# Patch, MyCite, Pouched, D-Tect

# SPC-2684

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## 1. Purpose/Description

This document describes the manufacturing requirements and specifications of the "Patch, MyCite, Pouched, D-Tect (SPC-2684)" for Otsuka America Pharmaceutical, Inc., Hayward (OAPI-Hayward).

## 2. Definitions, Acronyms, and Abbreviations

| | |
|---|---|
| REF | Reference number. The part number of the assembled product. |
| BOM | Bill of Material |

## 3. References

| Doc Number | Title |
|---|---|
| BOM-0107 Rev 1 | BOM, Patch, MyCite, Pouched, D-Tect, SPC-2684 |
| WI-0376 | Work Instruction, Bulk D-Tect Patch Packaging |

## 4. Supplier

| Primary Manufacturer |
|---|
| **Screentec Oy**<br>Konekuja 2<br>FI-90620 Oulu, Finland |

## 5. Handling Requirements

5.1 Batteries should be handled such that they do not contact and short to each other or contact metal surfaces which may cause the charge to drain.

5.2 Finished pouched patch assemblies shall be handled with care. Avoid pouch and label damage either from external contact or from the patch assembly pushing against the pouch from the inside.

5.3 Production shall occur in a clean area to minimize contamination.

## 6. Patch Assembly Requirements

Design/finished Patch assembly requirements are defined by component and assembly specification documentation listed on the Pouched Patch Assembly BOM.

## 7. Data Recording and Labeling

7.1 Lot Number: A unique lot number shall be assigned to identify the batch of pouched Patches that were assembled at one time.

7.2 A lot history record shall be maintained with a record of at least the following:

7.2.1 REF number and revision (Note: This document number and revision)

7.2.2 Lot number

7.2.3 Quantity

7.2.4 BOM-0107 part number and revision

7.2.5 Component/Raw material part numbers and Lot numbers

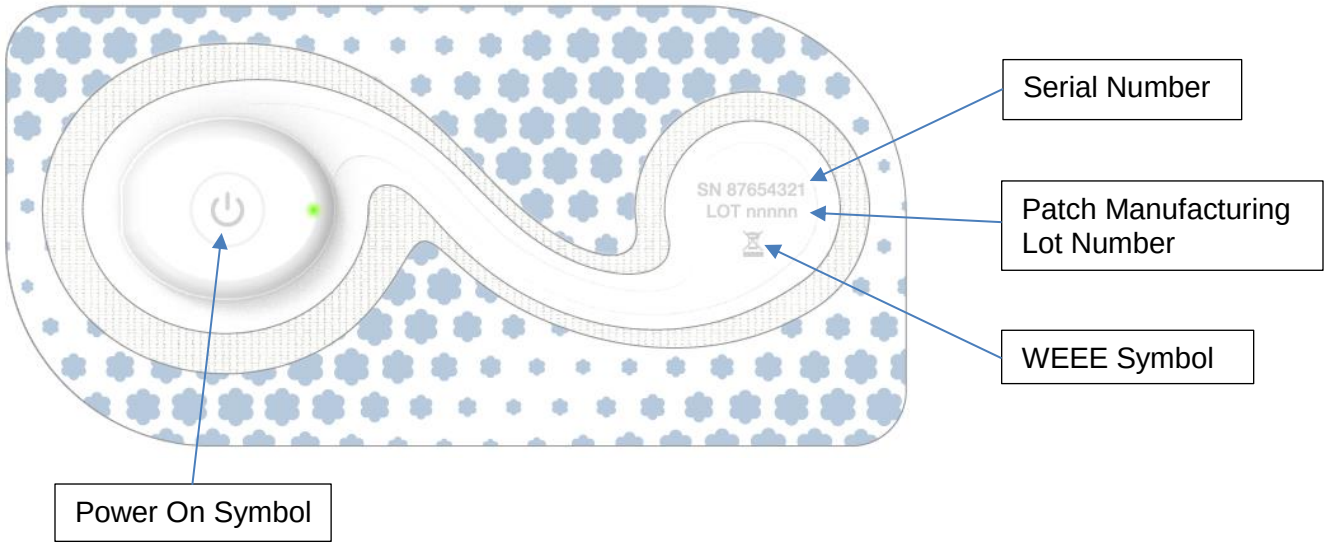
7.2.6 Record of all production documentation part numbers and revisions

7.2.7 Record of who assembled the product

7.2.8 Expiration date of pouched Patch

7.2.9 Part number and revision of product labeling

7.3 Graphics on patch: The following image shows the content that will be laser etched onto the top surface of each patch. Font size for text is 7pt = 1.76mm tall.




7.4 Primary Packaging Variable Data Labeling: The following are variable data content requirements of Label, Pouch, MyCite, D-Tect (LBL-0554):

Note: To avoid potential damage to the pouch, it is recommended that the printed label be applied to the pouch prior to loading the Patch assembly. It is understood that the images below are of a sealed pouch with Patch already inside. This is due to a lack of unsealed pouches to work with for purposes of generating this document.

7.4.1 Part number: The part number of the pouched Patch adjacent to the REF box. REF: SPC-2684

7.4.2 Lot number: Human readable and barcode of Manufacturing lot number

- Code 128 format at 600dpi or better
  - Note: OAPI-Hayward will approve variable data label print quality and may choose to allow less than 600dpi

7.4.3 Expiration Date: [yyyy-mm-dd].

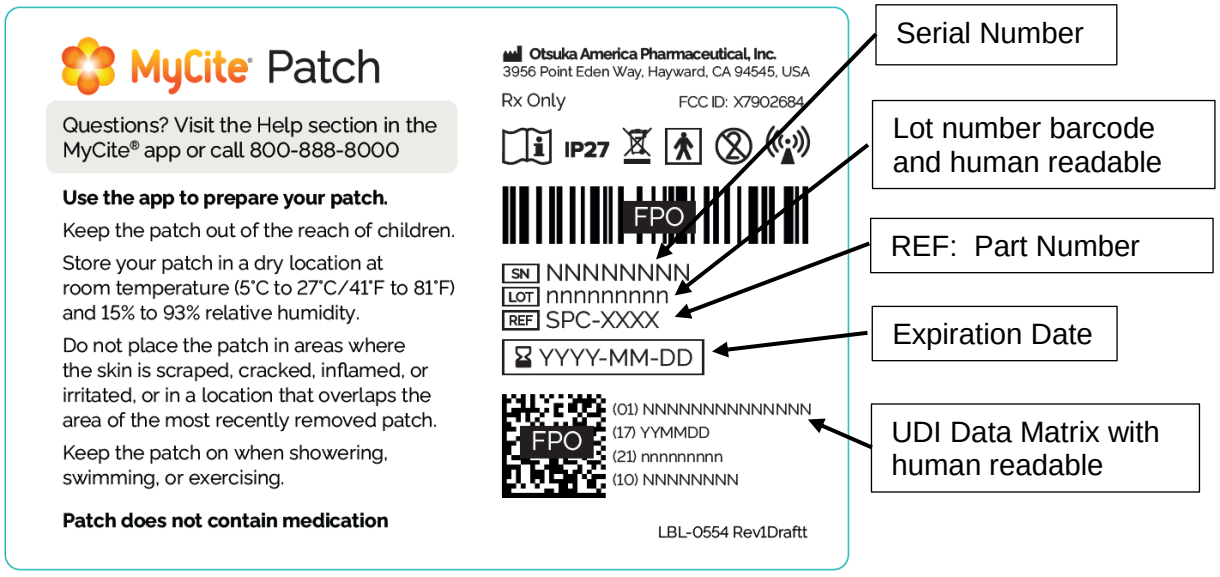
- Expiration date is defined as three (3) years from the date the manufacturing of the lot started.

7.4.4 UDI (Unique Device Identifier): A GS1 DataMatrix barcode and human readable content containing the following:

- Device Identifier: (01) **00857335005114**
- Expiration Date: (17) yymmdd
- Lot Number: (21) nnnnnnnn
- Serial Number: (10) NNNNNNNNN

When the UDI barcode is scanned, the data shall be presented in the following way: (01) **00857335005114** (17) yymmdd (21) nnnnnnnn (10) NNNNNNNN

*Note: All label images in this document are for product definition only. The current revision of the label is governed by the label component specification.*



7.5 Pouch Label Placement: The variable data label shall be applied as indicated below.

- It is important that the label is applied with the same orientation relative to the pouch for all Patch assemblies. Note: The notches in the pouch are to the right when the label is readable.
- Label shall be centered vertically and positioned horizontally as indicated. Care should be taken to avoid tilted/crooked labels.


7.6 Patch Assembly Insertion: The Patch assembly shall be inserted with the bump facing up and bump first into pouch.


7.7 Pouch Seal: The bottom of the pouch shall be sealed with a 11mm wide seal.

## 8. In-process Inspection/Test Requirements

The manufacturer must establish an In-Process Inspection based on an appropriate statistical sampling method. The following In-Process Inspection plan can be used as guidance. If this plan is not used, OAPI-Hayward must approve the alternate plan.

### 8.1 Visual Inspection – Non-destructive Tests

| Requirement | Description/Specification |
|---|---|
| Sample Size | ANSI AQL 1.0 or better. Typically, General Level II should be used, however, the inspection level may be varied depending on the nature of the inspection.<br>Samples should be taken across the manufacturing lot, i.e., beginning, middle, and end, or at specific time intervals |
| Print Quality-Pouch Label | Printing of variable data on pouch label (Lot Number, Serial Number, REF Number, and Expiration Date etc.) shall be clearly legible and must not flake or fade under proposed storage condition. |
| Pouch Label Location | Pouch label shall be located as indicated above. Label should not be tilted/crooked on the pouch. |
| Pouch Damage | No damage including tears or pinholes in pouch are allowed. |
| Pouch Seal Integrity | Pouch seal of bottom of pouch shall be 11mm wide.<br>Seals shall be complete, continuous, and uniform. Voids or creases are not allowed in the pouch seal. |

### 8.2 Functional Test

| Requirement | Description/Specification |
|---|---|
| Sample Size | All (100%) of Patch assemblies shall be tested at the final tester. |
| Patch Battery<br>- Depassivation and voltage confirmation | Battery shall have a measured voltage greater than 2.9V with a 600Ohm load. Batteries that do not pass this test shall not be used in a patch.<br>Note: Prior to confirming/measuring the voltage, each battery shall be depassivated by applying a 40 Ohm load for 25 Seconds across the battery. |

8.3 Visual Inspection – Destructive Tests

| Requirement | Description/Specification |
|---|---|
| Sample Size | ANSI AQL 1.0 or better. Typically, General Level II should be used, however, the inspection level may be varied depending on the nature of the inspection.<br>Samples should be taken across the manufacturing lot, i.e., beginning, middle, and end, or at specific time intervals |
| Patch Quality | Reference component and assembly drawings for detailed specifications for the following:<br>Patch shall be centered within the applicator window/opening<br>Edge cuts of visible layers shall be clean/smooth without noticeable inconsistencies as visible from 18-24 inches with ambient lighting and unaided eyes.<br>Hydrogel shall be positioned inside the perimeter of the holes in the skin adhesive.<br>Patch edges shall not be ragged, torn or sharp. |
| Liner Removal | The liner shall remove fully from the Patch. There shall be no portion of removed adhesive greater than 5mm x 5mm, nor removal of the hydrogel. |
| Contamination | No visible particles greater than 2.0 square mm per Patch. (As visible from 18-24 inches with ambient lighting and unaided eyes.)<br>No more than 3 visible particles per pouch. |

## 9. Storage

9.1 Store at 5°C to 27°C/41°F to 81°F and 15% to 93% relative humidity (See hydrogel manufacturer's specification for short- and long-term storage considerations)

9.2 To avoid potential pouch damage care should be taken not to put too much weight on pouched Patch assemblies.

## 10. Ship-To-Address & Tariff Code

Ship to information is defined in the OAPI-Hayward Purchase Order.
Product to be packaged per WI-0376 unless Purchase Order states otherwise.

**Tariff Code: 9018 19 10 00**
Code Description: Instruments and appliances used in medical, surgical, dental or veterinary sciences, including scintigraphic apparatus, other electromedical apparatus and sight-testing instruments

- Electrodiagnostic apparatus (including apparatus for functional exploratory examination or for checking physiological parameters)
- Monitoring apparatus for simultaneous monitoring of two or more parameters

## 11. Compliance Requirements

11.1 Prior to incorporation, the supplier shall notify OAPI-Hayward and obtain OAPI-Hayward's approval of changes to the specification, supplier, material, or process which deviate from established parameters or quality requirements contained in this document.

11.2 All specifications and related documents provided by Otsuka America Pharmaceutical, Inc. and any of its companies are considered proprietary and confidential and shall be handled as such by the supplier.

11.3 All manufacturing of this product must comply with all Quality and Supplier agreements between Vendor/Supplier and Otsuka America Pharmaceutical, Inc.

## 12. OAPI-Hayward Incoming Receiving and Inspection Requirements

Incoming material must conform to the requirements and procedures as defined in WI-0376

12.1 Packing Slip

The following packing slip documentation shall accompany all material shipments:

| Requirement | Description/Specification |
|---|---|
| Date (Print Date) | Date of shipment |
| Purchase Order Number | PO#[nnnnnn] |
| Part Number | SPC-[nnnn] |
| Item Description | Patch, MyCite, Pouched, D-Tect |
| Quantity | [n] each |

12.2 Certificate of Conformance

Shipments from the supplier must include a Certificate of Conformance which includes the following requirements:

| Requirement | Description/Specification |
|---|---|
| Date (Print Date) | Date |
| Purchase Order Number | PO#[nnnnnn] Note: May have a different format such as "Customer PO: nnnnnn" |
| Part Number and Revision | SPC-[nnnn]/Rn |
| Bill of Material Number and Revision | BOM-[nnnn]/Rn |
| Quantity of Patches in shipper or on pallet (total quantity of Patches in shipment) | [n] |
| Screentec Lot Number | Screentec Lot# [nnnnn…] |
| Quality Assurance Approval and Date | Signature and Date |

12.3 Lot History/Batch Record

A lot history/batch record shall be shared with OAPI-Hayward for each shipment. The document may be shared electronically, or a copy may be sent with the product.

## 13. Retains

Additional product that will be retained by OAPI-Hayward shall be ordered, assembled and shipped for each manufacturing build campaign. Ideally the retains product will ship at the same time as the commercial shipment. The retains will have the following characteristics:

13.1 Retains will be assembled as part of the same manufacturing build as the commercial product.

13.2 Retains are fully assembled product including packaging and labeling up to the shipper box level.

13.3 Retains will ship in a separate container from the commercial shipment so that it may be easily stored without having to disturb the commercial product packaging.

13.4 The external packaging (shipper box) of the retains shall be identified with the word "Retains". This will enable receiving to easily identify them.

The following quantity of retains shall be purchased for each line item of commercial product:

| Total Finished Lot Quantity | Quantity of SPC-2540 |
|---|---|
| ≤ 500 | 6 |
| ≤ 1,000 | 12 |
| > 1,000 | 24 |

## 14. Safety Precautions

14.1 Proper lifting mechanics should be observed.

## 15. Document History

| Rev | Originator | Description of Change |
|---|---|---|
| 1 | T. Schoenberger | Initial release to support Otsuka branded product |