

# **Delivery instructions**

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**Raw materials** 



In addition to the Delivery Instructions, General Section, the following specifications apply to raw materials:

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## 1. Raw materials

Deliveries must consist of a single batch. If this is not possible, the supplier must obtain Teva's approval.

#### 1.1 Packaging/pallets

Product and batch mixtures are not permitted on the pallet (pure batch).

Containers of raw materials (API, excipients) must be placed in a single layer on the pallet. The containers should ideally be secured on the pallet with tension straps. In this case, the use of plastic wrap is not required.

Owing to the danger of injury, containers must not have sharp-edged surfaces (e.g. drums with sharp-edged tension rings).

Containers must not extend past the edge of the pallet by more than 3cm. Max. pallet weight: 800kg incl. pallet

Pallet height national: max. 1.20m international: max. 1.15m

For deliveries in Big Bags and containers, the supplier can agree exceptional conditions with Teva.

### 1.2 Analysis certificate

The batch-related analysis certificate must in general contain the following details:

- Details of the pharmacopoeia used for testing
- All test points according to the pharmacopoeia or Teva raw material specifications (according to the purchase order text), providing the target and actual values
- Reference of the COS with date and version, if available
- Manufacturing date
- Manufacturing location
- Retest date
- For mixtures, the mix ratio and specifications of the individual components
- Manufacturer's batch number
- Exact values for quantitative determinations
- Identification of the test points which are not routinely tested
- Legally binding signature

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The original version of the analysis certificate is to be sent to the follow email address:

> RSK@ratiopharm.de

For deliveries from a non-EU country, a Written Confirmation Letter is required for each delivery. The supplier must ensure that a copy of this document is a component of the delivery papers and accompanies each delivery.

For drop shipping, the analysis certificate and release certificate must remain with the goods. In addition, both documents must be sent to the follow email address:

batchdocumentation@tevaeu.com