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**1. Purpose**

The purpose of this procedure is to define minimum delivery requirements for external vendors delivering into Teva. This document shall give guidance, there might be local procedures for some markets which differ from this document in some aspects. Transport to Teva requires temperature-controlled loading and transport processes using temperature monitoring logging devices – data loggers.

**2. Scope**

All Teva global external contract manufacturers delivering into Teva sites. This includes but is not limited to finished goods, bulk and API shipments if temperature controlled.

**3. References**

- 3.1 European Commission: Guidelines on Good Distribution Practice of medicinal products for human use, 2013/C 343/1, November 2013.
- 3.2. USP: General Chapter 1079, Good Storage and Distribution Practices for Drug Products, December 1st 2020
- 3.3. USP: 1079.2 Mean Kinetic Temperature in the Evaluation of Temperature Excursions During Storage and Transportation of Drug Products, December 1st 2020
- 3.4. USP: 659 Packaging and Storage Requirements. December 1st 2020
- 3.5 CORP-0129 Wooden Pallet Acceptance Criteria
- 3.6 CORP-0048 Control and Monitoring of Transportation of Pharmaceutical Products within Teva

**4. Definitions**

**EMSO** – External Manufacturing & Supply Operations


**API** – Active pharmaceutical ingredients

**Labeled Storage Conditions** – A storage statement established for the labeling in accordance with relevant national/regional requirements. The statement is based on the stability evaluation and temperature sensitivity of the product. The defined temperature limits are described on the product outer packaging.

**Transport** - Movement of pharmaceutical products within a designated supply chain starting after finishing the loading process at the shipping site and ending at the point of positioning at the receiving site.

**Control Room Temperature** – CRT. The temperature maintained thermostatically that encompasses the usual and customary working environment of 20°C–25°C (68°–77° F).

**Controlled cold temperature** - CCT. The temperature maintained thermostatically between 2° and 8° (36° and 46° F), which allows for temperature excursions between 8°C and 15°C (36° and 59° F) but not

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to exceed 24 h, such that the allowable calculated mean kinetic temperature (MKT) is NMT 8°C (46° F) with no excursions below 2°C or above 15°C (36° and 59° F). These limits (time and temperature) and the calculated MKT must be documented

**Monitoring devices** - Teva utilizes two types of monitoring devices, Controlant and Sensitech.

**FTL** – Full truck load – typically a road transport shipment consisting of more than 24 euro/US pallets per trailer (Pallet footprint)

**LTL** – Less than full truck load – typically up to 24 EU pallet (Pallet footprint) per shipment booked.

**Airfreight shipments** – mode of transportation that utilizes aircrafts with or without combined inland transportation.

**Ocean Shipments** - mode of transportation that utilizes ocean vessels and containers with or without combined inland transportation.

**Inland transportation** - mode of transportation that utilizes trucks, trailers, vans or any other vehicle on road/rail.

**HT** - An identification code for Heat Treated Wood Pallets. HT wood pallets are treated according to internationally agreed phytosanitation (measures requiring removal or destruction of infected or infested plant material likely to form source of re-infection or re-infestation) standards using a heat technology and conform to ISPM 15.

**IPPC** - International Plant Protection Convention. IPPC logo should appear on all wooden pallets treated according to national and international standards.

**ISPM 15** - International Standards for Phytosanitary Measures Publication No. 15.

**MB** - An identification code for Methyl Bromide Wood Pallets.

**ISO** – The International Organization for Standardization.

**Incoterms** - Short for "International Commercial Terms", the Incoterms rules are a set of 11 globally recognized standard trade terms created by the International Chamber of Commerce (ICC) to facilitate domestic and international B2B sales of goods.

## 5. Packaging requirements

The vendor must pack and identify product the items to be delivered in the required and appropriate manner so that they cannot be damaged under normal transport conditions (validation by ASTM 22 distribution protocol) and will not damage other goods. Furthermore, the regulations in Section Hazardous goods must be observed.

### 5.1 Pallet specification


The total pallet weight of the upper pallet shall not exceed 300 kg if pallets are considered being stacked

Pallet height:

Road freight: 1.20m if pallets are stackable; 1.15m if pallets are non-stackable being able to transport in double-deck trailers

Air freight: 1.20m

Ocean freight: 1.20m

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**6. Loading and transport**

The product-specific requirements for transportation and storage (e.g., +2 °C to +8 °C (36° to 46° F), +15 °C to +25 °C) (59° F to 77° F) or any other as required, must be observed when handling, loading and transporting time and temperature medicines. Product and batch mixtures are not permitted in containers or on pallets.

6.1 Loading

Insofar as the conditions or common usage do not provide otherwise, the shipping site must load, stow and secure the goods safely for transport (loading).

This does not affect the identification of hidden defects and is subject to the contractual arrangements where a supply contract is in place. The legal regulations are otherwise in force.

For road and multimodal transports, recording of date and time when loading/unloading in road transport started is required on the CMR, or other documented record for all temperature controlled shipments, in order to distinguish transportation duration from handling/warehouse process. Record of loading shall be entered at loading warehouse and offloading at the point of offload or cross-dock.


6.2 Transport vehicle

All pharmaceutical transport is to be carried out exclusively using GDP (Good Distribution Practice)-compliant vehicles. The Requirements can be found in the current valid version of the applicable GDP regulatory documents. Shipping site, if responsible for transport, will use only qualified transport vendors. The risk assessment shall be conducted to determine appropriate shipping system, equipment and lane used for temperature sensitive products.

**7. Cardboard packaging**

7.1 Cardboard quality

The vendor 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 and climatic stresses. It must be ensured that the cartons can be stacked. The following chapters 7.2 to 7.5 indicate best practices and recommendations.

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7.2 Tablets, ointments, and suppositories

Shipping carton quality: 1.4, single flute  
 Folding box quality: GC2 cardboard  
 Deviation from filling material to inner dimension of shipping carton: max. 2 cm

7.3 Ampules

Shipping carton quality: 2.3, double flute  
 Folding box quality: GC2 cardboard  
 Deviation from filling material to inner dimension of shipping carton: max. 1 cm

7.4 Vials and bottles

Shipping carton quality: 2.3, double flute  
 Folding box quality: F-flute with tab, GC2 cardboard  
 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

7.5 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

7.6 Carton size

The following formats shall 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 shall be greater than the height, and the carton opening must always be on top.

ASTM – single item transport  
 Required compression strength (N) =  $M_f \times J \times \frac{l \times w \times h}{K} \times \frac{(H - h)}{h} \times F$

M<sub>f</sub> = Shipping density, if unknown use 160 kg/m<sup>3</sup>  
 J = Metric conversion factor (kg to Newton) = 9,81

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H = Maximum stacking height, (if unknown use 2,7 m  
 If the packaged-product weighs less than 13,6 kg or has a volume lower than 0,056 m3, H will be reduced to 1,4 m)

h = Height of shipper (m)

l = Length of shipper (m)

w = Width of shipper (m)

K = 1 m3/m3

F = safety factor =7 (based on ASTM protocol assurance level II)

### 7.7 Weight

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

### 7.8 Filling material

Recycled paper, bubble plastic or chips made of starch is used as the filling material.

## 8. Labels

### 8.1 Pallet labels

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 be GS1 compliant and must contain the following information:

- Shipper
- Ship to address / destination
- Count (packages per pallet)
- Teva batch number e.g. G001, E002...
- 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



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### 8.2 Container labels

Container label requirements are listed. More specific requirements could be applicable as required and agreed upon.

Product and batch mixtures are only permitted with sufficient separation method.

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



123456

**TEST MATERIAL**

FOR SALE

Germany



Batch: S45675



000020 Pc/Box



Exp. Date: 12/2019



PCN -00452178

MFD 03/2017

### 8.3 Data logger labels


- Place this sticker on the carton with the temperature monitor (data logger)
- Place this sticker on the pallet with the temperature monitor (data logger)



### 8.4 Sample labels

- Place this sticker on the carton which contains samples



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- Place this sticker on the pallet which contains samples



## 9. Documents


Shipment should always contain the following documents: Commercial invoice, packing list, transport form, and data logger sheet indicating start date/time. There may be additional documents required, based on the product and ship to country, consult with the appropriate CTC team prior to export.

### 9.1 Commercial invoice

A single copy of the invoice must be sent by the vendor to the invoicing address given on the order.

- The full name and postal address of the vendor and the postal address of the service recipient specified on the invoice
- The tax number of the vendor issued by the Tax Office or the VAT identification number issued by the Federal Central Tax Office
- The VAT identification number of the service recipient specified on the Teva order
- The date of issue
- A unique, consecutive number with one or more rows of numbers allocated by the biller to identify the invoice (invoice number)
- The quantity and type (standard trade name) of the items delivered or the scope and type of the other service
- The time of the delivery or other service
- The fee for the delivery or other service itemized by tax rate and individual tax exemption, as well as each previously agreed reduction of the fee, insofar as these have not already been incorporated into the fee
- The price of each item in the shipment and total value of the items
- The tax rate to be used for the fee and the amount of tax to be paid, or in the case of a tax exemption, a note that a tax exemption has been applied to the delivery or other service
- Teva material number
- Teva product name
- Purchase order number

The Teva purchase order number or the cost center of the Teva unit that has placed the order is also required.

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## 9.2 Packing list

The vendor packing list should contain always:

- 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
- Vendor'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/AND.
- If the substances are subject to Section 35(1) of ADR/RID/ADNR/AND, indicate compliance with Section 35.
- For carriage under Chapters 3.4 and 3.5 of ADR/RID/ADNR/AND, a general reference to the dangerous goods in limited and excepted quantities is required.

## 9.3 COA/COC


A Certificate of Compliance (COC) is the documented form of the vendor that a batch conforms to a specified standard.

Certificates of Analysis (COA) on the other hand are the results of the physical testing that took place for each batch, to verify the specifications of the batch. They include not only the exact test results appropriate to the material being tested, but also information about the qualifications of those who performed the tests, the measurement systems used, as well as the tolerances appropriate to the materials.

Both the COC as the COA should be available with each batch sold to Teva.

## 9.4 Controlled substances (DEA) – Narcotic or Psychotropic Goods



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In case of controlled substance, shipping the export / import licenses are required per entry level. The original license must reach Teva Import department prior to the shipping out of the origin country.

#### 9.5 Narcotics

Narcotics of Classes II/III must be delivered exclusively to the location and person specified in the contract together with the relevant documentation pursuant to the Ordinances, following prior written notification.

On delivery, the delivery documentation must be surrendered spontaneously to the employees in Goods Inward.

#### 9.6 Hazardous goods

##### A) Legal specifications

Insofar as the ordered product concerns a dangerous good in the sense of the Hazardous Goods Act, you are obliged to observe and conform with all national and international legal regulations as amended from time to time (e.g. regulation-compliant packaging, identification and labelling of containers, preparation of transport documentation, etc.).

##### B) Hazard classification


The correct hazard classification for all modes of transport is part of the scope of delivery and must conform minimally to Item 14 of the EU Safety Data Sheet.

##### C) Safety Data Sheet

Where the delivered material is a hazardous good, the vendor is obliged to submit the current safety data sheet for the corresponding product pursuant to Regulation (EC) No. 1907/2006/EC, Annex 2 (in the current valid version) with the order confirmation.

In the event of changes, the vendor is obliged to provide Teva with each current version spontaneously and promptly.

The vendor must ensure that the registration number in the safety data sheet assigned pursuant to Article 20(1) in the ordinance above is provided.

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## 10. Stackability

It's a default requirement to have all pallets stackable as described in the below paragraph.


### 10.1. When to stack

A pallet is stackable where:

- Maximum pallet height is clarified under point 5.1 of this document
- Maximum pallet weight of the upper pallet does not exceed 300kgs
  - Pallets over 300kgs must be marked with a large label saying "HEAVY PALLET"
- Each layer of boxes must have the same dimension as the pallet they are loaded on
  - Overhang not allowed
  - Excess space not allowed
- The boxes must be sealed or strapped to the pallets to avoid shifting
- Corner protectors to be used at all times
- Supporting cardboard layer on top of lower pallet.
- The top layer of each pallet must be flat and complete
- All boxes on each pallet must be full (still allowing data logger in the central top layer box as in paragraph 11) and strong enough to carry the weight of the goods stacked on top
- No such labels can be applied to the pallets stating, eg.
  - Do not stack/ Do not stack on top
  - Not stackable



*Please find appendix for additional examples*

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10.2. When not to stack

- Irregular shape and layers' dimensions different from pallet's dimensions
- Top layer incomplete, not flat
- Boxes too far within the pallet's dimensions
- Boxes too far within the pallet's dimensions AND top layer incomplete
- Boxes too far within the pallet's dimensions, irregularly shaped and not flat
- Vendor are to indicate clearly the number of stackable and non-stackable pallets in the transportation form.



*Please find appendix for additional examples*

**11. Data loggers**

Data loggers shall be set to record temperature four (4) to six (6) times within an hour depending in the respective regulatory requirement.

11.1. Number of data loggers

The number of loggers that should accompany each shipment are as follows, unless otherwise justified and documented:


**Air Shipments**

Shipments loaded in air freight active temperature controlled unit loading devices (containers) will have two (2) data loggers per unit loading device regardless of the number of pallets in container.

When passive pallet shippers are used, two (2) data loggers shall be applied for single pallet shipment and one (1) data logger per pallet for more than one pallet in the passive pallet shipper.

For the airfreight shipment using only thermal blankets:

- One (1) data logger per pallet shall be used for shipments of more than one pallet where this is a regulatory expectation
- Two (2) data loggers shall be used for single pallet shipments.

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- Split shipments for a single AWB (Airway Bill) are not allowed in Teva, and must follow single airline throughout the airfreight destination. If there is no specific regulatory expectation for 1 data logger per pallet on the receiving market, the shipping site can utilize fewer data loggers (not less than 2) in multiple pallet shipments based on documented risk assessment.

**Ocean Shipments**

For temperature sensitive products, the use of temperature controlled ocean reefers is mandatory throughout the year. For ocean freight shipments in temperature controlled reefer containers two (2) data loggers shall be used per container.


**Road Shipments**

Full temperature controlled truck loads (FTL) shall be utilized with max. two (2) data loggers per truck. For the less than full truck loads in road transport (LTL) following provisions are applicable:

- Two (2) data loggers shall be used in LTL service for shipments of one pallet.
- For the LTL shipments of more than one pallet, two (2) data loggers should be used per each shipment.

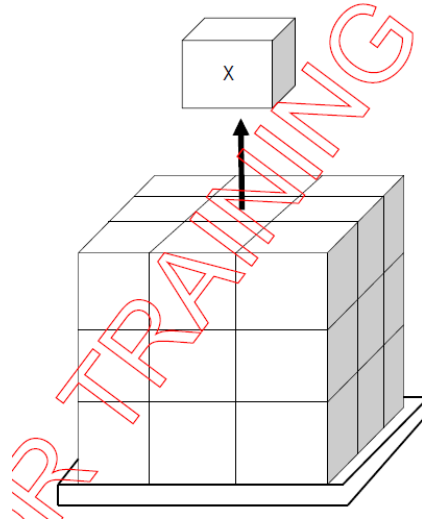
11.2. Process of use of data loggers includes but is not limited to:


- The data loggers must be activated in the preconditioned area only and labelled with the date and batch designation
- Two data loggers per delivery or payload must be placed in two different positions of the delivery/payload
- The data loggers must be included in a separate carton on the incomplete pallet
- The carton must be clearly labelled and bear the following text: “Data logger inside” (corresponding labels are provided with the data loggers if required)
- The delivery papers must note the pallet on which the loggers are located
- Shipper has to check with consignee before dispatch the shipment on shipping documentation requirements for data loggers. In particular, if there should be a separate set of shipping documents for data loggers (i.e. a separate invoice or proforma-invoice, packing list and/ or transport document) and what regional requirements for the content of such documents are.

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### 11.3. Placement of data loggers

The loggers should, wherever possible, be placed in shipper cartons within the shrink-wrap and included in the center of the top horizontal layer of the pallet. If there is no place for the loggers inside the cartons, it is acceptable to place the loggers inside small cardboard containers or paper envelope. Each transport of pharmaceuticals requires data loggers. In any case the they should be part of the package layer.



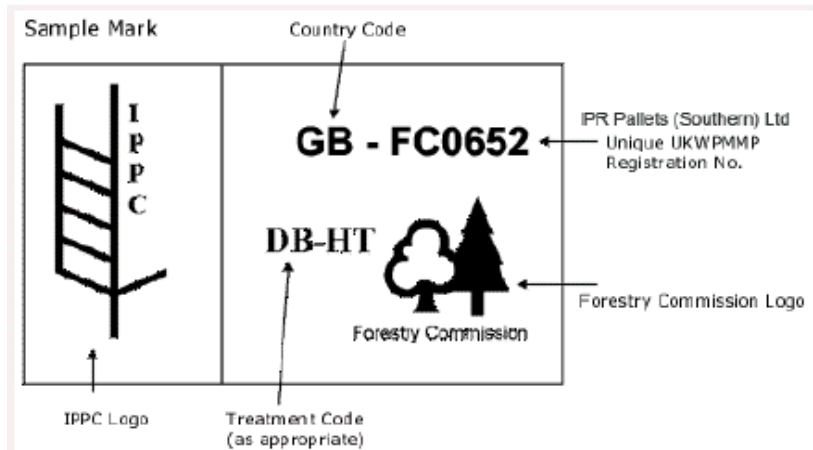
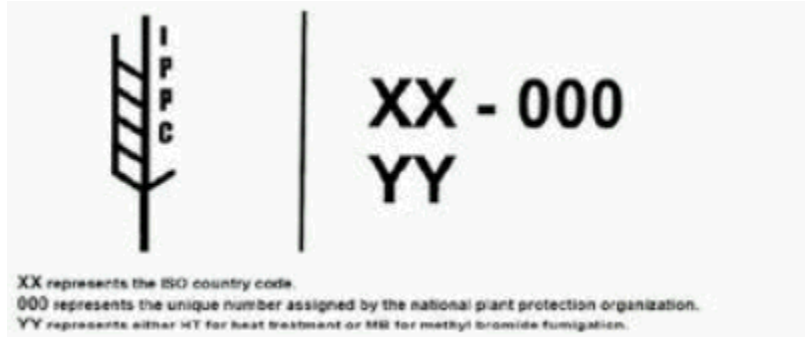
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### 12. Pallets

All shipments must be on wooden pallets and need to be heat treated using standards according to ISPM 15. IPPC logo should appear on all wooden pallets treated according to national and international standards. Pallets that are chemically treated (methyl bromide fumigated pallets) according to internationally agreed phytosanitation standards and conform to ISPM 15.

Pallets that are acceptable both nationally and internationally in shipping operations make use of standard identifications and include the following treatment or quality marks (see pictures):

- IPPC logo: Pallets with this symbol do not require treatment certificates.
- ISO regulated country code: A two-letter abbreviation code, such as "US" for the United States, "CA" for Canada, "GB" for United Kingdom, "CZ" for Czech Republic, "HR" for Croatia, "PL" for Poland.
- A unique three digit number assigned to the treatment facility by an inspection agency or by the exporting country's national plant protection organization.
- An "HT" or "MB" code that represents type of treatment. "HT" for heat treated or "MB" for



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methyl bromide fumigation.

**13. Incoterms**

It is critical that a buyer and seller agree to the appropriate INCOTERMS to clearly define the respective obligations, costs and risks involved with the delivery of goods from the seller to the buyer. These include, but are not limited to:

- legal “exporter of record” and “importer of record”
- national and international freight arrangements and costs
- Insurance
- Customs, license, authorization etc. responsibilities


The Incoterm exists of a 3 letter code and the location, as specific as possible. For example “DAP 2020 Teva, Weston, FL USA.” The Incoterm in the contract, PO and any other document should match.

Teva is unable to accept ExWorks in cross border transactions because we are unable to act as the “exporter of record” from a foreign country. Further, ExWorks imposes additional Compliance, Regulatory, Legal and Tax obligations.

Given the restrictions with DDP (it can only be used when purchasing products), our strong recommendation is to refrain from using DDP in cross-border transaction to avoid any customs/tax issues and to be aware of the obligation to handle all customs clearance formalities both on the export and import side.

Please utilize use one of the following INCOTERMS to ensure that one logistics service provider (LSP) is managing the shipment “door-to-door” to preserve the chain of custody and ensure proper temperature and handling conditions.

<b>Incoterms + location (must always list a location)</b>	<b>LSP Account (who pays for freight)</b>	<b>Foreign Country “Exporter of Record”</b>	<b>“Importer of Record”</b>
<b>DAP (Teva Site)</b> “Delivered At Place” Example: “DAP Teva, Weston, FL USA”	Seller / Shipper Account	Seller / Shipper	Teva importer – must be in the possession of required licenses
<b>FCA (Shipper Site)</b> “Free Carrier” Example: “FCA Watson Goa”	Teva’s Account Logistics “door-to-door” service	Seller / Shipper	Teva Branded Pharmaceutical Products R&D, Inc.

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If your vendor requests alternate terms, would you please contact the Customs team for guidance who will liaise with the appropriate internal functions: (i.e.: CIF, CIP, CPT et al)

**14. Penalties (Extra charges)**

When not following the guidelines described in this document, Teva reserves the right to charge additional costs. The extra charges could be:

- Demurrage costs (caused by waiting hours)
- Wasted journey costs (caused by confirmed shipment not ready for pick up / or wrong pickup address)
- Re-palletize costs (cause by wrong pallets used)
- Inbound charges (caused by mislabeling from the vendor)
- Cost of delay (caused by not providing the complete (filled out) set of documents / transport form)
- Damage cost (caused by stacking non-stackable pallets)
- In case of non-performance (delays) which makes an expedited transport (e.g. airfreight, dedicated truck) necessary




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## 15. Appendix

### 14.1. Appendix A – Stackability

#### Examples of stacked pallets:




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**Examples of pallets that are not stackable:**


- Irregular shape and layers' dimensions different from pallet's dimensions:



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- Top layer incomplete, not flat



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- Boxes too far within the pallet's dimensions



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- Boxes too far within the pallet's dimensions AND top layer incomplete



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- Boxes too far within the pallet's dimensions, irregularly shaped and not flat



**SUMMARY OF CHANGES**

Date	Summary of Revision	Reason for Revision
10 October, 2022	New Document	N/A