in accordance with ISO/IEC 15 415 and verified to at least grade C (2).

2.6.2 Inkjet with waterbased inks

Codings or other markings must be wipe resistant after a drying time of ≤ 0.3 s[7]. After the wipe test any datamatrix code must still meet grade C according to ISO/IEC 15 415.

Cardboard fulfills the requirement, if testing in accordance with PTS-method PTS-DF 103/2019: Assessment of markability of cardboard with DOD-Inkjet-printers including wipe test after a drying time of 0.3 s is passed.

2.6.3 Inkjet with UV-curable inks

If the surface of the cardboard intended to be marked is unprinted and unvarnished, no special specifications are required.

If the surface is printed and/or varnished, the surface energy should not be lesser than 38 mN/m.

Surface energy can be determined in accordance with PTS-method PTS-PP 103/85.

In any case the marking must be tape resistant in accordance with PTS-method PTS-DF 102/90.

Codes and other markings must be wipe resistant, which must be tested in accordance with PTS-DF 103/2019 and then verified as grade C (2) or above according to ISO/IEC 15 415.

2.6.4 Laser-Ablation

Cardboard fulfills the requirement of marking with laser ablation if either of the following tests passes:

Method A: Assessment based on IR-spectroscopy in accordance to PTS-DF 105/2017. Criterion for markability is:

$(E_L/E_{7.1})\bullet 100 > 15$ %

$E_{7.1}$ is the extinction (absorbance) of IR-Radiation in the coating layer at the maximum of the peak nearby wave number[8] k =

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[5] The term „whiteness" is common in paper technology language, but strictly speaking wrong. Actually, the meaning of the term is the diffuse reflectance factor, measured at a center wavelength λ = 457 nm. For whiteness measurement in accordance with ISO 2470-2 often the term „D65-Brightness" is usual instead of "whiteness", which describes better the measured value.

[6] In general, areas intended to be marked with inkjet should be free of ink and varnish. If laser-ablation is used the intended areas must be printed with contrasting black or dark blue ink. Inks with dyes are more suitable than inks with pigments or carbon black. The ink layer should be thin (< 2 µm) and printed in full tone, not half tone. Red, orange or brown colors should be avoided due to illumination of reading devices. UV-varnishes should be avoided in any case.

[7] Depending on details of application and configuration of machines it is possible that longer drying times are acceptable. Special specifications with respect to drying time must be agreed upon.

[8] In spectroscopy it is common to use the term wave number k instead of wavelength λ with λ=1/k. To determine $E_{7.1}$ a characteristic and strong absorption peak in the IR-spectrogram of calcium carbonate is used, since calcium carbonate is the most frequently used white pigment in coating layers.
Pure calcium carbonate absorbs weakly in the area of laser radiation, which results in low E_L-values and poor marking quality. E_L-values are higher at λ = 9,3 µm. Often with corresponding lasers good marking quality is achievable. Also, with special coating additives it is possible to increase extinction E_L. The method uses the ratio of E_L to $E_{7,1}$ to designate markability of coating layer by defining a

1.400 cm^{-1} or corresponding wavelength λ = 7.1 µm.
E_L is the extinction at the wave number corresponding to wavelength of laser radiation. If the laser radiated at wavelength λ = 10.6 µm the corresponding wave number is k = 943 cm^{-1}. Also, lasers are available radiating at wavelength λ = 9,3 µm respectively k = 1.075 cm^{-1}.

Method B: Testing in accordance with PTS-method PTS-DF 105/2017.

2.6.5 Durability

Supplementary codings with datamatrix-codes that meets the requirements of chapters 2.6.2, 2.6.3 or 2.6.4 respectively must be verified with grading C (2) also 1 year after expiration date. This is the case if the lifetime factor f determined in accordance to PTS-DF 109/2019 is $\geq$ 0,4.

2.7 Other properties

Cardboard must lay flat and must have surface properties to provide proper printability and varnishability.

Cardboard must be able to be die cut, creased and embossed. If Braille embossing is required, the cardboard must enable embossing in accordance with ISO 17351.

relative minimum value for extinction E_L, without specifying how high values of E_L can be achieved.

Cardboard must be printable with hot-stamping foil printing and similar printing methods.

Cardboard must be glueable with both adhesives used within the folding box production process and adhesives used within packaging processes e.g. cartooning process[9].

Date of issue: October 8, 2019
Replaces the Technical Bulletin FFPI-SP 08/2018, August 2018

Contact:
FFPI
Dr. R. Wilken
Friedenstraße 12
D-82194 Gröbenzell
Tel.: 0049 8142 60511
Fax: 0049 8142 667156
rwilken@t-online.de

[9] In the folding box production process normally waterbased emulsion adhesives are used to glue the longitudinal seam.
Glueing processes performed during packing processes e.g. to maintain tamper evidence features by glue the flaps of folding boxes. For this purpose generally hot melt adhesives are applied.
The quality of longitudinal seams can be evaluated by measurement (PTS-method PTS-PR 301/2008).

Glued flaps to ensure tamper evidence must be in accordance to DIN EN 16679.

Cited Standards

DIN 53 121 (08.2014)
Testing of paper and board - Determination of the bending stiffness by the beam method

ISO 2493 (11.2010)
Paper and board -- Determination of resistance to bending

ISO 534 (05.2005)
Paper and board - Determination of thickness and apparent bulk density or apparent sheet density (ISO 534:1988)

Technische Richtlinie „Gute Rillbarkeit"
Fachverband Faltschachtel-Industrie e.V. (FFI), Frankfurt am Main (2018)
(Technical Guideline "Good Creasability" of association of folding box manufacturer (FFI))

ISO 2470-2:2008
Paper, board and pulps -- Measurement of diffuse blue reflectance factor -- Part 2: Outdoor daylight conditions (D65 brightness)

DIN 19 303 (03.11)
Paperboard - Terms and grades

DIN 53 145-2 (03.2012)
Testing of paper and board - Basic parameters for determination of reflectance factor - Part 2: Measurements made on fluorescent specimens

DIN 53 118 (08/98)
Testing of paper and board - Determination of equilibrium moisture content in bulk or in reel

ISO/IEC 15 415 (12.2011)
Information technology - Automatic identification and data capture techniques - Bar code print quality test specification - Two-dimensional symbols (ISO/IEC 15415:2011);

PTS-Methode PTS-DF 103/2019
Bewertung der Codierbarkeit von Faltschachtelkarton mit DOD-Inkjet-Druckern
(Assessment of markability of paperboard with DOD-inkjet printers)

PTS-Methode PTS-PP 103/1985
Prüfung von Papier, Pappe und Folien - Prüfung der Oberflächenspannung und Polarität aus Randwinkelmessungen (Methode der harmonischen Mittelung)
(Testing of paper, board and films - determination of surface energy and polarity from measurements of contact angles (method of harmonic averaging)

PTS-Methode PTS-DF 102/1990
Prüfung von Drucken und Druckfarben: Prüfung der Haftfestigkeit von UV-Drucken mit dem Klebebandtest
(Testing of prints and inks – determination of adhesion using tape test)

ISO 17351 (10.2014)
Packaging - Braille on packaging for medicinal products

PTS-Methode PTS-DF 105/2017
Bewertung der Codierbarkeit von Faltschachtelkarton mit Laser-Ablationsverfahren, Verfahren A (IR/VIS-Spektralfotometer) und Verfahren B (Codierversuche)
(Assessment of markability of board using laser-ablation, method A (IR/VIS-spectral fotometry) and method B (testing of markability))

PTS-Methode PTS-PR 301/2008
Bestimmung der Klebenahtfestigkeit von Faltschachteln (Looptest nach Edelmann)
(Determination of strength of longitudinal seams of folding boxes (Edelmann looptest))

DIN EN 16679 (03.2015)
Verpackung - Merkmale zur Überprüfung von Manipulationen an Arzneimittelverpackungen; Deutsche Fassung EN 16679:2014
(Packaging - Tamper verification features for medicinal product packaging)

PTS-Methode PTS-DF 109/2019
Prüfung der Verifizierbarkeit von Datamatrix-Codes auf Faltschachtelkarton nach beschleunigter Alterung
(Assessment of verifiability of datamatrix-codes on paperboard after accelerated aging)