TRACELINK UNIVERSITY

Set up products

Master data records include the product's item code, target market, item information, packaging information, and export market information on TraceLink. Owners can search for, view, and add product master data. The product's master data is used by other Tracelink applications when taking an action on a product.

Access to setting up products

Companies or Partners that own or link to Opus apps have access to the Administration menu item, which displays in the side menu of the Opus Platform. The products functionality available to users depends on the role they are assigned.

Master data roles

Role	Description
Full Access	Allows users to administer the Master Data solution to add and edit a product's item code, target market, item information, packaging information, and export market information for product master data records using the product APIs.
Member - Expanded UI Access	Allows users to administer the Master Data solution that their company owns to filter and view product's item code, target market, item information, packaging information, and export market information for product master data records.

At this time, a user needs to be assigned the **Full Access** role and the **Member - Expanded UI Access** role to add and edit product's item code, target market,

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item information, packaging information, and export market information for product master data records in the Administer UI.

Add a product

Master data records include the product item code, description, and item information on TraceLink. Owners and Partners can search for, view, and add product master data. The product master data is used by other Tracelink applications when taking an action on a product.

Add product information

Add the product information including the item codes, target market, item information, packaging information and export market information.

1. Select the Main Menu icon.
2. Select Master Data from the drop-down.
3. Select Products.
4. Select the Add icon to add product information, item codes, and target market information.
5. Fill in the following fields in the Product Information section:
    a. Product Group Code field – An internal code defined by the user's company that identifies products in the same product classification (e.g. group code for all products related to oncology).
    b. Effective Date field – The date that the product master data takes effect.
    c. Data Status drop-down – Required. The product information is either active or inactive within TraceLink:
        - Active – The data can be used in messages and UI functions, and TraceLink leverages the data when necessary.
        - Inactive – The data cannot be used for other functions within TraceLink.
    d. Item Status drop-down – Required. The product's commercial status:

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- Alternate items available – An alternate product is available.
- Items no longer stocked – The product is not currently stocked.
- Phase out – The product is no longer available for production or sale.
- Released – The product is approved for commercial sale.
- Withdrawn – The product is removed from the market.

6. Fill in the following fields in the Item Codes section:
   a. Item Code Type drop-down – Required. The item code used for this product. Each item code type can only be used once for each product, except for internal material number.
   b. Item Code Value field – Required. The value associated with the item code. The value must be unique within the **Item Code Type**, and special characters (e.g. -, ., /. \) are removed from this value.
   c. Select the Add icon to add another Item Code Type drop-down and Item Code Value field.
7. Select the Add icon in the Target Market section.
8. Fill in the required Country Code in the Country Market section.
9. Fill in the following fields in the Market Information section:
   a. Product Type drop-down – The type of product:
      - Bulk Pharmaceutical – A bulk pharmaceutical product.
      - Derivative Product – A derivative product.
      - Food Supplement – A nutritional product.
      - Medical Device – A medical device.
      - Nutritional Product – A nutritional product.
      - OTC Drug – An over the counter product.
      - Prescription Drug – A prescription medicine.
   b. Registration Classification drop-down – The product classification at the time of registration:
      - Biological – The product is classified as biological.
      - Chemical – The product is classified as chemical.

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- Patent Medicine – The product is classified as a patented medicine.

c. Prescription Drug Type drop-down – Specifies whether the medicine is available by prescription only:
   - Anabolic steroid – An anabolic steroid prescription product.
   - Antiretroviral – An antiretroviral prescription product.
   - Controlled plant – A controlled plant prescription product.
   - Immunosuppressive – An immunosuppressive prescription product.
   - Narcotic – A narcotic prescription product. It is applicable if the target market for this product is India.
   - Other – A prescription product that does not fall into another category. It is applicable if the target market for this product is India.
   - Pharmaceutical precursor chemical – A pharmaceutical precursor chemical prescription product.
   - Prohibited Substance – A prohibited substance prescription product.
   - Psychoactive anorectic – A psychoactive anorectic prescription product. It is applicable if the target market for this product is India.
   - Psychoactive anti-anxiety – A psychoactive anti-anxiety prescription product. It is applicable if the target market for this product is India.
   - Psychoactive antidepressant – A psychoactive antidepressant prescription product. It is applicable if the target market for this product is India.
   - Psychoactive antiepileptic – A psychoactive anti-epileptic prescription product. It is applicable if the target market for this product is India.
   - Psychoactive antipsychotic – A psychoactive anti-psychotic prescription product. It is applicable if the target market for this product is India.
   - Psychoactive mood stabilizer – A psychoactive mood stabilizer prescription product. It is applicable if the target market for this

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product is India.

- Psychoactive sleep inducer – A psychoactive sleep inducer prescription product. It is applicable if the target market for this product is India.
- Psychoactive stimulant – A psychoactive stimulant prescription product. It is applicable if the target market for this product is India.
- Radioactive – A radioactive prescription product.
- Retinoid – A retinoid prescription product.
- Toxic drug for medical use – A toxic medical prescription product.

d. Point of Dispense Verification drop-down – Specifies whether the product has a point of dispense verification requirement:
   - Not Required – The product does not have a point of dispense verification requirement.
   - Required – (default) The product has a point of dispense verification requirement.

e. Traceability Required drop-down – Specifies whether the product legally needs to be traced through the pharmaceutical supply chain:
   - Not Required – The product is exempt from tracking.
   - Required – The product requires tracking.

f. Product Origin drop-down – Specifies how the product was sourced by the company selling the product:
   - DirectPurchaseExclusiveDistributor – The company acquires the product as a direct purchase from the exclusive distributor of the manufacturer.
   - DirectPurchaseManufacturer – The company acquires the product as a direct purchase from the manufacturer
   - DirectPurchaseRepackager – The company acquires a product as a direct purchase from a repackager who purchased directly from the manufacturer.
   - IndirectPurchase – The company acquires a product as an indirect

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purchase from a supplier or repackager that did not acquire the product directly from the manufacturer.

- Originator (Manufactuer) – The company is the manufacturer of the product and sells the product into the supply chain.
- Originator (Exclusive Distributor) – The company that purchased the product is the exclusive distributor of the product.

g. Scheduled Drug drop-down – Specifies whether the product is classified in one of the schedules assigned to controlled substances:
   - Yes – The target market considers the product a scheduled drug.
   - No – The target market does not consider the product a scheduled drug.

h. PCID field – The medicinal product package identifier (i.e. PCID) that determines the EU Hub's Article 57 Code on master data compliance reports.

i. Reporting Item Code Type drop-down – The product's Item code that is used in a specific target market instead of the target market's default Item Code for compliance reporting.

j. Reporting Item Code Value field – The reporting item code value for this target market.

k. Marketing Authorization Number field – The product’s authorization number issued by a government agency.

l. Product Category Identifier field – The commodity tariff code that classifies the product when determining its customs value.

10. Fill in the following fields in the Manufacturing Information section:
    a. Production Type drop-down – Specifies where the product is manufactured relative to the country defined in the Target Market:
       - Imported – The company manufactures the product outside the target market.
       - Imported and Repackaged Locally – The company manufactures the product outside of the target market but packages it in the target

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market.

- Locally Manufactured – The company manufactures the product in the target market.

b. Manufactured By drop-down – The type of organization manufacturing the product:
   - CMO – (Contract Manufacturer Organization) The company contracts a third-party organization to manufacture the product for this Target Market.
   - MAH – (Marketing Authorization Holder) The company is registered as the product's MAH for this Target Market.
c. MAH ID Type drop-down – Conditionally required if MAH is selected in the Manufactured By field. The company or location identifier of the MAH, which must exist in Company or Partner Master Data. If the Target Market is in India, this value must be the GS1 Company Prefix.
d. MAH ID Value field – The value associated with the MAH ID. The value must be unique within the **MAH ID Type** and special characters (e.g. -, ., /. \) are removed from this value.
e. Manufacturing CMO ID Type drop-down – The company ID for the CMO manufacturing the product.
f. Manufacturing CMO ID Value field – The value associated with the Manufacturing CMO ID Type. The value must be unique within the **Manufacturer CMO ID Type**, and special characters (e.g. -, ., /. \) are removed from this value.
g. MAH Internal Material Code field – The Internal Material Code used by the MAH for the product.
h. CMO Internal Material Code field – The Internal Material Code used by the CMO that manufactured the product.
i. Virtual CMO ID Type drop-down – The Internal Material Code used by the Virtual CMO for the product.
j. Virtual CMO ID Value field – The value associated with the Virtual CMO ID.

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The value must be unique within the **Virtual CMO ID Type**, and special characters (e.g. -, ., /. \) are removed from this value.

k. License for Permanent Import field – The license number granted to import product that cannot be exported and will remain in the country permanently.
l. License for Permanent Import End Date field – The date on which the License for Permanent Import expires.
m. License for Temporary Import field – The license number granted to import product that will remain in the country temporarily before being re-exported.
n. License for Temporary Import End Date field – The date on which the License for Temporary Import expires.
o. Importer ID Type drop-down – The identifier type and value of the company that is importing the product into the Target Market.
p. Importer ID Value field – The value associated with the Importer ID. The value must be unique within the **Importer ID Type**, and special characters (e.g. -, ., /. \) are removed from this value.
q. Repackaging License Number field – The repackager license number.
r. End Date field – The date when the repackaging license number expires (YYYY-MM-DD format).
s. Repackager ID Type drop-down – The identifier type and value of the company that repackages the product.
t. Repackager ID Value field – The value associated with the Repackager ID. The value must be unique within the **Repackager ID Type**, and special characters (e.g. -, ., /. \) are removed from this value.
u. Virtual CMO Internal Material Code field – The language for the item information.
v. Distribution Partner ID Type drop-down – The trade partner companies or internal locations that the MAH uses to distribute the product in the Target Market (e.g. 3PL). This company must exist in Partner Master Data

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or as a location in Company Master Data.

w. Distribution Partner ID Value field – The value associated with the Distribution Partner ID. The value must be unique within the **Distribution Partner ID Type**, and special characters (e.g. -, ., /. \) are removed from this value.

x. Select the Add ⊕ icon to add another Distribution Partner ID Type drop-down and Distribution Partner ID Value field.

11. Select Next to add item information, packaging information and export market information.
12. Fill in the required Language Code in the Add Item Information section.
13. Fill in the following fields in the Language Information section:
    a. Product Description field – Required. The product description, which includes the product name, dosage, form, and the number of doses.
    b. Product Code field – The regulatory product code associated with the product in China, or an additional product code in other target markets.
    c. Product Name field – Required. The name of the medicine that is displayed on the product label.
    d. Generic Name field – The chemical or non-proprietary name of the product. The generic name describes the chemical make up (atomic or molecular structure) of the product in contrast to the brand name that is used to market it.
    e. Manufacturer field – Required. The name of the manufacturer as it appears on the product label.
    f. Manufacturer ID drop-down – The ID for the manufacturer or re-packager of the product as it appears on the product label (e.g. GLN 123412341).
    g. Strength field – The strength of the product (e.g. 100 mg).
    h. Drug Composition field – The chemical composition of the product. The maximum character length is 500 characters if the Target Market is in India.
    i. Dosage Form field – The dosage form of the product (e.g. tablet,

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capsule).

j. EMVS Dosage Form drop-down – The form the product is dispensed in according to the EU's standard set of values.
k. Market Dosage Form drop-down – The form the product is dispensed according to a specific Target Market's set of values.
l. Container Size and Spec field – The number of individual doses in the pack.
m. EMVS Pack Code drop-down – The way the product is packaged to be sold according to the EU's standard set of values.
n. Comments field – Product-related instructions or comments not described in the previous fields.
o. Minimum Temperature field – The coldest temperature the product can be exposed without compromising its quality and safety. If the Maximum Temperature and Minimum Temperature values are both provided, the Minimum Temperature must be less than or equal to the Maximum Temperature value.
p. Maximum Temperature field – The hottest temperature the product can be exposed to without compromising its quality and safety. If the Maximum Temperature and the Minimum Temperature values are both provided, the Maximum Temperature value must be greater than or equal to the Minimum Temperature value.
q. Temperature Scale drop-down – Conditionally required if either Minimum Temperature or Maximum Temperature are present. The temperature scale that the Minimum Temperature and Maximum Temperature are entered in:
    - Celsius
    - Farenheit
    - Kelvin
r. Sensitive to Light drop-down – Specifies whether exposure to light can compromise the product's quality and safety:

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- Yes – Exposure to light can compromise the product's quality and safety.
- No – Exposure to light does not compromise the product's quality and safety.

s. Shelf Life drop-down – Specifies the length of time that a product remains consumable. The value must be a number between 1-9999:
   - Days – The shelf-life value is provided in days.
   - Months – The shelf-life value is provided in months.
   - Years – The shelf-life value is provided in years.

14. Select the Add icon in the Packaging Information section.
15. Fill in the following fields in the Packaging Information section:
    a. Data Status drop-down – The packaging information is either active or inactive within TraceLink:
       - Active – The data can be used in messages and UI functions, and TraceLink leverages the data when necessary.
       - Inactive – The data cannot be used for other functions within TraceLink.
    b. Packaging Code Type drop-down – The serial numbers for the product are generated according to the packaging code type. If necessary, define a packaging code for each **Packaging Level** that needs to be tracked:
       - CN-ResCode – This packaging code type is specific to China (must be 5 digits).
       - GTIN-14 – (Global Trade Item Number) This packaging code type is accepted in any country (must be 14 digits).
       - NTIN – (National Trade Item Number) This packaging code type is specific to a single country (must be 14 digits).
16. Packaging Code Value field – The value associated with the Packaging Code Type. The value must be unique within the **Repackager ID Type**, and special characters (e.g. -, ., /. \) are removed from this value.
17. Container Aggregation Quantity drop-down – The number of children

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contained in this level of shipment. (e.g. For a Case, the Container Aggregation Quantity lists the number of Inner Packs contained in each Case.):

- Primary – The level of packaging that physically touches the product (i.e. blister packs). This level is not available for CN-ResCode.
- Each – The smallest salable unit of the product.
- Inner Pack and Bundle – A grouping of eaches.
- Case and Shipper – A grouping of inner packs/bundles or a grouping of eaches if the packaging hierarchy does not include inner packs/bundles.
- Pallet – The level of packaging with cases grouped together on a pallet. This level is not available for CN-ResCode
- None – Available only for CN-ResCode.

18. Packaging Level drop-down – (Packaging Unit of Measure) Determines the level of the packaging hierarchy for this packaging code. If multiple packaging codes are defined, serial numbers can be generated for each level of the packaging hierarchy:

- Primary – The level of packaging that physically touches the product (i.e. blister packs). This level is not available for CN-ResCode.
- Each – The smallest salable unit of the product.
- Inner Pack and Bundle – A grouping of eaches.
- Case and Shipper – A grouping of inner packs/bundles or a grouping of eaches if the packaging hierarchy does not include inner packs/bundles.
- Pallet – The level of packaging with cases grouped together on a pallet. This level is not available for CN-ResCode.
- None – Available only for CN-ResCode.

1. Packaging Ratio field – Conditionally required if the Packaging Code Type is CN-ResCode. The ratio of the packaging levels included within this packaging code (e.g. 1:5:10 refers to one large case, with 5 smaller inner packs/bundles inside, each of which contains 2 eaches for a total of 10 eaches).

TraceLink only uses this field for compliance reporting purposes, not validation

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during aggregation.

2. Batch Size Maximum field – The maximum batch size that is acceptable for the product. This field is only used when the value of Packaging Level is EACH.
3. Batch Size Acceptable field – The acceptable size of the batch determined by percent. The numeric values must be between 1-100.
4. Serialization Type drop-down – The type of serialization required for the packaging code:
    - None – No serialization.
    - Random – Random serialization.
    - Sequential – Sequential serialization.
5. Requires Aggregation drop-down – Specifies if each Packaging Level requires serial numbers:
    - Aggregated – Each Packaging Level requires serial numbers.
    - Not Aggregated – Not every Packaging Level requires serial numbers.
6. Filter Value field – drop-down. Control information that allows an RFID reader to select only the packaging code for this packaging level, out of many other levels of packaging codes. The numeric values must be between 0-7.
7. GS1 Company Prefix field – Conditionally required if the Packaging Code Type is GTIN-14. The prefix is included in the packaging code and it is assigned by the GS1 organization.

   TraceLink uses this prefix to convert serial numbers in barcode format to the EPC URN format used in EPCIS messages.

8. Code Version field – Conditionally required if the Packaging Code Type is CN-ResCode. The product code version number (e.g. 81, 88).
9. Code Level field – Conditionally required if the Packaging Code Type is CN-ResCode. The packaging level associated with this ResCode. The numeric values must be between 1-9 with the innermost packaging level.
10. Select the Add icon in the Export Market section.
11. Fill in the following fields in the Export Information section:
    a. Export from Country drop-down – The country where the exported products are being shipped from. The country is identified using the standard two- or three-letter abbreviation specified in ISO 3166-1alpha-2:1997 country code.
    b. Export to Country drop-down – The country where the exported products are being received. The country is identified using the standard two- or three-letter abbreviation specified in ISO 3166-1alpha-2:1997 country code.

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c. Manufactured By drop-down – The type of organization manufacturing the product:
    - MAH – (Marketing Authorization Holder) The company is registered as the product's MAH for this Target Market.
    - CMO – (Contract Manufacturer Organization) The company contracts a third-party organization to manufacture the product for this Target Market.
d. Unit Price field – The price per unit of the product in the target market. If a unit price is entered and the country manufacturer is IN (India), the value must be a number from 0.50 – 9999999.99.
e. Currency Code drop-down – Conditionally required if the Unit Price is specified. The currency code for the product's unit price in ISO 4217:2015 format.
f. Manufacturer ID Type drop-down – The type of identifier used for this manufacturer.
g. Manufacturer ID Value field – The value associated with the Manufactuer ID. The value must be unique within the **Repackager ID Type**, and special characters (e.g. -, ., /. \) are removed from this value.

12. Fill in the following fields in the Exemption Information section:

a. Export Country Exemption drop-down – Specifies if the product is exempt from regulatory compliance in the Export to Country field.
b. Exemption Reference field – The name of the law or regulation in the destination country for which the exporter has obtained exemption permission.
c. Export Country Exemption Code drop-down – The exemption category code for exempted product with enumeration values in India:
    - IN - Consignment – Consignments that contain products for export to countries that are eligible for exemption from India's bar-coding law.
    - IN - Manufacturer – Products that need bar-coding for the import countries' bar-coding requirements, rather than the requirements in

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India.

d. Exemption Date field – The date the exemption request has been granted to the exporter by the governing agency of the destination country (can be the date of the published law).

13. Select Add.

The product information, item code, target market information, item information, packaging information and export market information is saved to the product.

Export product master data

Export and download a CSV file with product master data.

1. Select the Main Menu icon.
2. Select Master Data from the drop-down.
3. Select Products.
4. Select the Export icon to generate and export the product master data file.

   A notification displays when the file is ready, and the file downloads automatically.

Tips

- Select View Imports and Exports to view the Product export details on a separate screen.

See the columns that display in the product master data CSV file

The element headers below are all required in the CSV file, in order, and separated by commas. The data in the individual cells can be empty.

- **Primary Item Code Value** – The value used to identify the primary item code. If a product has multiple item code types and values, the Primary Item Code Value and Primary Item Code Type are the same for each entry in the

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CSV file.

- **Primary Item Code Type** – The primary item code used for this product. If a product has multiple item code types and values, the Primary Item Code Value and Primary Item Code Type are the same for each entry in the CSV file.
- **Item Code Value** – The item code value. The value must be unique within the Item Code Type, and special characters (e.g. -, ., /. \) are removed from this value.
- **Item Code Type** – The item code used for this product. Each item code type can only be used once for each product, except for internal material number.
- **Item Code Is Primary** – The primary item code for this product.
- **Product Group Code** – An internal code defined by the user's company that identifies products in the same product classification (e.g. group code for all products related to oncology).
- **Data Status** – Specifies whether the product information is active or inactive within TraceLink.
- **Item Status** – The product's commercial status.
- **Effective Date** – The date that the product master data takes effect (YYYY-MM-DD format).
- **Target Market Country** – The product country code.
- **Target Market Product Type** – The type of product.
- **Target Market Point of Dispense Verification** – Specifies whether the product must be verified as authentic before being dispensed.
- **Target Market Traceability Required** – Specifies whether the product legally needs to be traced through the pharmaceutical supply chain.
- **Target Market Product Origin** – Specifies how the product was sourced by the company selling the product.
- **Target Market Scheduled Drug** – Specifies whether the product is classified in one of the schedules assigned to controlled substances.
- **Target Market Manufactured By** – The type of organization manufacturing the product.

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- **Target Market Production Type** – Specifies where the product is manufactured relative to the Target Market Country.
- **Target Market MAH ID Value** – The value used to identify the target market MAH. The value must be unique within the Target Market MAH ID Type and special characters (e.g. -, ., /. \) are removed from this value
- **Target Market MAH ID Type** – The company or location identifier of the MAH, which must exist in company or Partner master data. If the Target Market Country is India, this value must be the GS1 Company Prefix.
- **Target Market CMO ID Value** – The value used to identify the Target Market CMO. The value must be unique within the Target Market CMO ID Type, and special characters (e.g. -, ., /. \) are removed from this value.
- **Target Market CMO ID Type** – The company ID for the CMO manufacturing the product.
- **Target Market Virtual CMO ID Value** – The value used to identify the Target Market Virtual CMO. The value must be unique within the Target Market Virtual CMO ID Type, and special characters (e.g. -, ., /. \) are removed from this value.
- **Target Market Virtual CMO ID Type** – The company ID for the virtual CMO manufacturing the product.
- **Target Market Distribution Partner ID Value** – The value used to identify the distribution partner. The value must be unique within the Target Market Distribution Partner ID Type, and special characters (e.g. -, ., /. \) are removed from this value.
- **Target Market Distribution Partner ID Type** – A trade partner company or internal location that the MAH uses to distribute the product in the Target Market (e.g. 3PL). This company must exist in Partner master data or as a location in company master data.
- **Target Market Product Category Identifier** – The commodity tariff code that classifies the product when determining its customs value.
- **Target Market MAH Internal Material Code** – The Internal Material Code

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used by the MAH for the product.

- **Target Market CMO Internal Material Code** – The Internal Material Code used by the CMO that manufactured the product.
- **Target Market VCMO Internal Material Code** – The Internal Material Code used by the Virtual CMO that manufactured the product.
- **Target Market Reporting Item Code Value** – The reporting item code value for this target market.
- **Target Market Reporting Item Code Type** – The product's item code that is used in a specific target market instead of the target market's default item code for compliance reporting.
- **Target Market Marketing Authorization Number** – The product’s authorization number issued by a government agency.
- **Target Market Registration Classification** – The product classification at the time of registration.
- **Target Market Prescription Drug Type** – Specifies whether the medicine is available by prescription only.
- **Target Market License for Permanent Import** – The license number granted to import product that cannot be exported and will remain in the country permanently.
- **Target Market License for Permanent Import End Date** – The date on which the Target Market License for Permanent Import expires (YYYY-MM-DD format).
- **Target Market License for Temporary Import** – The license number granted to import product that will remain in the country temporarily before being re-exported.
- **Target Market License for Temporary Import End Date** – The date on which the Target Market License for Temporary Import expires (YYYY-MM-DD format).
- **Target Market Importer ID Value** – The value used to identify the target market importer. The value must be unique within the Target Market Importer

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ID Type, and special characters (e.g. -, ., /. \) are removed from this value.

- **Target Market Importer ID Type** – The type of identifier used to identify the company that is importing the product into the Target Market.
- **Target Market Repackaging License Number** – The repackager license number.
- **Target Market Repackaging License Number End Date** – The date when the repackaging license number expires (YYYY-MM-DD format).
- **Target Market Repackager ID Value** – The value associated with the repackager. The value must be unique within the Target Market Repackager ID Type, and special characters (e.g. -, ., /. \) are removed from this value.
- **Target Market Repackager ID Type** – The type of identifier used to identify the company that repackages the product.
- **Export Market Export from Country** – The country where the exported products are being shipped from. The country is identified using the standard two- or three-letter abbreviation specified in ISO 3166-1alpha-2:1997 country code.
- **Export Market Export to Country** – The country where the exported products are being received. The country is identified using the standard two- or three-letter abbreviation specified in ISO 3166-1alpha-2:1997 country code.
- **Export Market Unit Price** – The price per unit of the product in the target market. If a unit price is entered and the export country manufacturer is IN (India), the value must be a number from 0.50 – 9999999.99.
- **Export Market Currency Code** – The currency code for the product's unit price in ISO 4217:2015 format.
- **Export Market Target Market Exemption** – Specifies if the product is exempt from regulatory compliance in the Export Market Export to Country.
- **Export Market Export Country Exemption Code** – The exemption category code for exempted product with the enumeration values in India.
- **Export Market Exemption Reference** – The name of the law or regulation in the Export Market Export to Country for which the exporter has obtained

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exemption permission.

- **Export Market Exemption Date** – The date the exemption request is granted to the exporter by the governing agency of the Export Market Export to Country (YYYY-MM-DD format).
- **Export Market Manufactured By** – The type of organization manufacturing the product.
- **Export Market Manufacturer ID Value** – The value used to identify the manufacturer. The value must be unique within the Export Market Manufacturer ID Type, and special characters (e.g. -, ., /. \) are removed from this value.
- **Export Market Manufacturer ID Type** – The type of identifier used to identify the manufacturer.
- **Item Information Product Code** – The regulatory product code associated with the product in China, or an additional product code in other target markets.
- **Item Information Language Code** – The language for item information.
- **Item Information Product Description** – The product description, which includes the product name, dosage, form, and the number of doses.
- **Item Information Drug Composition** – The chemical composition of the product. The maximum character length is 500 characters if the Target Market Country is India.
- **Item Information Remarks** – Product-related instructions or comments not included in the previous fields.
- **Item Information Product Name** – The name of the product that is displayed on the product label.
- **Item Information Generic Name** – The chemical or non-proprietary name of the product. The generic name describes the chemical make up (atomic or molecular structure) of the product, in contrast to the brand name that is used to market it.
- **Item Information Manufacturer** – The name of the manufacturer as it

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appears on the product label.

- **Item Information Manufacturer ID Value** – The value associated with the manufacturer as it appears on the product label.
- **Item Information Manufacturer ID Type** – The type of identifier used to identify the manufacturer as it appears on the product label.
- **Item Information Strength** – The strength of the product (e.g. 100 mg).
- **Item Information Dosage Form** – The dosage form of the product (e.g. tablet, capsule).
- **Item Information EMVS Dosage Form** – The form the product is dispensed in according to the EU's standard set of values.
- **Item Information Container Size** – The number of individual doses in the pack.
- **Item Information EMVS Pack Code** – The way the product is packaged to be sold according to the EU's standard set of values.
- **Item Information Minimum Temperature** – The coldest temperature the product can be exposed to without compromising its quality and safety. If the maximum temperature and minimum temperature values are both provided, the minimum temperature must be less than or equal to the maximum temperature value.
- **Item Information Maximum Temperature** – The hottest temperature the product can be exposed to without compromising its quality and safety. If the maximum temperature and the minimum temperature values are both provided, then maximum temperature value must be greater than or equal to the minimum temperature value.
- **Item Information Temperature Scale** – The temperature scale that the minimum temperature and maximum temperature are entered in.
- **Item Information Sensitive to Light** – Specifies whether exposure to light can compromise the product's quality and safety.
- **Item Information Market Dosage Form** – The form in which the product is dispensed according to a specific Country Target Market's set of values.

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- **Item Information Shelf Life** – Specifies the length of time that a product remains consumable.
- **Item Information Shelf Life Unit** – The length of time (days, months, or years) must be a number between 1-9999.
- **Packaging Information Packaging Code Value** – The value used to identify the packaging code. The value must be unique within the Repackager ID Type, and special characters (e.g. -, ., /. \) are removed from this value.
- **Packaging Information Packaging Code Type** – The serial numbers for the product are generated according to the packaging code type.
- **Packaging Information Packaging Level** – The level of the packaging hierarchy for this packaging code.
- **Packaging Information Container Aggregation Quantity** – The number of children contained in this level of shipment (e.g. for a Case, the Container Aggregation Quantity lists the number of Inner Packs contained in each Case).
- **Packaging Information Packaging Ratio** – The ratio of the packaging levels included within this packaging code (e.g. 1:5:10 refers to one large case, with 5 smaller inner packs/bundles inside, each of which contains 2 eaches for a total of 10 eaches).
- **Packaging Information Batch Size Maximum** – The maximum batch size that is acceptable for the product. This field is only used when the value of Packaging Information Packaging Label is EA.
- **Packaging Information Batch Size Acceptable** – The acceptable size of the batch determined by percent. The numeric values must be between 1-100.
- **Packaging Information Batch Size Minimum** – The minimum batch size that is acceptable for the product. This field is only used when the value of Packaging Information Packaging Label is EA.
- **Packaging Information Serialization Type** – The type of serialization required for the packaging code.
- **Packaging Information Requires Aggregation** – Specifies if each

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Packaging Information Packaging Level requires serial numbers.

- **Packaging Information Filter Value** – Control information that allows an RFID reader to select only the packaging code for this packaging level, out of many other levels of packaging codes. Must be a numeric value between 0-7.
- **Packaging Information GS1 Company Prefix** – The prefix assigned by the GS1 organization. Must be included in the packaging code.
- **Packaging Information Code Version** – The product code version number.
- **Packaging Information Code Level** – The packaging level associated with the **Packaging Information Packaging Code Type** CN-ResCode. The numeric values must be between 1-9 with the innermost packaging level.
- **Packaging Information Data Status** – Specifies whether the packaging information is active or inactive within TraceLink.

Filter and view to find the product

1. Select the Main Menu icon.
2. Select Master Data from the drop-down.
3. Select Products.
4. Fill in one or more of the following fields in the Item Code tab to filter the results:
    a. Item Code Type drop-down – The item code used for this product. Each item code type can only be used once for each product, except for internal material number.
    b. Item Code field – The item code used for this product.
    c. Data Status drop-down – The packaging information is either active or inactive within TraceLink:
        • Active – The data can be used in messages and UI functions, and TraceLink leverages the data when necessary.
        • Inactive – The data cannot be used for other functions within TraceLink.
    d. Packaging Code Type drop-down – The serial numbers for the product are

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generated according to the packaging code type. If necessary, define a packaging code for each **Packaging Level** that needs to be tracked.

- CN-ResCode – This packaging code type is specific to China (must be 5 digits).
- GTIN-14 – (Global Trade Item Number) This packaging code type is accepted in any country (must be 14 digits).
- NTIN – (National Trade Item Number) This packaging code type is specific to a single country (must be 14 digits).

e. Packaging Code field – The serial numbers for the product.

f. Product Description field – The product descriptions which typically includes the product name, dosage, form, and the number of doses.

5. Select Apply.

The results display in the table.

See the information that displays in the table

- Data Status – The status of the packaging information:
  - Active – The data can be used in messages and UI functions, and TraceLink leverages the data when necessary.
  - Inactive – The data cannot be used for other functions within TraceLink.
- Product Name – The name of the product.
- Target Markets – The country where the product is distributed.
- Descriptions – The name of the company.
- Primary Item Code – The ID of the company.
- Item Status – The address of the company.

6. Select the Product Name hyperlink to open a specific location.

The View Product screen displays.

1. Select Master Data from the drop-down.

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Filter and view to find the product exports

1. Select the Main Menu icon.
2. Select Master Data from the drop-down.
3. Select Products.
4. Select the View Imports and Exports icon to view the exported product master data.
5. Make sure the My Exports tab is selected.
6. Fill in the following fields on the My Exports tab to filter the results:
    a. Status drop-down – Required. The status of the exported file.
    b. Document Name field – Required. The name of the exported file.
    c. Date Exported field – Required. The date the product master data was exported from TraceLink.
7. Select Apply.

   The results display in the table.

See the information that displays in the table

- Status – The status of the exported file.
- Date Exported – The date the product master data was exported from TraceLink.
- Expires On – The date the product master data expires.
- Document – The link of the exported product master data.

8. Select the exported document link to download the document.

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