


Name: ST-P17012-Carton, For OTFC Blister Packer 1200 MCG
ID: ST-DMS-Specification-PSMM-10006054
Version: 5.0.0.0 Effective Date: 09-Mar-2012

Packaging Specifications and Methods Manual

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| Page 1 of 6 |  COVIDIEN Mallinckrodt |
| | CODE: 17012 |
| | ITEM: CARTON, FOR OTFC BLISTER PACKER, 1200 MCG |
| SITE RESPONSIBLE: | St. Louis |
| INTENDED USE: | Packaging Component - Secondary |

Covidien St. Louis Plant – Label Department –
will perform testing for this PSMM

ACCEPT ON VENDOR'S CERTIFICATE OF COMPLIANCE:

| TEST | ACCEPTANCE LEVEL |
|--------------------------------|--|
| CERTIFICATE OF COMPLIANCE | Retained |
| PRODUCT DESCRIPTION AND PART # | 1701200 OTFC 1200 HIGH SPEED |
| CARTON DIMENSIONS | 4.449" x 3.150" x 5.394" ($\pm 1/32$ ") |
| SAMPLE NUMBER | S090628 |
| MOD-PAC PRODUCT CODE | 132907 |

Retain a copy of the Vendor's Certificate of Compliance in the Quality files. The test(s) listed above must be on the Certificate from the vendor and comply with the stated acceptance levels. Record the results in the log book on the Carton for OTFC Inspection Form 10006043.

COUNT ACCURACY

+ 1 %

Perform a count verification of the number of cartons received. Use *Table 1. Number of Containers/Boxes To Be Counted*, to verify the supplier's count. Evenly select the boxes/containers to be inspected throughout the lot. The total count should be within 1% of the supplier's stated amount in these boxes. If supplier's count is less than a 1% discrepancy, supplier's count may be used for the remaining boxes/containers. If supplier's count is more than a 1% discrepancy, notify supervision. Use the following formula to determine the count accuracy: $((\text{Total Verified Count of Containers/Boxes} - \text{Total Suppliers Stated Count on Containers/Boxes}) / \text{Total Suppliers Stated Count on Containers/Boxes}) * 100 = \text{Count Accuracy}$. Record the results in the log book on the Carton for OTFC Inspection Form 10006043.

TABLE 1. Number of Containers/Boxes To Be Counted


| Number of Containers / Boxes Received | Number of Containers/Boxes to Count |
|---------------------------------------|-------------------------------------|
| 1 – 24 | 5 |
| 25 – 35 | 6 |
| 36 – 48 | 7 |
| 49 – 63 | 8 |
| 64 – 80 | 9 |
| 81 – 99 | 10 |
| 100 - 121 | 11 |

Approved by Jane Rich (jane.rich) on 09-Mar-2012

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PROOFREAD CARTON

To pass test

Using the same containers/boxes selected for count accuracy, randomly select one sample to be proofread (see Table 2). Fully proofread sampled cartons to verify that all printed information and print alignment is identical to that found on the approved master carton or proof. Record the results of the test as "pass" or "fail" in the logbook on the Carton for OTFC Inspection Form 10006043. **Also use these samples for the following tests listed below: Appearance, Carton Evaluation, and Color Verification.**

TABLE 2: Sampling Chart

| Number of Containers/Boxes Received | Total Sample Size |
|-------------------------------------|-------------------|
| 1 - 24 | 5 |
| 25 - 35 | 6 |
| 36 - 48 | 7 |
| 49 - 63 | 8 |
| 64 - 80 | 9 |
| 81 - 99 | 10 |
| 100 - 121 | 11 |

APPEARANCE

White carton with seal and tuck flap ends

From the samples selected from Table 2, verify the samples are a white carton with a seal end and a tuck flap on the opposite end. Record the result on the log book on the Carton for OTFC Inspection Form 10006043.


CARTON EVALUATION

| | |
|-------------------|---------------------------------------|
| CARTON DIMENSIONS | 113 mm x 80 mm x 137 mm (± 1 mm) |
| PRINTED BOX COLOR | Green |
| STRENGTH | 1200 mcg |
| NDC NUMBER | 0406-9212-30 |
| REVISION NUMBER | 01/2012 |

From the samples selected from Table 2, verify the samples are a pre-printed carton with green boxes, the strength listed as 1200 mcg, the NDC number as 0406-9212-30, and the revision number as 01/2012. See representative diagram for carton dimension measurements.

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COLOR VERIFICATION

Meets Requirements

From the samples selected from Table 2, verify the samples match the vendor-issued color chart. Record the result on the log book on the Carton for OTFC Inspection Form 10006043.

Note: The vendor-issued color chart should be within one year of acceptance and prolonged exposure to light has been avoided.

CARTON PRINT QUALITY AND CONDITION INSPECTION PLAN

Sampling

Determine sample size according to ANSI/ASQC Z1.4 as listed in *TABLE 3. Sample Size for Carton Print Quality and Condition*. Select the number of samples evenly throughout from the number of containers/boxes from Table 1. For example, if your lot size is 15,000 pieces (36-48 boxes), sample 315 total cartons evenly from the 7 boxes chosen from Table 1.

Inspection level for this code: II

Single Sampling Plan: Normal

Acceptance Levels

| | |
|---------------------------|--------------------|
| For Critical Defects | One defect rejects |
| The AQL for Major defects | 1.0 |
| The AQL for Minor defects | 4.0 |


| TABLE 3. Sample Size for Carton Print Quality and Condition ANSI/ASQC Z1.4 | | | | |
|--|------------------|-----------------|-------------|-----------------|
| Lot Size | AQL = 1.0 | | AQL = 4.0 | |
| | Sample Size | Accept - Reject | Sample Size | Accept - Reject |
| 2 - 8 | 100 % Inspection | 0 - 1 | 3 | 0 - 1 |
| 9 - 15 | 13 | 0 - 1 | 3 | 0 - 1 |
| 16 - 25 | 13 | 0 - 1 | 3 | 0 - 1 |
| 26 - 50 | 13 | 0 - 1 | 13 | 1 - 2 |
| 51 - 90 | 13 | 0 - 1 | 13 | 1 - 2 |
| 91 - 150 | 13 | 0 - 1 | 20 | 2 - 3 |
| 151 - 280 | 50 | 1 - 2 | 32 | 3 - 4 |
| 281 - 500 | 50 | 1 - 2 | 50 | 5 - 6 |
| 501 - 1,200 | 80 | 2 - 3 | 80 | 7 - 8 |
| 1,201 - 3,200 | 125 | 3 - 4 | 125 | 10 - 11 |
| 3,201 - 10,000 | 200 | 5 - 6 | 200 | 14 - 15 |
| 10,001 - 35,000 | 315 | 7 - 8 | 315 | 21 - 22 |
| 35,000 - 150,000 | 500 | 10 - 11 | 315 | 21 - 22 |
| 150,000 - 500,000 | 800 | 14 - 15 | 315 | 21 - 22 |
| 500,001 to over | 1250 | 21 - 22 | 315 | 21 - 22 |

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Defect Procedure:

Once the sample size is determined, inspect these samples for critical, major and minor defects. Record the results on the log book on the Carton for OTFC Inspection Form 10006043. To pass tests, product must meet the specifications stated for the defect criteria. A minor defect must be readily apparent. A minor defect affects the function of the carton. Contact your supervisor for disposition of any defects that can not be clearly categorized using *TABLE 4. Defect & Description of Critical, Major, and Minor Defects.*

If product meets the specification, record the result as "Passes Test," in the summary section of the log book on the Carton for OTFC Inspection Form 10006043. Discard the cartons that were found to have minor or major defects (adjust lot count accordingly). If the product does not meet the specification, record the failing result and retain all defective cartons with the lot for return to the vendor.

TABLE 4. Defect & Description of Critical, Major, and Minor Defects.

| Defect | Description | Specification |
|--|--|---------------|
| CRITICAL DEFECTS (One Defect Rejects Lot) | | |
| Mixed Components | There should be no cartons of any other product name, dosage, strength, or type mixed with the shipment. | To Pass Test |
| Illegible printing | There should be no cartons that contain illegible printing due to smearing, partial printing, smudging, misalignment, ghosting, ink spots, etc. | To Pass Test |
| Bar Code Defect – Not Scannable | There should be no cartons in which the bar code is not scannable. | To Pass Test |
| MAJOR DEFECTS (AQL = 1.0) | | |
| Incorrect Orientation | Orientation of printing on cartons should match Master. | To Pass Test |
| Damage or Torn | Cartons that are torn or damaged. | To Pass Test |
| Dirt, grease, or contamination | Cartons that are contaminated with dirt, grease, or other contamination. | To Pass Test |
| MINOR DEFECTS (AQL = 4.0) | | |
| Bar Code Defect-Scannable | Cartons with bar codes containing a defect but remain scannable. | To Pass Test |
| Printing Defect - Legible | Cartons that contain defects such as smearing, partial printing, smudging, misalignment, ghosting, ink spots, etc. but all printed material remains legible. | To Pass Test |

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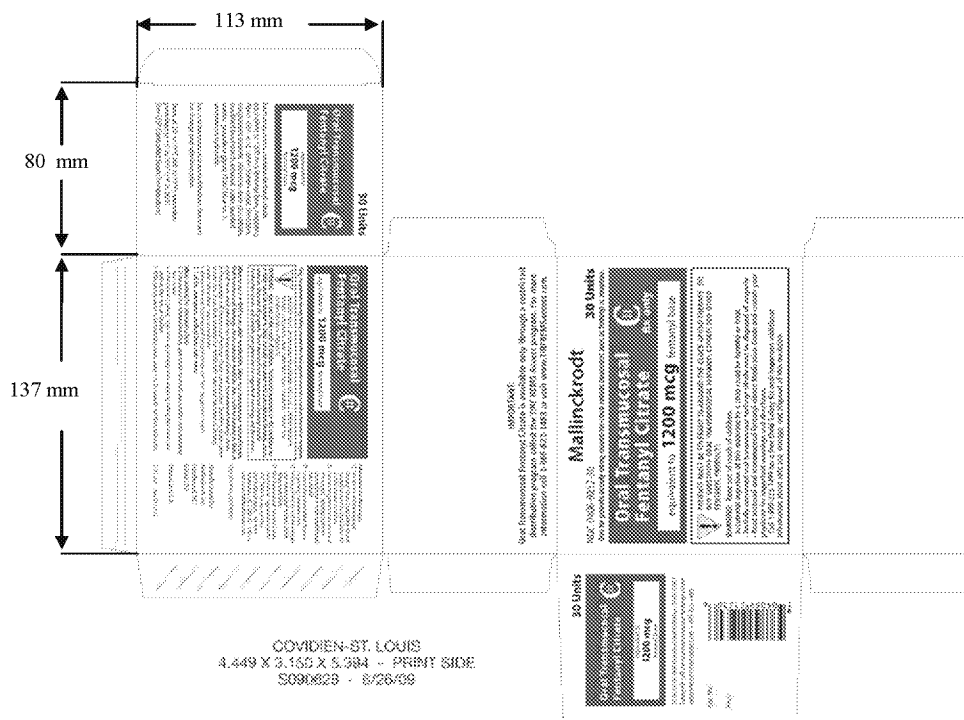
**Oral Transmucosal Fentanyl Citrate
3.2.P.7 Container Closure System**

Sequence 0044 - Annual Report
October 31, 2011 through October 30, 2012
ANDA 078907

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Representative Drawing:


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PURCHASING SPECIFICATIONS:

Note: this information is for the Purchasing and QA departments only.

ITEM: Covidien-Mallinckrodt Code 17012 - OTFC 1200 HIGH SPEED

DESCRIPTION: Stock Type: SBS .018
Sample number: S090628

MFG PART NO: 132907

ART NO: A035044

DIMENSIONS: 4.449" x 3.15" x 5.394" ($\pm 1/32$ ")

COLOR: Black, Process Yellow, PMS 335 Green

STYLE: Tuck top, seal end

INCOMING SPECIFICATIONS: Each outer carton to be marked with Covidien-Mallinckrodt PO Number and Part Number, 17012.

MARKINGS: These cartons are to be lot marked internally.

CLEANLINESS: All cartons to be free of dirt, foreign matter and other contaminants

MANUFACTURER: MOD-PAC Corp.
Buffalo, NY

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