

## SPL Data Element Examples

### SPL Data Element Examples

Version	Date of Change	Description of Change
1	December 2005	Original version
2	February 2006	Change to translation code for example 4.4

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## SPL Data Element Examples

### 1. Product

- 1.1. Describing the product name, code and dosage form

Text:

The product is MiracleDrug (gooddrug) is supplied as tablets.

XML:

```
<manufacturedMedicine>
  <code code="0001-0001" codeSystem="2.16.840.1.113883.6.69"/>
  <name>MiracleDrug</name>
  <formCode code="C42998" codeSystem="2.16.840.1.113883.3.26.1.1"
  displayName="TABLET"/>
  <asEntityWithGeneric>
    <genericMedicine>
      <name>gooddrug</name>
    </genericMedicine>
  </asEntityWithGeneric>
</manufacturedMedicine>
```

## SPL Data Element Examples

### 2. Active ingredient

#### 2.1. Describing the strength of an active ingredient

Text:

MiracleDrug Sodium is a tablet containing goodingredient sodium equivalent to 500 mg of goodingredient.

XML:

```
<activeIngredient>
  <quantity>
    <numerator value="500" unit="mg">
      <translation code="C28253" codeSystem="2.16.840.1.113883.3.26.1.1"
        displayName="MILLIGRAM" value="500"/>
    </numerator>
    <denominator value="1" unit="1">
      <translation code="C48542" codeSystem="2.16.840.1.113883.3.26.1.1"
        displayName="TABLET" value="1"/>
    </denominator>
  </quantity>
  <activeIngredientSubstance>
    <name>goodingredient sodium</name>
    <activeMoiety>
      <activeMoiety>
        <name>goodingredient</name>
      </activeMoiety>
    </activeMoiety>
  </activeIngredientSubstance>
</activeIngredient>
```

## SPL Data Element Examples

### 2.2. Describing the strength of an active ingredient powder for oral suspension

Text:

MiracleDrug for Oral Suspension is a white powder. When constituted as directed, MiracleDrug for Oral Suspension contains 20 mg of gooddrug per 5 mL.

XML:

```
<activeIngredient>
  <quantity>
    <numerator value="20" unit="mg">
      <translation code="C28253" codeSystem="2.16.840.1.113883.3.26.1.1"
        displayName="MILLIGRAM" value="20" />
    </numerator>
    <denominator value="5" unit="mL">
      <translation code="C28254" codeSystem="2.16.840.1.113883.3.26.1.1"
        displayName="MILLILITER" value="5" />
    </denominator>
  </quantity>
  <activeIngredientSubstance>
    <name>goodingredient sodium</name>
    <activeMoiety>
      <activeMoiety>
        <name>goodingredient</name>
      </activeMoiety>
    </activeMoiety>
  </activeIngredientSubstance>
</activeIngredient>
```

## SPL Data Element Examples

### 2.3. Inclusion of the Unique Ingredient Identifier (UNII) with the active ingredient.

Text:

MiracleDrug Sodium contains goodingredient sodium equivalent to 500 mg of goodingredient.

XML:

```
<activeIngredient>
  <quantity>
    <numerator value="500" unit="mg">
      <translation code="C28253" codeSystem="2.16.840.1.113883.3.26.1.1"
        displayName="MILLIGRAM" value="500"/>
    </numerator>
    <denominator value="1" unit="1">
      <translation code="C48542" codeSystem="2.16.840.1.113883.3.26.1.1"
        displayName="TABLET" value="1"/>
    </denominator>
  </quantity>
  <activeIngredientSubstance>
    <code codeSystem="2.16.840.1.113883.4.9" codeSystemName="FDA SRS"
      code="xxxxxxxxx"/>
    <name>good ingredient sodium</name>
    <activeMoieties>
      <activeMoiety>
        <code codeSystem="2.16.840.1.113883.4.9" codeSystemName="FDA
          SRS" code="xxxxxxxxx1"/>
        <name>good ingredient</name>
      </activeMoiety>
    </activeMoieties>
  </activeIngredientSubstance>
</activeIngredient>
```

## SPL Data Element Examples

### 3. Inactive ingredient

#### 3.1. Describing the strength of an inactive ingredient

Text:

The inactive ingredients include 25 mg of mannitol per 5 mL and sodium hydroxide to adjust the pH.

XML:

```
<inactiveIngredient>
  <quantity>
    <numerator value="25" unit="mg">
      <translation code="C28253" codeSystem="2.16.840.1.113883.3.26.1.1"
        displayName="MILLIGRAM" value="25" />
    </numerator>
    <denominator value="5" unit="mL">
      <translation code="C28254" codeSystem="2.16.840.1.113883.3.26.1.1"
        displayName="MILLILITER" value="5" />
    </denominator>
  </quantity>
  <inactiveIngredientSubstance>
    <name>mannitol</name>
  </inactiveIngredientSubstance>
</inactiveIngredient>
<inactiveIngredient>
  <inactiveIngredientSubstance>
    <name>sodium hydroxide</name>
  </inactiveIngredientSubstance>
</inactiveIngredient>
```

## SPL Data Element Examples

### 4. Packaging

#### 4.1. Describing one package configuration for one product

Text:

MiracleDrug for Oral Suspension is a white powder. When constituted as directed, MiracleDrug for Oral Suspension contains 20 mg of gooddrug per 5 mL. It is available in a 50 mL bottle containing 200 mg of gooddrug (NDC 0001-0002-02). [See example 2.2 for the description of the active ingredient]

XML:

```
<asContent>
  <quantity>
    <numerator value="50" unit="mL">
      <translation code="C28254" codeSystem="2.16.840.1.113883.3.26.1.1"
        displayName="MILLILITER" value="50"/>
    </numerator>
    <denominator value="1" unit="1">
      <translation value="1"/>
    </denominator>
  </quantity>
  <containerPackagedMedicine>
    <code code="0001-0002-02" codeSystem="2.16.840.1.113883.6.69"
      codeSystemName="NDC"/>
    <formCode code="C43169" codeSystem="2.16.840.1.113883.3.26.1.1"
      displayName="BOTTLE"/>
  </containerPackagedMedicine>
</asContent>
```

## SPL Data Element Examples

### 4.2. Describing more than one package configuration for one product

Text:

The product is available in a bottle of 100 tablets (NDC 0001-0001-01) and a bottle of 30 tablets (NDC 0001-0001-02).

XML:

```
<asContent>
  <quantity>
    <numerator value="100" unit="1">
      <translation code="C48542" codeSystem="2.16.840.1.113883.3.26.1.1"
        displayName="TABLET" value="100"/>
    </numerator>
    <denominator value="1" unit="1">
      <translation value="1"/>
    </denominator>
  </quantity>
  <containerPackagedMedicine>
    <code code="0001-0001-01" codeSystem="2.16.840.1.113883.6.69"
      codeSystemName="NDC"/>
    <formCode code="C43169" codeSystem="2.16.840.1.113883.3.26.1.1"
      displayName="BOTTLE"/>
  </containerPackagedMedicine>
</asContent>
<asContent>
  <quantity>
    <numerator value="30" unit="1">
      <translation code="C48542" codeSystem="2.16.840.1.113883.3.26.1.1"
        displayName="TABLET" value="30"/>
    </numerator>
    <denominator value="1" unit="1">
      <translation value="1"/>
    </denominator>
  </quantity>
  <containerPackagedMedicine>
    <code code="0001-0001-02" codeSystem="2.16.840.1.113883.6.69"
      codeSystemName="NDC"/>
    <formCode code="C43169" codeSystem="2.16.840.1.113883.3.26.1.1"
      displayName="BOTTLE"/>
  </containerPackagedMedicine>
</asContent>
```



## SPL Data Element Examples

### 4.3. Describing packaging with more than one level of packaging

Text:

MiracleDrug Tablets comes packaged with 5 tablets in a blister pack with 2 blister packs in a box (NDC 0001-0001-04) with 3 boxes in a carton (NDC 0001-0001-05).

XML:

```
<asContent>
  <quantity>
    <numerator value="5" unit="1">
      <translation code="C48542" codeSystem="2.16.840.1.113883.3.26.1.1"
        displayName="TABLET" value="5"/>
    </numerator>
    <denominator value="1" unit="1">
      <translation value="1"/>
    </denominator>
  </quantity>
  <containerPackagedMedicine>
    <code/>
    <formCode code="C43168" codeSystem="2.16.840.1.113883.3.26.1.1"
      displayName="BLISTER PACK"/>
    <asContent>
      <quantity>
        <numerator value="2" unit="1">
          <translation code="C44278"
            codeSystem="2.16.840.1.113883.3.26.1.1"
            displayName="UNITS" value="2"/>
        </numerator>
        <denominator value="1" unit="1">
          <translation value="1"/>
        </denominator>
      </quantity>
      <containerPackagedMedicine>
        <code code="0001-0001-04" codeSystem="2.16.840.1.113883.6.69"
          codeSystemName="NDC"/>
        <formCode code="C43178" codeSystem="2.16.840.1.113883.3.26.1.1"
          displayName="BOX"/>
        <asContent>
          <quantity>
            <numerator value="3" unit="1">
              <translation code="C48478"
                codeSystem="2.16.840.1.113883.3.26.1.1"
                displayName="BOX" value="3"/>
            </numerator>
            <denominator value="1" unit="1">
              <translation value="1"/>
            </denominator>
          </quantity>
        </asContent>
      </containerPackagedMedicine>
    </asContent>
  </containerPackagedMedicine>
</asContent>
```

## SPL Data Element Examples

```
        </denominator>
    </quantity>
    <containerPackagedMedicine>
        <code code="0001-0001-05"
            codeSystem="2.16.840.1.113883.6.69"
            codeSystemName="NDC"/>
        <formCode code="C43182"
            codeSystem="2.16.840.1.113883.3.26.1.1"
            displayName="CARTON"/>
    </containerPackagedMedicine>
</asContent>
</containerPackagedMedicine>
</asContent>
</containerPackagedMedicine>
</asContent>
```

## SPL Data Element Examples

### 4.4. Describing packaging for a combination of two or more products that have no individual packaging

Text:

MiracleDrug Monthly (gooddrug) contains 14 MiracleDrug 10 mg tablets and 14 MiracleDrug 20 mg tablets in a Dialpack (NDC 0001-0003-01).

XML:

```
<manufacturedMedicine>
  <code code="0001-0003" codeSystem="2.16.840.1.113883.6.69" codeSystemName="NDC"/>
  <name>MiracleDrug Monthly</name>
  <formCode code="C48504" codeSystem="2.16.840.1.113883.3.26.1.1" displayName="KIT"/>
  <asEntityWithGeneric>
    <genericMedicine>
      <name> gooddrug</name>
    </genericMedicine>
  </asEntityWithGeneric>
  <asContent>
    <quantity>
      <numerator value="1" unit="1">
        <translation code="C48504" codeSystem="2.16.840.1.113883.3.26.1.1"
          displayName="KIT" value="1"/>
      </numerator>
      <denominator value="1" unit="1">
        <translation value="1"/>
      </denominator>
    </quantity>
    <containerPackagedMedicine>
      <code code="0001-0003-01" codeSystem="2.16.840.1.113883.6.69"
        codeSystemName="NDC"> </code>
      <formCode code="C43192" codeSystem="2.16.840.1.113883.3.26.1.1"
        codeSystemName="NCI Thesaurus" displayName="DIALPACK"/>
    </containerPackagedMedicine>
  </asContent>
  <part>
    <quantity>
      <numerator value="14" unit="1">
        <translation code="C48542" codeSystem="2.16.840.1.113883.3.26.1.1"
          displayName="TABLET" value="14"/>
      </numerator>
      <denominator value="1" unit="1">
        <translation value="1"/>
      </denominator>
    </quantity>
  </partMedicine>
</manufacturedMedicine>
```

## SPL Data Element Examples

```
<name>MiracleDrug 10 mg Tablet</name>
<formCode code="C42998" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus" displayName="TABLET"/>
<activeIngredient>
  <quantity>
    <numerator value="10" unit="mg">
      <translation code="C28253"
codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"
displayName="MILLIGRAM" value="10"/>
    </numerator>
    <denominator value="1" unit="1">
      <translation code="C48542"
codeSystem="2.16.840.1.113883.3.26.1.1"
displayName="TABLET" value="1"/>
    </denominator>
  </quantity>
  <activeIngredientSubstance>
    <name>gooddrug sodium</name>
    <activeMoiety>
      <activeMoiety>
        <name>gooddrug</name>
      </activeMoiety>
    </activeMoiety>
  </activeIngredientSubstance>
</activeIngredient>
</partMedicine>
</part>
<part>
  <quantity>
    <numerator value="14" unit="1">
      <translation code="C48542" codeSystem="2.16.840.1.113883.3.26.1.1"
displayName="TABLET" value="14"/>
    </numerator>
    <denominator value="1" unit="1">
      <translation value="1"/>
    </denominator>
  </quantity>
  <partMedicine>
    <name>MiracleDrug 20 mg Tablet</name>
    <formCode code="C42998" codeSystem="2.16.840.1.113883.3.26.1.1"
displayName="TABLET"/>
    <activeIngredient>
      <quantity>
        <numerator value="20" unit="mg">
          <translation code="C28253"
codeSystem="2.16.840.1.113883.3.26.1.1"
displayName="MILLIGRAM" value="20"/>
        </numerator>
```

## SPL Data Element Examples

```
<denominator value="1" unit="1">
  <translation code="C48542"
    codeSystem="2.16.840.1.113883.3.26.1.1"
    displayName="TABLET" value="1"/>
</denominator>
</quantity>
<activeIngredientSubstance>
  <name>gooddrug sodium</name>
  <activeMoiety>
    <activeMoiety>
      <name>gooddrug</name>
    </activeMoiety>
  </activeMoiety>
</activeIngredientSubstance>
</activeIngredient>
</partMedicine>
</part>
</manufacturedMedicine>
```

## SPL Data Element Examples

### 4.5. Describing packaging for a combination of more than one individually packaged product

Text:

MiracleDrug Combo (gooddrug) is packaged in a carton (NDC 0001-0003-01) with two parts. One part is MiracleDrug Solution with 50 mg of gooddrug sodium in 2 mL of solution for injection packaged in a vial with 4 mL (NDC 0001-0002-01) with a route of administration of IV or IM. The second part is MiracleDrug Tablets with 25 mg of gooddrug sodium packaged in a bottle of 30 tablets (NDC 0001-0001-02) with an oral route of administration.

XML:

```
<manufacturedMedicine>
  <code code="0001-0003" codeSystem="2.16.840.1.113883.6.69" codeSystemName="NDC"/>
  <name>MiracleDrug Combo</name>
  <formCode code="C47916" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
  Thesaurus" displayName="KIT"/>
  <asEntityWithGeneric>
    <genericMedicine>
      <name> gooddrug</name>
    </genericMedicine>
  </asEntityWithGeneric>
  <asContent>
    <quantity>
      <numerator value="1" unit="1">
        <translation code="C48504" codeSystem="2.16.840.1.113883.3.26.1.1"
        displayName="KIT" value="1"/>
      </numerator>
      <denominator value="1" unit="1">
        <translation value="1"/>
      </denominator>
    </quantity>
    <containerPackagedMedicine>
      <code code="0001-0003-01" codeSystem="2.16.840.1.113883.6.69"
      codeSystemName="NDC"/>
      <formCode code="C43182" codeSystem="2.16.840.1.113883.3.26.1.1"
      codeSystemName="NCI Thesaurus" displayName="CARTON"/>
    </containerPackagedMedicine>
  </asContent>
  <part>
    <quantity>
      <numerator value="4" unit="mL">
        <translation code="C28254" codeSystem="2.16.840.1.113883.3.26.1.1"
        displayName="MILLILITER" value="4"/>
      </numerator>
      <denominator value="1" unit="1">
        <translation value="1"/>
      </denominator>
    </quantity>
  </part>
</manufacturedMedicine>
```

## SPL Data Element Examples

```
</denominator>
</quantity>
<partMedicine>
  <code code="0001-0002" codeSystem="2.16.840.1.113883.6.69"
  codeSystemName="NDC"/>
  <name>MiracleDrug Solution</name>
  <formCode code="C42945" codeSystem="2.16.840.1.113883.3.26.1.1"
  codeSystemName="NCI Thesaurus" displayName="INJECTION,
  SOLUTION"/>
  <activeIngredient>
    <quantity>
      <numerator value="50" unit="mg">
        <translation code="C28253"
        codeSystem="2.16.840.1.113883.3.26.1.1"
        codeSystemName="NCI Thesaurus"
        displayName="MILLIGRAM" value="50"/>
      </numerator>
      <denominator value="2" unit="mL">
        <translation code="C28254"
        codeSystem="2.16.840.1.113883.3.26.1.1"
        codeSystemName="NCI Thesaurus"
        displayName="MILLILITER" value="2"/>
      </denominator>
    </quantity>
    <activeIngredientSubstance>
      <name>gooddrug sodium</name>
      <activeMoiety>
        <activeMoiety>
          <name>gooddrug</name>
        </activeMoiety>
      </activeMoiety>
    </activeIngredientSubstance>
  </activeIngredient>
  <asEntityWithGeneric>
    <genericMedicine>
      <name>gooddrug</name>
    </genericMedicine>
  </asEntityWithGeneric>
  <asContent>
    <quantity>
      <numerator value="4" unit="mL">
        <translation code="C28254"
        codeSystem="2.16.840.1.113883.3.26.1.1"
        codeSystemName="NCI Thesaurus"
        displayName="MILLILITER" value="4"/>
      </numerator>
      <denominator value="1" unit="1">
        <translation value="1"/>
      </denominator>
```

## SPL Data Element Examples

```
</quantity>
<containerPackagedMedicine>
  <code code="0001-0002-01"
    codeSystem="2.16.840.1.113883.6.69"
    codeSystemName="NDC"/>
  <formCode code="C43226"
    codeSystem="2.16.840.1.113883.3.26.1.1"
    codeSystemName="NCI Thesaurus" displayName="VIAL"/>
</containerPackagedMedicine>
</asContent>
</partMedicine>
</part>
<part>
  <quantity>
    <numerator value="30" unit="1">
      <translation code="C48542" codeSystem="2.16.840.1.113883.3.26.1.1"
        displayName="TABLET" value="30"/>
    </numerator>
    <denominator value="1" unit="1">
      <translation value="1"/>
    </denominator>
  </quantity>
  <partMedicine>
    <code code="0001-0001" codeSystem="2.16.840.1.113883.6.69"/>
    <name>MiracleDrug Tablet</name>
    <formCode code="C42998" codeSystem="2.16.840.1.113883.3.26.1.1"
      displayName="TABLET"/>
    <activeIngredient>
      <quantity>
        <numerator value="25" unit="mg">
          <translation code="C28253"
            codeSystem="2.16.840.1.113883.3.26.1.1"
            displayName="MILLIGRAM" value="25"/>
        </numerator>
        <denominator value="1" unit="1">
          <translation code="C48542"
            codeSystem="2.16.840.1.113883.3.26.1.1"
            displayName="TABLET" value="1"/>
        </denominator>
      </quantity>
      <activeIngredientSubstance>
        <name>gooddrug sodium</name>
        <activeMoiety>
          <activeMoiety>
            <name>gooddrug</name>
          </activeMoiety>
        </activeMoiety>
      </activeIngredientSubstance>
    </activeIngredient>
  </partMedicine>
</part>
</quantity>
</asContent>
</partMedicine>
</part>
```



## SPL Data Element Examples

```
<asEntityWithGeneric>
  <genericMedicine>
    <name>gooddrug</name>
  </genericMedicine>
</asEntityWithGeneric>
<asContent>
  <quantity>
    <numerator value="30" unit="1">
      <translation code="C48542"
        codeSystem="2.16.840.1.113883.3.26.1.1"
        codeSystemName="NCI Thesaurus"
        displayName="TABLET" value="30"/>
    </numerator>
    <denominator value="1" unit="1">
      <translation value="1"/>
    </denominator>
  </quantity>
  <containerPackagedMedicine>
    <code code="0001-0001-02"
      codeSystem="2.16.840.1.113883.6.69"
      codeSystemName="NDC"/>
    <formCode code="C43169"
      codeSystem="2.16.840.1.113883.3.26.1.1"
      codeSystemName="NCI Thesaurus" displayName="BOTTLE"/>
  </containerPackagedMedicine>
</asContent>
</partMedicine>
</part>
</manufacturedMedicine>
```

## SPL Data Element Examples

### 5. Route of Administration

#### 5.1. Describing route of administration

Text:

MiracleDrug (gooddrug) can be given either intravenously or intramuscularly.

XML:

```
<consumedIn>
  <substanceAdministration>
    <routeCode code="C38276" codeSystem="2.16.840.1.113883.3.26.1.1"
      codeSystemName="NCI Thesaurus" displayName="INTRAVENOUS"/>
  </substanceAdministration>
</consumedIn>
<consumedIn>
  <substanceAdministration>
    <routeCode code="C28161" codeSystem="2.16.840.1.113883.3.26.1.1"
      codeSystemName="NCI Thesaurus" displayName="INTRAMUSCULAR"/>
  </substanceAdministration>
</consumedIn>
```

## SPL Data Element Examples

### 6. Solid Oral Dosage Form Characteristics

#### 6.1. Describing characteristics of a solid oral dosage form.

Text:

MiracleDrug is a scored capsule shaped tablet. One side of the tablet is white to off white and the other side is yellow. Printed on one side is "Miracle C55". Printed on the other side is 20 mg.

XML:

```
<subjectOf>
  <characteristic classCode="OBS">
    <code code="SPLCOLOR" codeSystem="2.16.840.1.113883.1.11.19255"/>
    <value code="C48325" codeSystem="2.16.840.1.113883.3.26.1.1"
      displayName="WHITE" xsi:type="CE">
      <originalText>white to off white</originalText>
    </value>
  </characteristic>
</subjectOf>
<subjectOf>
  <characteristic classCode="OBS">
    <code code="SPLCOLOR" codeSystem="2.16.840.1.113883.1.11.19255"/>
    <value code="C48330" codeSystem="2.16.840.1.113883.3.26.1.1"
      displayName="YELLOW" xsi:type="CE">
      <originalText/>
    </value>
  </characteristic>
</subjectOf>
<subjectOf>
  <characteristic classCode="OBS">
    <code code="SPLSCORE" codeSystem="2.16.840.1.113883.1.11.19255"/>
    <value value="2" xsi:type="INT"/>
  </characteristic>
</subjectOf>
<subjectOf>
  <characteristic classCode="OBS">
    <code code="SPLSHAPE" codeSystem="2.16.840.1.113883.1.11.19255"/>
    <value code="C48345" codeSystem="2.16.840.1.113883.3.26.1.1"
      displayName="OVAL" xsi:type="CE">
      <originalText>capsule shaped</originalText>
    </value>
  </characteristic>
</subjectOf>
<subjectOf>
  <characteristic classCode="OBS">
    <code code="SPLSIZE" codeSystem="2.16.840.1.113883.1.11.19255"/>
    <value unit="mm" value="10" xsi:type="PQ"/>
  </characteristic>
</subjectOf>
```

## SPL Data Element Examples

```
</subjectOf>
<subjectOf>
  <characteristic classCode="OBS">
    <code code="SPLCOATING" codeSystem="2.16.840.1.113883.1.11.19255"/>
    <value value="false" xsi:type="BL"/>
  </characteristic>
</subjectOf>
<subjectOf>
  <characteristic classCode="OBS">
    <code code="SPLSYMBOL" codeSystem="2.16.840.1.113883.1.11.19255"/>
    <value value="false" xsi:type="BL"/>
  </characteristic>
</subjectOf>
<subjectOf>
  <characteristic classCode="OBS">
    <code code="SPLIMPRINT" codeSystem="2.16.840.1.113883.1.11.19255"/>
    <value xsi:type="ST">Miracle;C55;20;mg</value>
  </characteristic>
</subjectOf>
```

## SPL Data Element Examples

### 7. DEA Schedule

- 7.1. Describing the DEA schedule of a product

Text:

MiracleDrug is classified as a Schedule II controlled substance.

XML:

```
<subjectOf>  
  <policy classCode="DEADrugSchedule">  
    <code code="C48675" codeSystem="2.16.840.1.112883.3.26.1.1" displayName="CII" />  
  </policy>  
</subjectOf>
```