

DAVA

Drugs Authentication and Verification Application

A portal for Indian Drugs authentication, track and trace

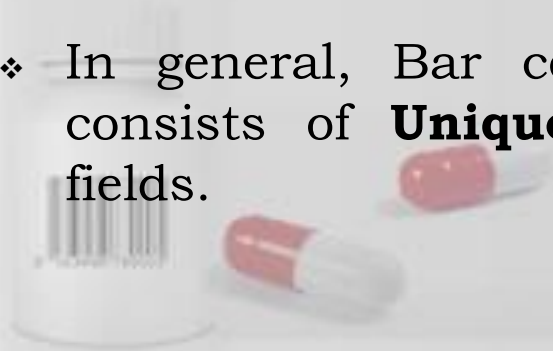


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About Application

- ❖ The current software is developed by National Informatics Centre, Department of Information Technology, Government of India.
- ❖ It provisions and envisages authentication, track and trace of drugs at strip/blister/vial level i.e. primary level, intermediate packing i.e. secondary level and shipment packing i.e. Tertiary level.
- ❖ Unique Serial Number needs to be maintained by the manufacturers using their own algorithm or through third party at primary as well as secondary levels of packaging.
- ❖ In general, Bar code labeling as per GS1 Global Standards consists of **Unique Identification Key** and other mandatory fields.



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About Application (contd.)

- ❖ Manufacturer is responsible for uploading their products' data on Central Portal for all three level of packaging maintaining Parent-Child relationship and their movement in its supply chain.
- ❖ Data at each hop i.e. every time the movement of drugs take place, wherever possible, is to be uploaded by the manufacturer/authorised distribution point on the central portal.
- ❖ The solution provides facility of authentication of the drugs to the consumer by means of portal / Mobile App supplemented by the details of the movement in its complete supply chain using the Unique Identification Key.

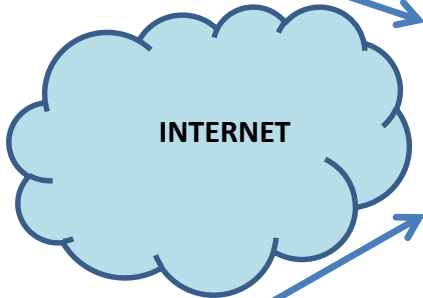




GS1 India

- Manufacturer Details

XML Format



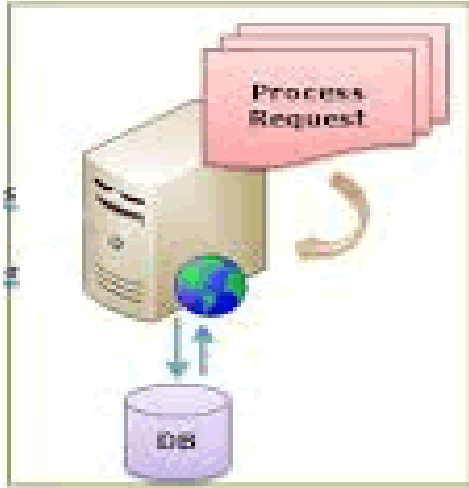
XML Format



Manufacturer

- Distribution Point Details
- Product Details
- Batch Detail
- Production Detail s
- Movement Details

Central Portal

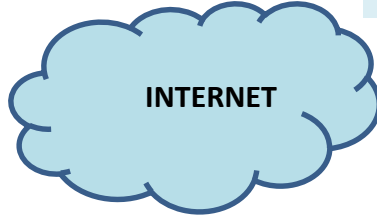
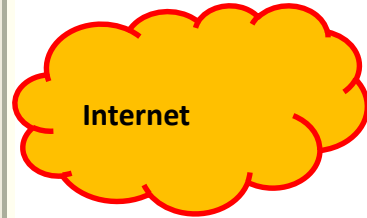


Central Data Base

- Manufacturer details
- Product details
- Batch details
- Production details.(TSP)
- User information
- Upload File details
- Movement details
- Authentication logs

National Informatics Centre(NIC)

GTIN14 + Serial No



Mobile Phone



- Authentication Details
- Basic Details & Movement Detail

GTIN14 + Serial No



Web/ Mobile App/ Barcode Scanner

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Technical Features of application

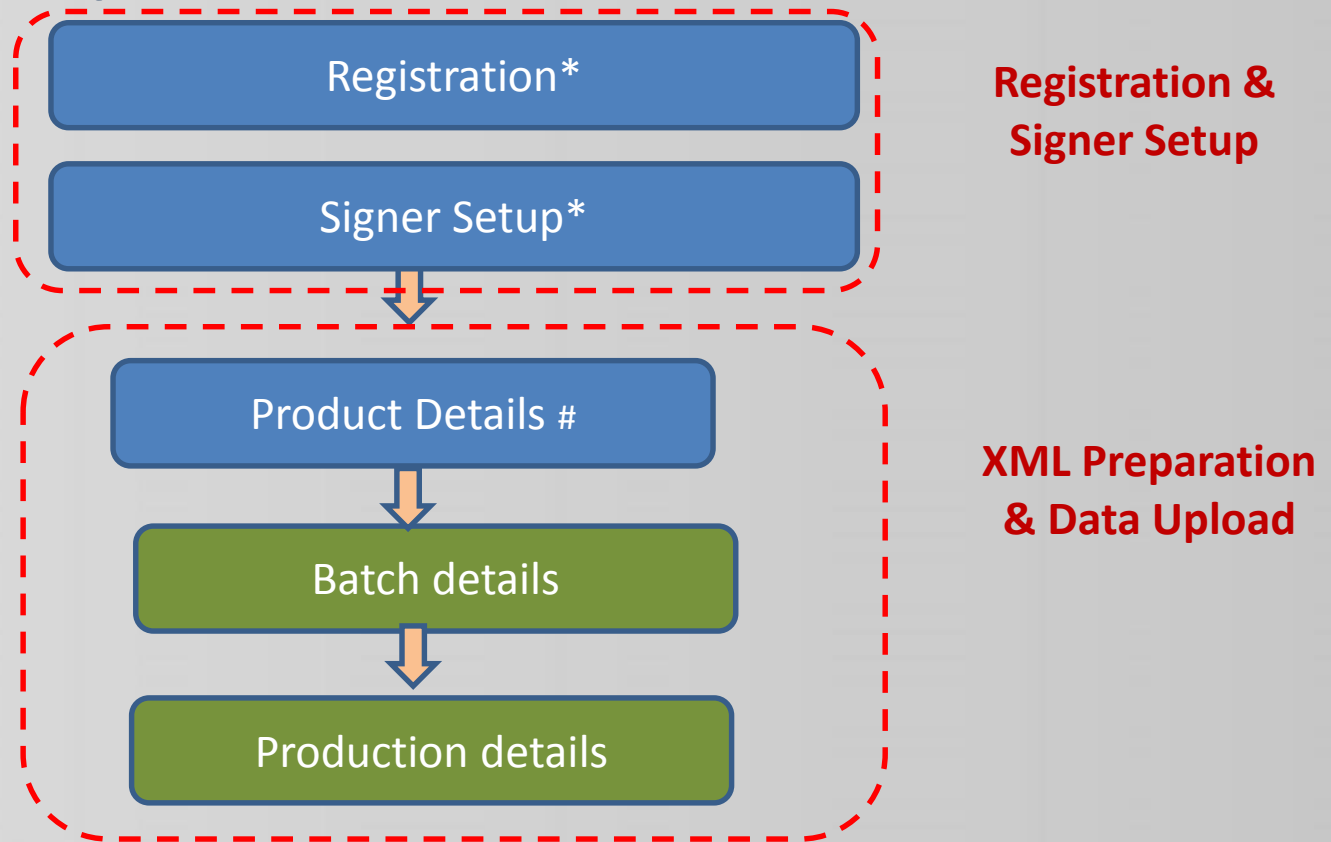
- ✓ Platform independent XML for data exchange
- ✓ Open source (Java) for application development
- ✓ Digital Signatures for Authentication and authorisation
(2048 characters long SHA-II standard PKI technology approved by CCA)
- ✓ Secured, Scalable, industry neutral aggregation and tracking mechanism
- ✓ New stake holders can easily plug in with web services
- ✓ Accessibility via portal, barcode reader and Mobile App etc



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Process flow for manufacturer



Batch, Production detail uploading are Repetitive processes

* One time

One time or when new product is added.

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Actions required by Manufacturer:

- I. Registration with GS1 India,
- II. Procurement of Digital Signature Certificate (DSC) of Class-2 or above from any CA in India in the name of authorized person,
- III. Registration with valid DSC on DAVA Portal,
- IV. Master data XML preparation and upload
(one time and whenever there is any change)
 - a) Product Details
 - I. Transaction data XML preparation and upload
 - a) Batch Details
 - b) Production Details



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XML Preparation and Data upload



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Latest Changes:

- ✓ Primary Pack details (upload) is now optional.
- ✓ Do not upload Dummy/Place holder primary pack serial number .
- ✓ Use TSP upload only when Primary serialisation is implemented .
- ✓ Introduced New File type TNS (Tertiary and Secondary) to upload Only Secondary and Tertiary data.
- ✓ Only Tertiary Data upload
 - Only Single Exemption code ELL
- ✓ Changes in XML file to address security issues.
 - FILENAME element is now inside ENVELOPE element.



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Convention for the Data upload File:

Structure

| Manufacturer code (10) | | | | | | | | | | Type of upload (3) | | | File Creation date DDMMYYYY (8) | | | | | | | | Running seq. no (3) | | |
|---------------------------|---|---|---|---|---|---|---|---|---|--------------------------|---|---|------------------------------------|---|---|---|---|---|---|---|---------------------------|---|---|
| 0 | 8 | 9 | 0 | 0 | 1 | 1 | 7 | 0 | 0 | T | S | P | 2 | 7 | 0 | 8 | 2 | 0 | 1 | 4 | 0 | 0 | 1 |

e.g. Code for uploading production details.

File type

: XML file

Name of XML file

: Exact 24 characters in length.

File Size

: Maximum 10 Mb.

For reasonable response time, it is recommended to restrict file size **upto 4 Mb** while uploading through interactive mode.

For large data upload, use Compressed file upload.

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Types of Upload

| Type of Upload | Code |
|---|------|
| Product Details | PRO |
| Batch Details | BAT |
| Production Details (Tertiary, Secondary ,Primary Production and packaging details data) | TSP |
| Only Tertiary Pack details | TER |
| Tertiary Pack Withdrawal | WIT |
| Compressed File Upload | ZIP |



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Parameters to be exchanged along with validation checks

- I. Product details
- II. Batch Details
- III. Production Details
- IV. Intermediate Pack details
- V. Only Tertiary Details
- VI. Tertiary pack withdrawal



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Product details



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Product details:

The Product detail process involves uploading of information about products being manufactured by a Drug Manufacturer on DAVA server.

- Manufacturer is supposed to upload the product details after successful registration.
- Manufacture has to upload all products details. Upload details of new product as and when it is introduced.
- All existing products can be included in single Product XML file



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Product Details information to be uploaded:

| Parameter to be exchanged | XML Element Name | Type, Length | Mandatory | Validations |
|---------------------------|-------------------|--------------|-----------|---|
| Manufacturer code | MANUFACTURER_CODE | Char(10) | Yes | ✓ 7 to 10 characters numeric (company prefix As assigned by GS-1) |
| For each product: | | | | |
| Product Type | PRODUCT_TYPE | Char(1) | No | ✓ Character 01, ✓ Allowed value O:Own L:loan licence ✓ Default O |
| Product code | PRODUCT_CODE | Char(12) | Yes | ✓ Exact 12 characters numeric (As per GS-1 standard) (Manufacturer code + product number) |
| Product Brand Name | PRODUCT_NAME | Char(50) | Yes | ✓ Max 50 characters. ✓ Minimum 3 characters ✓ Allowed Characters: a-zA-Z0-9/&;.-_`%!*,;=<> |
| Generic Salt (Name) | GENERIC_NAME | Char(200) | Yes | ✓ Max 200 characters. ✓ Minimum 3 characters ✓ Allowed Characters: a-zA-Z0-9/&;.-_`%!*,;=<> |

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Product Details information to be uploaded (Contd.)

| | | | | |
|-----------------------|---------------|-----------|------|---|
| Composition | COMPOSITION | Char(500) | Yes | <ul style="list-style-type: none">✓ Max 500 characters.✓ Minimum 3 characters✓ Allowed Characters: a-zA-Z0-9/&;-_%()*!*,;=<> |
| Is it a Schedule Drug | SCHEDULED | Char(1) | Yes | <ul style="list-style-type: none">✓ Character 01,✓ Allowed value Y:Schedule Drug N:Non Schedule Drug |
| Dose /Usage | USAGE | Char(100) | Yes | <ul style="list-style-type: none">✓ Max 100 characters.✓ Minimum 3 characters✓ Allowed Characters: a-zA-Z0-9/&;-_%()*!*,;=<> |
| Remark if any | REMARK | Char(100) | Yes* | <ul style="list-style-type: none">✓ Max 100 characters.✓ Allowed Characters: a-zA-Z0-9/&;-_%()*!*,;=<>✓ *Blank element allowed e.g. <REMARK/> |
| Product Image | PRODUCT_IMAGE | Varchar | Yes* | <ul style="list-style-type: none">✓ Image in Base64 format of Primary pack only✓ Maximum Image size is of 10 KB✓ *Blank element allowed e.g. <PRODUCT_IMAGE/> |

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Batch details



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Batch Details:

The Batch detail process involves uploading of Batch information on DAVA server.

- Manufacturer is supposed to upload the Batch details when batch is finalized and ready for production. Mandatory to upload before uploading the production information.
- Manufacturer has to upload the details whenever new batch is started.
- Multiple Batch information can be clubbed together in single XML file.



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Batch Detail information to be uploaded:

| Parameter to be exchanged | XML Element Name | Type, Length | Mandatory | Validations |
|--|-------------------|--------------|-----------|--|
| Manufacturer Code | MANUFACTURER_CODE | Char(10) | Yes | ✓ 7 to 10 characters numeric (As assigned by GS-1) |
| For each Batch: | | | | |
| Batch Number as assigned by Manufacturer | BATCH_NUMBER | Char(20) | Yes | ✓ Max 20 characters alphanumeric ✓ Allowed characters A-Z a-z 0-9 / - |
| Expiry Date | EXPIRY_DATE | Date | Yes | ✓ Date in yyyy-mm-dd format ✓ Must be greater than current date |
| Batch Size (No. of primary Units to be produced in the batch) | BATCH_SIZE | Integer (7) | Yes | ✓ Numeric. Max allowed range 1-9999999 |
| Product code of the product being manufactured in this batch . | PRODUCT_CODE | Char(12) | Yes | ✓ Exact 12 characters numeric (As per GS-1 standard) (Manufacturer code + product number) |

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Batch Detail information to be uploaded (Contd.)

| | | | | |
|--|-------------------------------------|---------------|-------|---|
| Unit price | UNIT_PRICE | Decimal(10,2) | Yes* | ✓ Blank element allowed e.g. < UnitPrice/> ✓ Numeric : Range 0.50 to 9999999.99 |
| Is the batch is for Export or Domestic Consumption ? | BATCH_FOR_EXPORT | Char(1) | Yes | ✓ Character 01 ✓ Allowed value Y: for Export N:for Domestic |
| Indian Barcode is mandatory on packaging? | EXEMPTED_FROM_B ARCODING | Char(1) | Yes | ✓ Character 01 ✓ Allowed values Y: Yes Exempted from bar-coding N: No (Bar coding is mandatory) |
| Exemption Notification and date | EXEMPTION_NOTIFIC ATION_AND_DATE | Varchar(100) | Yes * | ✓ Blank element allowed ✓ Maximum 100 characters ✓ Minimum 10 characters ✓ Alphanumeric ✓ '-', '/', ' ', spaces are allowed |
| Country Code for which exemption is taken | EXEMPTED_COUNTRY _CODE | Char(2) | Yes * | ✓ Blank element allowed ✓ Two characters country code |
| Status of the Batch | BATCH_STATUS | Char(1) | Yes | ✓ A (Active) / D (Deleted) |

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Production details



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Production details :

The Production details process involves uploading of production information on DAVA server.

- Manufacturer is supposed to upload the production details after Tertiary level packaging is completed with serialization and goods are ready to dispatch from factory.
- Multiple tertiary packs details can be included in single Production XML file subject to file size restriction.



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Packaging Scenarios for Tertiary Packs:

Homogeneous (*Default scenario*)

- One or more Secondary packs and Primary pack(s) of **same** product

Heterogeneous

- One or more Secondary packs and Primary pack(s) of **different** products

Special case

- Homogenous /Heterogeneous Tertiary packs containing one or more **intermediate level packs** between Secondary and Tertiary level packs.



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Production Details Information to be uploaded Homogeneous Tertiary Pack (Default scenario)

For each Tertiary level pack:

| Parameter to be exchanged- | XML Element Name | Type, Length | Mandatory | Validations |
|---|------------------|--------------|-----------|---|
| Tertiary pack Serial number (SSCC) | SSCC | Char(18) | Yes | ✓ Exact 18 characters numeric (As per GS-1 Standard) |
| No. of Secondary pack(s) in this Tertiary | SubItemCnt | Integer | Yes | ✓ Numeric ✓ Minimum value : 01 |
| Product code of the product packed in this Tertiary | ProductCode | Char(12) | Yes | ✓ Exact 12 characters numeric (As per GS-1 standard) (Manufacturer code + product number) |

Continued...

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Production Details Information to be uploaded

Homogeneous Tertiary Pack (Default scenario)

.....Continued

For each Secondary pack in this Tertiary

| | | | | |
|--|---------------|----------|-----|---|
| Secondary Serial Number | SecSrNo | Char(20) | Yes | ✓ Max 20 characters alphanumeric ✓ Special characters '/', '-' allowed |
| Batch number | BatchNo | Char(20) | Yes | ✓ Max 20 characters alphanumeric ✓ Special characters '/', '-' allowed |
| No. of Primary packs in this Secondary | NoOfPrimaries | Integer | Yes | ✓ Numeric ✓ Minimum value : 01 |

For each primary in this Secondary pack

| | | | | |
|-----------------------|---------|----------|-----|---|
| Primary Serial Number | PriSrNo | Char(20) | Yes | ✓ Max 20 characters alphanumeric ✓ Special characters '/', '-' allowed |
|-----------------------|---------|----------|-----|---|

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Production Details Information to be uploaded

Heterogeneous Tertiary Pack

For each Tertiary level pack:

| Parameter to be exchanged- | XML Element Name | Type, Length | Mandatory | Validations |
|---|------------------|--------------|-----------|---|
| Tertiary pack Serial number (SSCC) | SSCC | Char(18) | Yes | ✓ Exact 18 characters numeric (As per GS-1 Standard) |
| No. of Secondary pack(s) in this Tertiary | SubItemCnt | Integer | Yes | ✓ Numeric ✓ Minimum value : 01 |



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Production Details Information to be uploaded

Heterogeneous Tertiary Pack

.....Continued

For each Secondary pack in this Tertiary

| | | | | |
|---|---------------|----------|-----|--|
| Product code of the product packed in this Tertiary | ProductCode | Char(12) | Yes | ✓ Exact 12 characters numeric (As per GS-1 standard) (Manufacturer code + product number) |
| Secondary Serial Number | SecSrNo | Char(20) | Yes | ✓ Max 20 characters alphanumeric ✓ Special characters '/', '-' allowed |
| Batch number | BatchNo | Char(20) | Yes | ✓ Max 20 characters alphanumeric ✓ Special characters '/', '-' allowed |
| No. of Primary packs in this Secondary | NoOfPrimaries | Integer | Yes | ✓ Numeric ✓ Minimum value : 01 |

For each primary in this Secondary pack

| | | | | |
|-----------------------|---------|----------|-----|---|
| Primary Serial Number | PriSrNo | Char(20) | Yes | ✓ Max 20 characters alphanumeric ✓ Special characters '/', '-' allowed |
|-----------------------|---------|----------|-----|---|



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Intermediate level packaging :

Intermediate Level 2:

Besides parameters mentioned in default scenario, following additional parameters are to be exchanged for each Intermediate Level 2 pack

| Parameter to be exchanged | XML Element Name | Type, Length | Mandatory | Validations |
|---------------------------------------|------------------|--------------|-----------|---|
| L2 pack serial number | Level2SrNo | Char(20) | Yes | ✓ Max 20 characters alphanumeric ✓ Special characters '/', '-' allowed |
| No of secondary packs in this L2 pack | SecondaryCnt | Integer | Yes | ✓ Numeric ✓ Minimum value : 01 |



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Intermediate Level 3

Besides parameters mentioned in Intermediate Level 2, following additional parameters are to be exchanged for each Intermediate Level 3 pack.

| Parameter to be exchanged | XML Element Name | Type, Length | Mandatory | Validations |
|--------------------------------------|------------------|--------------|-----------|---|
| L3 pack serial number | Level2SrNo | Char(20) | Yes | ✓ Max 20 characters alphanumeric ✓ Special characters '/', '-' allowed |
| No of L2 level packs in this L3 pack | L2Cnt | Integer | Yes | ✓ Numeric ✓ Minimum value : 01 |



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Bulk Data Upload



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Bulk Data Upload:

- In case of high volume of data upload (large numbers of Tertiary packs e.g. 16000 Tertiary pack /day), large numbers of files will have to be created and uploaded online. It's time consuming and not cost efficient task.
- Bulk Data upload feature facilitates large volume of Production data upload (TSP) in batch mode on DAVA portal.



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Steps involved in Bulk Data upload:

- Prepare production data(TSP) Files as per predefined XML format
- Digitally Sign each file.
- Prepare a compressed (ZIP) file of above prepared XML files
- Name compressed (ZIP) file with same naming convention as used for TSP file except use 'ZIP' instead of 'TSP'. e.g. 8901148000ZIP21042016002
- Upload this compressed (ZIP) file on DAVA portal using upload type as 'Compressed Files'. On successful uploading System will provide acknowledgement of receipt of files in XML format



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Continued...

- “Bulk Processor”, a scheduled task, will run at predefined time (non peak hour) to process above uploaded files individually and generate acknowledgment for each file. After processing all files in uploaded compress (ZIP) file, system will generate ZIP of acknowledgment files generated. The compress (ZIP) file so generated will be available for downloading through ‘Download Acknowledgment File’ option.
- User can download the Acknowledgement file from DAVA portal and extract it to get acknowledgment for individual file.



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Special cases Only Tertiary pack upload

Packages exempted from requirement of bar-coding on Primary and secondary pack and upload of Primary and secondary pack(s) information on central DAVA portal :

Exempted Categories:

| Case | Exemption Code |
|--|----------------|
| Consignments containing drugs/ devices for export purposes to countries eligible for exemption from bar-coding as per rule 21 of “Drugs and Cosmetic Act” with specific notification number. | E21 |
| Drugs/devices having bar coding as per importing countries bar-coding requirements. | ELL |



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Special cases

Only Tertiary pack upload

- ✓ In all the above cases, an exporter is required to put bar-code on Tertiary pack as per Indian standard and upload data on the central DAVA portal using option Upload Type: 'TER' (Tertiary Pack only)
- ✓ Bar-coding on tertiary level packaging will be in addition to bar-coding requirement as per importing country, if any.
- ✓ Following information need to be provided:
 - ✓ a) SSCC
 - ✓ b) Total number of sub packs (packets) in the Tertiary pack.
- ✓ No automatic validation will be applied by the system. It will be the responsibility of exporter to satisfy regulating authorizes at the time of export.



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Sample xml file containing 5 Tertiary packs Exemption code: ELL

```
<ProductionInfo>
  <FILENAME>8906038280TER17062015001</FILENAME>
  <ExemptionCode>ELL</ExemptionCode>
<ENVELOPE>
  <Tertiary>
    <SSCC>189060382838092179</SSCC>
    <SubItemCnt>10</SubItemCnt>
  </Tertiary>
  <Tertiary>
    <SSCC>189060382838092513</SSCC>
    <SubItemCnt>15</SubItemCnt>
  </Tertiary>
  <Tertiary>
    <SSCC>189060382838092520</SSCC>
    <SubItemCnt>25</SubItemCnt>
  </Tertiary>
  <Tertiary>
    <SSCC>189060382838092544</SSCC>
    <SubItemCnt>40</SubItemCnt>
  </Tertiary>
  <Tertiary>
    <SSCC>189060382838092445</SSCC>
    <SubItemCnt>100</SubItemCnt>
  </Tertiary>
</ENVELOPE>
</ProductionInfo>
```

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Production withdrawal details



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Production Details Information to be uploaded Tertiary Pack withdrawal

For each Tertiary level pack:

| Parameter to be exchanged- | XML Element Name | Type, Length | Mandatory | Validations |
|--|------------------|--------------|-----------|---|
| Tertiary pack Serial number (SSCC) | SSCC | Char(18) | Yes | ✓ Exact 18 characters numeric (As per GS-1 Standard) |
| File name through which the Tertiary is uploaded | UploadFname | Char(24) | Yes | ✓ Alphanumeric ✓ Exact 24 characters |
| Reason for Withdrawal | Reason | Char(200) | Yes | ✓ Maximum length 200 ✓ Minimum length 5 ✓ Alphanumeric Allowed Characters: a-zA-Z0-9/&;- _`%()*!*+,:;=<> |

Continued...

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Sample withdrawal xml for a Tertiary pack

```
<TSPWithdrawal>
<FILENAME>8906000990WIT11022016001</FILENAME>
<ENVELOPE>
<Tertiary>
  <SSCC>089041840000004040</SSCC>
  <UploadFname>8906000990TSP10022016001</UploadFname>
  <Reason>Wrongly added</Reason>
</Tertiary>
<Tertiary>
  <SSCC>089041840000004041</SSCC>
  <UploadFname>8906038280TSP10022016012</UploadFname>
  <Reason>mistakes in primary numbers </Reason>
</Tertiary>
</ENVELOPE>
</TSPWithdrawal>
```



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Modification, Deletion, withdrawal policy

- I. Product details
- II. Batch Details
- III. Production Details



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Modification Policy Product Information

| Task | When allowed | How | Remarks if any | Effect |
|--|---|---|--|--|
| Modification required due to Typographical errors, mistakes etc | Any time before deletion Caution : Due care need to be taken by Manufacturer as earlier name, description may have been reflected in various reports | Upload new Product XML file with same product code and status as 'A' | All parameters (elements in xml file) can be modified except Product code and Manufacturer code | System will show new information about given product code |
| Deletion to be used only when wrong product code was uploaded | Before first Batch /production information is uploaded | Upload new Product XML file with same product code details and status as 'D' | | Product code is deleted from DAVA portal. No log maintained as it is treated as mistake at time of upload. |
| Withdrawal required when product is no more manufactured | When Batch /production information is already uploaded for given product code | Upload new Product XML file with same product code details and status as 'W' | | Product status changes to "Withdrawn" |
| Re-activation | Same as Modification | | | |

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Modification Policy Batch Information

| Task | When allowed | How | Remarks if any | Effect |
|--|--|---|--|--|
| Modification required due to Typographical errors, mistakes etc | A. before uploading production data B. after partial upload | Upload new batch XML file with same product code with status as 'A' | A: All parameters (elements in xml file) can be modified except batch number and Manufacturer code. B: New Batch size cannot be less than already uploaded data. Product code, Manufacturer code, Expiry date can Not be changed All Other parameters can be modified. | System will show new information about given batch |
| Deletion to be used only when wrong batch number was uploaded | <i>Before</i> production information is uploaded for given batch number. | Upload new batch XML file with same product code details and status as 'D' | | Batch is deleted from DAVA portal. No log maintained as it is treated as mistake at time of upload. |
| Withdrawal | Not Supported | | As withdrawal will lead to irrelevance to production data of that batch. | |
| Re-activation | Not Supported | | | |

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Modification Policy Production Information

| Task | When Allowed | How | Effect |
|--------------|--|---|--|
| Modification | Not supported/Allowed. Only withdrawal of complete Tertiary pack is allowed. | | |
| Withdrawal | Before movement of tertiary pack | Prepare TSPWithdrawal file as shown in sample and upload with upload type as "Tertiary Pack withdrawal" | <ul style="list-style-type: none">•All information about given tertiary pack is deleted from DAVA portal and user can upload fresh data with same /new Tertiary pack number.•Withdrawal log will be maintained. |

Steps

- User to provide SSCC(s) and File name (earlier Uploaded with) in TSP withdrawal xml
- System will cross check and if in order then withdrawal will be done.
- User will get acknowledgement xml as response.
- User may upload the corrected information through fresh file of TSP upload process.

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Data Uploaded in Apr. 2018

| | |
|---|-----------|
| Companies/Manufacturers | 156 |
| TSP Tertiary packs uploaded | 6.52 Lakh |
| Only Tertiary Packs uploaded | 2.27 Lakh |
| Upload through Compressed File (ZIP) mode | |
| No of Files | 1184 |
| No of Tertiary uploaded | 7400 |

