FFPI
FORSCHUNGSGEMEINSCHAFT FALTSCHACHTELN FÜR DIE PHARMAINDUSTRIE

Research Group Folding Carton for the Pharmaceutical Industry

Cartonboard for Pharmaceutical Folding Carton

Specification
Technical Bulletin FFPI-SP 08/2025

1 Scope

This specification describes technical requirements for cartonboard intended to manufacture folding cartons to package pharmaceutical products.

2.0 Preliminary remark

In the following, reference is made to DIN/EN/ISO standards, PTS methods and other technical regulations. The current versions of these documents are valid[1].

2.1 Cartonboard grades

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

2.2 Bending stiffness and thickness

The combination of bending stiffness and thickness is essential for designating the technical properties of cartonboard. It is recommended to specify an upper limit for thickness and simultaneously a lower limit for bending stiffness in cross direction (CD)[2].

2.2.1 Bending stiffness

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

Bending stiffness must be determined in accordance with DIN 53 121[3] (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[4].

2.3 Creasability

The creasability is to be evaluated according to DIN 55437-1, -2 and -3. The board has good creasability if the creases produced in accordance with DIN 55437-1 pass a) visual and b) technical assessments.

a) Visual assessment in accordance with DIN 55437-2: The test creases must allow the cartonboard to be folded 180° without visually detectable damage to the outside of the cartonboard.
b) Technical evaluation in accordance with DIN 55437-3: The technical evaluation is carried out on the basis of folding factors, the values of which must be agreed.

2.4 Whiteness

The whiteness[5] must exceed 82 %.

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[1] Reference sources:
DIN/EN/ISO standards: www.din.de
PTS methods: www.ptspaper.de
FFI technical guidelines: www.ffi.de

[2] Cartonboard is often specified by means of grammage. In contrast to bending stiffness and thickness, however, it does not characterize a technical, but rather a commercial cartonboard property.

[3] 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.

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

[5] The term „whiteness" is common in paper technology language, but strictly speaking wrong.

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

2.5 Moisture content

The relative equilibrium moisture content of cartonboard at 20°C[6] 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 carton must be subsequently marked (serial numbers, codes, or other individual markings etc.) the cartonboard 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[7].

Datamatrix-codes must be tested in accordance with ISO/IEC 15 415 and verified to at least grade 2.0.

Note:
Delegated Regulation (EU) 2016/161 stipulates a minimum grade of 1.5 for printed codes. In contrast, this technical bulletin with a minimum grade of 2.0 applies explicitly to the testing of cartonboard under defined laboratory conditions. Such a higher requirement for cartonboard is necessary because influencing parameters in the industrial environment can reduce the grading of printed codes compared to the grading of the cartonboard.

2.6.2 Inkjet with waterbased inks

Codings or other markings must be wipe resistant after a drying time of ≤ 0.3 s[8]. After the wipe test any datamatrix code must still meet grade 2.0 according to ISO/IEC 15 415.

Cartonboard fulfills the requirement, if testing in accordance with PTS-method PTS-DF 103/2019: Assessment of markability of cartonboard 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 cartonboard 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 2.0 or above according to ISO/IEC 15 415.

2.6.4 Laser-Ablation

Cartonboard is printable with the laser ablation process if it has passed the test according to PTS method PTS-DF 105: "Evaluation of the markability of folding carton with the laser ablation process".

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 2.0 also 1 year after expiration date. This is the case if the lifetime factor f determined in accordance to PTS-DF 109 is ≥ 0,4.

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] The test temperature of 20°C is common in the folding carton industry (see FFI/VMK technical guideline "Quality characteristics for folding carton board". The test temperature for the DIN 53118 test is 23°C.

[7] 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.

[8] 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.

2.7 Other properties

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

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

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

Cartonboard 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: 25.07.2025
Replaces the Technical Bulletin FFPI-SP 08/2024, October 2019

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[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 carton. 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)

DIN 55437-1
Testing of folding cartonboard - Creasings - Part 1: Laboratory production of test creasings

DIN 55437-2
Testing of folding cartonboard - Creasings - Part 2: Visual assessment of creasings

DIN 55437-3
Testing of folding cartonboard - Creasings - Part 3: Determination of the technical quality of creasings

FFI/VMK Technical Guideline "Quality characteristics for folding cartonboard"
Fachverband Faltschachtel-Industrie e.V. (FFI), Frankfurt am Main (2015)

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 cartonboard 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 carton (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)