ANNEX of STADA Arzneimittel AG

As March 1st, 2015
Version: 17

The specifications listed in this document are mandatory for all finished products, for both national and international markets. All changes require the written consent of Logistics or STADA Arzneimittel AG. Deviations will be reworked in accordance with the delivery contract and charged.

Contents

1. Product bundle units

The product must be bundled into the following gripping units:

Solid and paste forms:

6-part or 12-part bundle

Liquid forms:

up to 100 ml always as 6**-part** bundle
from 100 ml **no** bundle

- Bundles are only permitted as banderole, they must **not** be shrink-wrapped.
- The bundle unit must fit into the smallest package (**250 x 250 x 150)** described in section 2.
- For professional samples, bundles are not needed
- For 1=1 articles, additional cartons as shown in this **negative example** are **not allowed** to use:

2. Package sizes

The overall dimensions of the packages as well as individual dimensions (length, width, height) must not exceed the following dimensions, and not fall below the minimum dimensions. This is necessary because different packages can't be transported with our conveyor systems. The package sizes have to be uniform for each batch. Packages of finished pharmaceuticals must not exceed the maximum weight:

Maximum dimension in mm: 600 x 450 x 400
Minimum dimension in mm: 250 x 250 x 150
Maximum weight: 20 kg

- The content of every package must **always** be the same, one exception is a partially filled package with the respective remaining amount.
- Only neutral, unprinted packages may be used.
- At least 85 % of the capacity of individual packages must be utilized.
- All packages on one pallet must
  - have the same dimensions
  - contain the same batch
  - contain the same number of items
  - strapping bands must not be used with cartons.

No loose forms should be inserted in the packages (such as QC testing). For example, these should be replaced with a stamp-marking directly on the outer package (eg "QC check passed"). If this is not possible, all forms should be inserted in the partly filled box.

3. Package labels

The package label must be attached at the side of each individual package. The partially filled package must additionally be labeled to allow for immediate identification.

For the purpose of identification cytostatic drugs, a label with the "yellow hand" symbol must be attached on each carton.

Only **thermal transfer paper** may be used for preparing the package label. We explicitly state that both direct thermal paper and high-gloss types will not be accepted.

The label must contain the following details:

- In legible text:
  - Customer item number
  - Item description
  - Batch number
  - Central pharmaceutical number (PZN)
  - Units contained (in pieces)
  - Package number (consignment number)
  - Expiration date (MM/YYYY)

- Barcode 128b with the following details:
  - Customer item number (11 digits)
  - Batch number (10 digits)
  - Package number (consignment number) (4 digits)

- Barcode 39 with the respective:
  - Central pharmaceutical number (7 digits or 8 digits)

Examples for a label with 7 and 8 digits for the PZN are on our SharePoint available. You can find the SharePoint address under point 10. When using this template, a release of the label is not necessary. The carton label must be filled out completely, for questions please contact the following contacts of our goods receipt departments.

If you cannot use our template, please send us in advance an email to the corresponding goods receipt with your new label to release it (see point 10):

- Finished goods for the german marked (except narcotics): Goods receipt Florstadt
- Finished goods for the export marked and narcotics: Goods receipt Bad Vilbel

Note: If you got our release for your label, a new release is only necessary if changes in layout / barcodes etc. are made. A new release is not necessary if material-based data is changed (e.g. batch number or product name).

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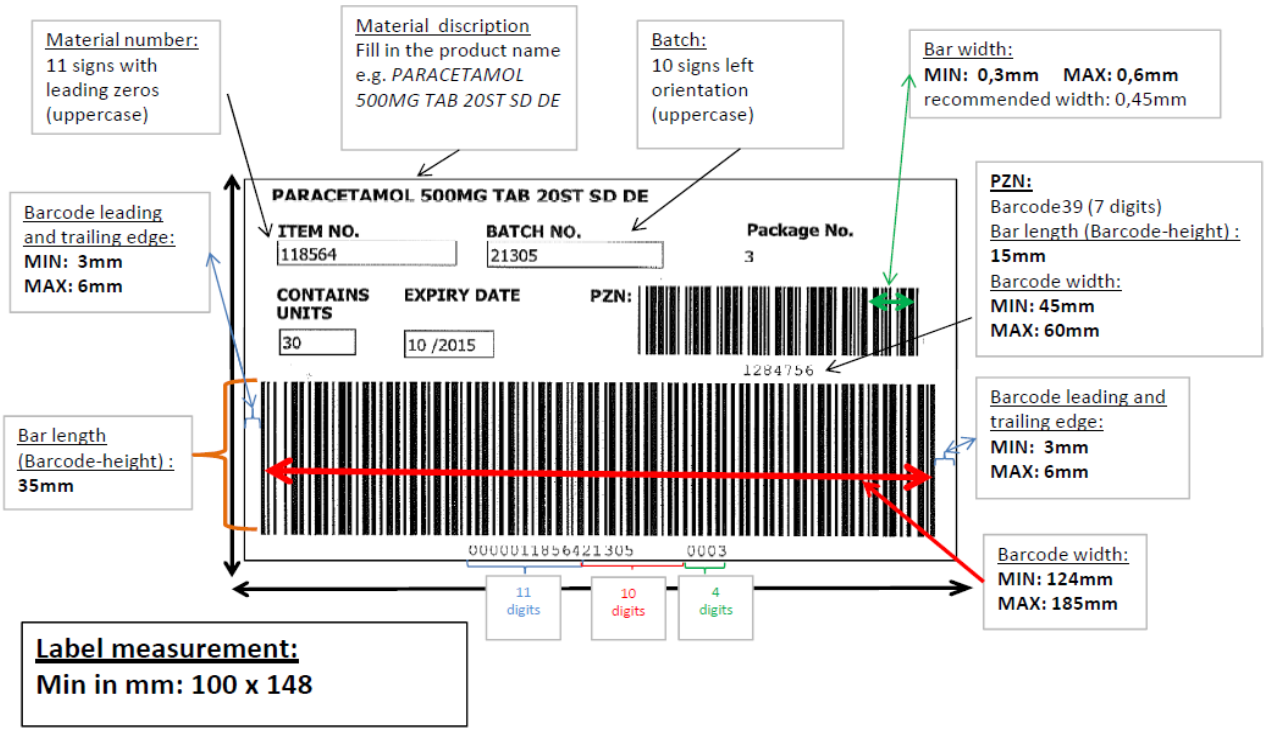
The following package label serves as example for preparation:

Material - Barcode-Type: **Code128B** (according to: **ISO/IEC 15417**)



Negative example: Print too weak

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Negative example: Non-compliance with blank area

Negative example: Modules too wide (bars)

4. Pallet height

Our logistics centers only accept deliveries on new, clean Euro pool pallets (length 1200 x width 800 x height 150 mm) pursuant to DIN EN 13698 (more information can be found on our SharePoint) and to the IPPC standard.

Pallet height/load height (pallet + load)

Norm 1	**max. 1050 mm**	(corresponds to a load height of 900 mm)
Norm 2	**max. 1500 mm**	(corresponds to a load height of 1350 mm)

Excess height is not permitted.

The maximum pallet weight of 750 kg must not be exceeded!
Stacking pallets is prohibited!

All delivered pallets must be wrapped in stretch film.
Too tight wrapping, a **stretch wrap underlayer** and **wrapping around the pallet** should be avoided.
Only when shipped by air or sea, the individual pallets must be equipped with edge protection.

5. Pallet label

The label must be placed visible on the outer layer of the stretch film of the pallet and contain the following details. Internal information / labels from the supplier / manufacturer as well must be placed on the outer layer of the stretch film of the pallet. On both sides of the pallet a good visible label with a temperature-note must be attached. If, for this purpose, the pallet label is used, it must be placed on both sides of the pallet as well.

- The pallet label has to contain following details in legible text:
  - Delivery address
  - Always mark items from the **narcotics** area with the address supplement **A11**
  - Customer item number
  - Item description
  - Batch number
  - Number of packages per pallet
  - Pallet number
  - Marking for data logger

6. Contents of delivery slip

Every delivery must be accompanied by a delivery slip, the following details are required:

- In legible text:
  - Delivery address
  - Always mark items from the **narcotics** area with the address supplement **A11**
  - Customer item number
  - Item number
  - Batch number
  - Customer order number
  - Delivery slip number
  - Name of supplier
  - Number of pallets per batch
  - Total amount per batch incl. partially filled package
  - Pallet number of pallet with partially filled package
  - Pallet number of pallet with data logger and position of pallet in truck
  - Total number of packages incl. partially filled package
  - Package contents
  - Temperature-note
  - Notes for Hazardous substances (even cytostatics)

7. Transport

Note: Following requirements have to be ensured from whom the transports are instructed, corresponding with the incoterms defined between the supplier and STADA Arzneimittel AG.

Delivery notifications:

Delivery notifications via fax, telephone or e-mail will not be accepted.
All deliveries must be registered at the online-portal:

www.cargoclix.com/stada

You'll find a detailed description how to register and how booking timeframes on our SharePoint at point 10 "contact and delivery times".

Delivery vehicles without agreed time frame have to expect waiting times; invoices for standing times as a result of disregarding the online notification duty will not be accepted.

For technical problems with the online-portal „cargoclix“ please contact their support.

For problems finding a time frame please contact the corresponding goods receipt (see point 10).

Transport temperatures:

The transport temperature should not adversely affect the quality of the product.

Cold transport:	+2°	to +8°C
Ambient transport:	+15°	to +25°C

Regardless of the duration of transport Temperature-records are to create for the complete supply chain of all transportations according to a validated process and validated technical equipment. At the time of delivery these are submitted per email in electronic form at “temptracking@stada.de”. Transport-temperature-Deviations have to be submitted in the same way.

All recording equipment must be qualified and calibrated for their purposes.

Data-Loggers should not be used - except in case of transportations as air-freight and/or sea-freight. Then Data-Loggers are to be used in addition to maybe (partially) existing other Temperature-recording-systems, please find more information and specifications about the use of data-loggers on our SharePoint (see point 10).

8. Consequences of missing labels

STADA Arzneimittel AG has the right to rectify missing or incomplete labels of the material with our own personnel at your expense. We reserve the right to reject acceptance of deliveries at your expense and your risk.

9. Consumption evidence to order

In case of deliveries of contract manufacturers it must be ensured that the delivery slips and the following proof of consumption have been completely filled in.

A form for the consumption evidence to order is available on our sharpoint. You´ll find the adress in point 10.

10. Contact and delivery times

STADA Arzneimittel AG
Stadastrasse 2 – 18
D- 61118 Bad Vilbel

Tel.: +49-(0)6101-603-320
Fax: +49-(0) 6101-603-3651
dscbv@stada.de
btm@stada.de

STADA Arzneimittel AG
Stadastrasse 11
D-61197 Florstadt

Tel.: +49-(0)6101-603-5010
Fax: +49-(0)6101-603-1717
dscfl@stada.de

The receipt of goods at the individual locations are open
Monday through Friday from **07.00 am – 05.00 pm**.

Further information on this Annex can be found on our SharePoint at:
https://www.stadaportal.de

User name: stadaag\barcode-supplier
Password: supplier1

Click on “Distribution & Logistics”, then choose “Barcode” and click on “Barcode Supplier”.

11. Delivery map

Your way to STADA