Delivery Specifications

Version: 05/2017

Finished Goods

Cytostatic Finished Goods

Give-Away and Service Items

As a supplement to the delivery specifications, general section, the following requirements apply to finished goods, cytostatic finished goods, and give-away and service items:

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General

The product-specific requirements for transportation and storage (e.g., +2 °C to +8 °C, +15 °C to +25 °C) must be observed when handling medicines. Product and batch mixtures are not permitted in containers or on pallets.

1 Cardboard packaging

Only neutral shipping cartons may be used to dispatch finished goods. Manufacturer-specific features are not permitted.

1.1 Cardboard quality

The supplier is responsible for inner and outer packaging. The quality of the cardboard must be suitable for shipping the products that are to be transported. Individual cartons must also be suitable for sole dispatch, e.g. as a parcel shipment. The package must protect the content of the carton against mechanical (fall on edge, corner, or side from approx. 1 m) and climatic stresses. It must be ensured that the cartons can be stacked. Cartons with fit-on lids are preferred.

1.1.1 Tablets, ointments, and suppositories:

Shipping carton quality: 1.4, single flute
Folding box quality: GC2 cardboard, no recycled cardboard
Deviation from filling material to inner dimension of shipping carton: max. 2 cm

1.1.2 Ampules:

Shipping carton quality: 2.3, double flute
Folding box quality: GC2 cardboard, no recycled cardboard
Deviation from filling material to inner dimension of shipping carton: max. 1 cm

1.1.3 Vials and bottles:

Shipping carton quality: 2.3, double flute
Folding box quality: F-flute with tab
50ml + 100ml OP5/OP10 partition from base to lid
F-flute from 200 ml - 500 ml individual carton (> 100 ml: No bundling

Deviation from filling material to inner dimension of shipping carton: max. 1 cm

1.1.4 Aerosols:

Shipping carton quality: 2.3, double flute
Folding box quality: No specifications
Deviation from filling material to inner dimension of shipping carton: max. 2 cm

1.2 Carton size

The following formats must be considered when using shipping cartons:

Large carton (=maximum dimensions):	60 cm x 40 cm x 32 cm
Medium carton:	30 cm x 40 cm x max. 32 cm (filling level)
Small carton (=minimum dimensions):	30 cm x 20 cm x max. 20 cm (filling level)

Other formats should not be used if possible.
The minimum dimensions are 24 cm x 20 cm x 11 cm. The shortest dimension of the base must be greater than the height, and the carton opening must always be on top.

1.3 Weight

For finished goods, a maximum weight of 10 kg per carton (net) must not be exceeded.

1.4 Filling material

Recycled paper is used as the filling material.

2 Supply quantity

The permissible tolerances for underdeliveries and overdeliveries are governed on a case-by-case basis in supply contracts. If there is no rule in the supply contract, the general practice is that an overdelivery or underdelivery of greater than 10% is permitted only with written approval by Teva.

3 Remaining term

Die remaining term for the finished goods to be supplied is governed on a case-by case basis in supply contracts. Unless otherwise stipulated, the remaining term from goods receipt to the expiry date must be at least 85% of the assured total term, but at least 20 months. It should also be noted that finished goods must not be more than 18 months old upon receipt.

4 Bundling of finished products

The individual folding boxes must be bundled into 5x and 10x units, depending on the basic dimensions of the folding boxes or the quantity of containers. No other bundles are accepted.
A transparent 70-µm-thick plastic banding film is to be used; full wrapping is not allowed.
No bundling is performed for liquids > 100 ml in individual folding boxes.
Large packages must be marked using a red band label with a separate PZN sticker.

5 Stockpiling packaging materials for finished goods

Printed packaging materials are to be procured from the supplier by order. If Teva has not granted written agreement in advance to stockpile, Teva shall not assume any costs for packaging materials that are no longer usable. Exception: If Teva orders less than 5000 packages for finished goods, the supplier may fulfill an order for 5,000 pieces of the required printed packaging materials. In this case, Teva guarantees acceptance of printed materials that are no longer required for the production of the ordered amount and for future orders.

Teva must consent in writing to the destruction of packaging materials. Prior to destruction, the supplier must proactively obtain written approval from Teva, indicating:

- Quantity remaining
- Costs
- Order reference (order number under which packaging materials were originally procured)

per packaging material.

In case of such destruction, Teva shall not accept any processing fees.

6 Pallet requirements

The total pallet weight must not exceed 500 kg (300 kg for cytostatics).

Pallet height

National: max. 1.50 m
max. 1.20 m (cytostatics)
max. 1.50 m (give-away and service items)

International: max. 1.15 m

7 Documents and labeling

7.1 Documents

7.1.1 Delivery note/packing list

The delivery note must contain the following information:

- Teva order number
- Teva material number
- Teva product name
- Commercial form (goods for sale, clinical, sample, export)
- Name and address of production facility
- Sequential pallet list with number of pallets
- Quantity per pallet (arranged by batches)
- Number of containers
- Quantity per container
- Number of partial containers
- Partial quantities
- Version number for printed packaging materials
- Teva batch number
- Supplier's batch number
- Number of batches
- Date of manufacture and (if applicable) expiry (to the day)
- Dangerous goods must be indicated by providing the information stipulated under paragraph 5.4.1.1.1 (a) to (d) of ADR/RID/ADNR/ADN.
- If the substances are subject to Section 35(1) of ADR/RID/ADNR/ADN, indicate compliance with Section 35.
- For carriage under Chapters 3.4 and 3.5 of ADR/RID/ADNR/ADN, a general reference to the dangerous goods in limited and excepted quantities is required.

7.1.2 Consumption report

If materials (raw materials/packaging materials/bulk goods/finished goods) are provided by Teva, an order-related consumption report must be enclosed with the delivery documents.
When labeling finished goods for the Italian market with Bollini labels, a separate form must be filled out. This form is also enclosed with the delivery documents for the specific orders (see ***Appendix 1***).

7.1.3 Production documentation for initial batches

The supplier shall provide complete production documentation, including the documentation specified under 7.1.4, for the first three batches delivered to Teva no later than at the time of goods receipt.
The documentation specified under 7.1.4 is required for all subsequent batches.

7.1.4 Production documentation for subsequent batches

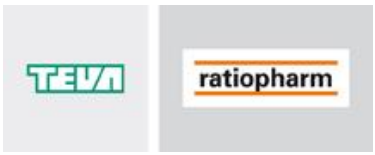
The production documentation must be submitted no later than at the time of goods receipt. The documentation must be available within one working day in the event of incidents, complaints, inquiries by authorities, etc.
The production documentation is sent to the following e-mail address:

- batchdocumentation@tevaeu.com

All documents must be compiled for the specific batch.

The production documentation should contain the following documentation and information:

- Certificate of analysis for the goods supplied
  - Indication of the test specifications applied
  - All test points in accordance with the pharmacopeia or Teva specifications, indicating all target and actual values
  - Date of manufacture (to the day)
  - Date of expiry, if applicable
  - Batch number (manufacturer)
  - Batch size
  - Exact values for quantitative test points
  - Legally binding signature



- Release certificate

- Certificate of analysis for the API
  - Specification of manufacturer/supplier batch (API)
  - Name of manufacturer/supplier
  - Address of production facility

- Confirmation of release
  Declaration of GMP conformity for release-compliant production and inspection by manufacturer/supplier QP (Qualified Person) in accordance with GMP Guidelines, Annex 16, with signature, date, and stamp

- Weighing log
  - Categorization as bulk or finished goods
  - Weigh-in date

- Deviation report (German or English), if applicable

7.2 Labeling

If a VNR number is specified in the order, it must be indicated on the pallet label and on the container label.

7.2.1 Pallet label

Product and batch mixtures are not permitted on the pallet.
A pallet label must be applied to the longitudinal side and the transverse side of the pallet. The pallet labels must be applied to the "external safeguarding material," not directly on the carton.
The pallet label must contain the following information:

- Count (packages per pallet)
- Teva batch number
- Date of manufacture
- Date of expiry
- Product/sales designation
- Teva item number
- Order number/delivery plan number
- Number of containers/partial containers

- Reference to dangerous goods

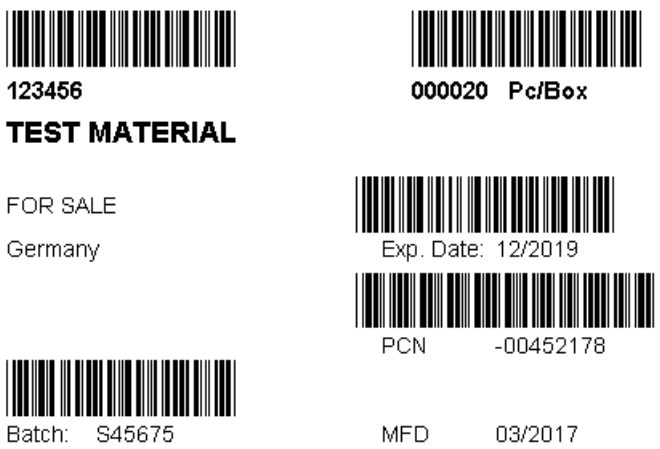
7.2.2 Container label

Product and batch mixtures are not permitted in the container.
Containers must be supplied with a label. References to the manufacturer or recipient on the label or the carton are not permitted.

The container label must contain the following data:

- Teva material number
- For products for DE: Pharmaceutical registration number (PZN)
- For products for NO, DK, SE, FI: VNR code
- Container quantity (number of finished packages per shipping carton)
- Partial container quantity (plain text + barcode)
- Product/sales designation
  - Distribution type (goods for sale, clinical, sample, export)
  - Country of distribution
  - Batch number
  - Date of expiry

The container label and the barcodes must not be applied vertically.
Teva provides a label generation program (Barcode 39), including manual, for the creation of the label. This program should be used.
Large packages must be marked using a band label with a separate PZN sticker.
Inquiries regarding the container label can be clarified with the contact person specified in the order.



8 Partial cartons/test samples/retention samples

Partial cartons must be clearly marked with a "Partial" sticker. The stickers are applied on the front, beside the container label. There must not be more than one partial carton per batch.

Included test samples/retention samples must be supplied in a separate carton, clearly labeled and easily visible, at the top of a partial pallet.

9 Initial deliveries and changes

Written release following prior sampling is required for initial deliveries or changes to packaging materials. The required data will be queried from Teva and communicated in writing by the supplier to the recipient specified by Teva.

In addition to specifying this data, the supplier is obligated to create a packing plan for the shipping carton and the pallet (see ***Appendix 2*** and ***Appendix 3***). Additionally, one sample label each (shipping carton and pallet and, for service and give-away items, a QR code for the item) is to be sent to

- inventory_master@transpharm.de

Any changes to containers, bundling, etc. following release by Teva must be indicated on the delivery note and the packing list (information: old/new).

10 Sample delivery

Two initial samples and two final samples from packing must be included for each packing batch. These can be supplied in a separate carton together with the goods. The carton must be clearly labeled as samples for QO final product control.
Alternatively, the samples can also be sent separately to the following address:

- Merckle GmbH
- QO Final Product Control
- Graf-Arco-Strasse 3
- 89079 Ulm, Germany

11 Addendum 1 (only for cytostatics)

The goods must be packed in a single layer in inner packages. The inner packages must each be wrapped in foil and supplied with a contents label. The goods are to be secured by a partition so that glass does not contact glass. Partial inner packages must be secured with sufficient filling material. Use recycled paper as the filling material. For cooling materials, each carton must be labeled "Cooling goods (e.g. 2-8 °C)."

Due to their CMR characteristics, cytostatics are generally not dangerous goods. However, with consideration to risks, the recommendation of hospital pharmacists should be followed and the label "Cytostatics - Hand" should be applied to every carton.

12 Addendum 2 (only for give-away and service items)

Specific information regarding give-away and service items is to be queried from Teva in case of initial shipments or changes to material and communicated in writing by the supplier to the recipient specified by Teva. The form "Material Master Data for Give-Away Items" (see ***Appendix 4*****)** is used for this purpose. It is sent to:

- inventory_master@transpharm.de

Carton size

Maximum dimensions: 60 cm x 40 cm x 32 cm

Minimum dimensions: 24 cm x 20 cm 11 cm

The shortest dimension of the base must be greater than the height, and the carton opening must always be on top.

Item labeling

Each piece of a service and give-away item should, where possible and contractually agreed, be supplied with a label (barcode): GS1 Data Matrix.

Barcode content and structure: (21)serialnumber(400)ordernumber

Example:
Plain text entry (input in barcode generator): (21)165202(400)45854988
Encoded:]d22116520240045854988

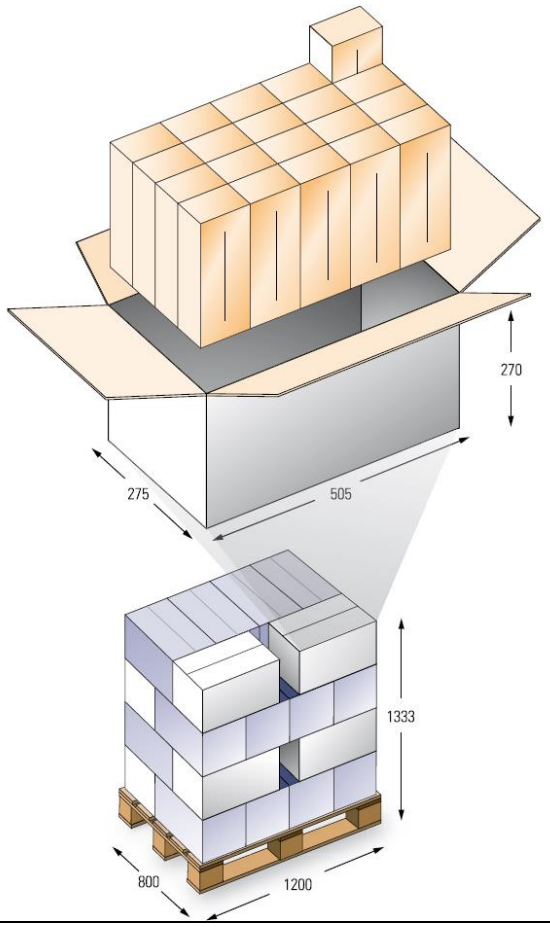
Explanation of code:

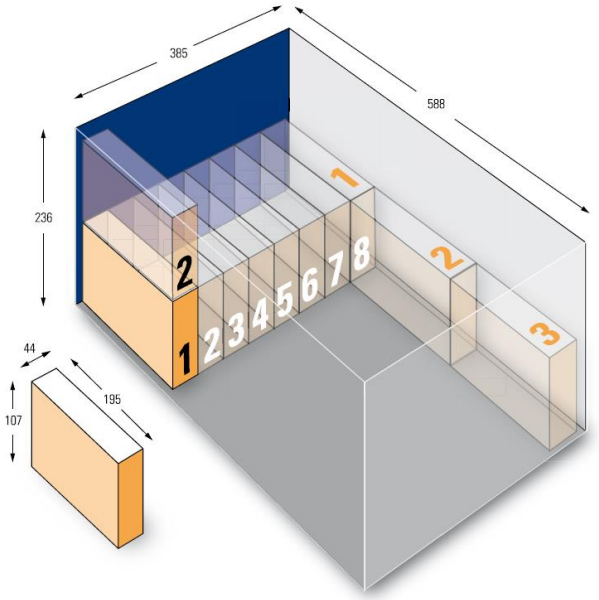
]	= Start character
d2	= FNC1 (unique identifier for a GS1 data matrix)
21	= Application identifier (serial number)
165202	= Serial number (material number)
400	= Application identifier (order number)
45854988	= Order number

The barcode should be adapted to the available space on the product. The larger the barcode, the more legible it is.

Maximum size:	40 mm x 40 mm
Minimum size:	5 mm x 5 mm

13 Appendices

Appendix 1 Consumption Report	Verbrauchsmeldung.docx Verbrachsmeldung Bolini.xls
Appendix 2 Pallet packing plan **Specify:** ○ Detailed drawing of the shipping carton, with dimensions (LxWxH) ○ Detailed drawing of the arrangement of shipping cartons on the pallet, with dimensions (LxWxH) ○ Weight of filled pallet ○ Indication of shipping braces used	

Appendix 3 Carton packing plan **Specify:** ○ Shipping carton inner dimension ○ Folding box/bundle outer dimension ○ Number of folding boxes/bundles ○ Total folding box weight ○ Weight of shipping carton ○ Total weight of filled carton ○ Detailed drawing of arranged bundles in shipping carton ○ Volume utilization	
Appendix 4 Material Master Data for Give-Away Items	Materialstammdatenblatt.docx