



Complaint Number: 101619

## Report 8D

Generated By: Christine Hulme  
Generated On: 04 Nov 2011

### I. COMPLAINT INFORMATION

Origination Date	17 Oct 2011		
Sales Name	Daniel Eng	Sales Office	Dunstable
Telephone	+44 (0)1636 821494	Fax Number	+44 (0)1582 478111
Email	daniel.eng@scapa.com		
Customer Complaint Ref			
Customer Name	F Hoffmann-La Roche AG		
SAP Customer Number	134718	Customer Order N°	
Customer Part Number			

#### 1) Invoices And Items On Complaint

#### 2) Problem Description

PO 7000055606  
Material number 10113479

visual inspection on 200 samples.  
82 showed serious folds on the body side liner  
5 showed black spots on the liner.

Actions Requested From The Customer

#### 3) Containment Actions

II. EVALUATION AND ACTION

Sample/photo Received	<input type="text" value="No"/>		
Date	<input type="text"/>		
Process Owner	<input type="text" value="Christine Hulme"/>		
Team Leader	<input type="text"/>		
Is Complaint Valid?	<input type="text" value="No"/>	Return The Goods	<input type="text"/>
		Dispose The Goods	<input type="text"/>
Comments	<input type="text"/>		

1) Analysis

8 samples returned.

7 samples show slight crease (100 micron wide by 20 -24mm) in top paper liner. These creases are not visible on the adhesive surface. These creases are not expected to be detrimental to adhesion performance of patch. We believe these creases have been caused during our lamination pre-op before converting into patches and we will work to eliminate the creases by ensuring improved line up of lamination layers. We will also add this type of cosmetic defect as an attribute check in the part Item Pack.

1 sample shows 100 micron contaminate embedded in top surface of paper. This particle appears to be below the silicone coating and will not become detached during use of the patch in application. This discoloured particle is part of the natural paper pulp used to make the paper. This cannot be eliminated by the paper supplier. Would a coloured paper (light blue?) be an option to camouflage discoloured particles?

Author	<input type="text" value="Terry O'Brien"/>	Date	<input type="text" value="28 Oct 2011"/>
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2) Root Causes

<input type="text"/>			
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Author	<input type="text"/>	Date	<input type="text"/>
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3) Possible Solutions

<input type="text"/>			
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Author	<input type="text"/>	Date	<input type="text"/>
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4) Implemented Perm Corrective Actions

<input type="text"/>			
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Author	<input type="text"/>	Date	<input type="text"/>
Estimated Date	<input type="text"/>	Implementation Date	<input type="text"/>
Validation Date	<input type="text"/>		

5) Corrective Actions Validation

Author		Date	

6) Preventive Actions

Author		Date	
Estimated Date		Implementation Date	
Validation Date			

7) Review Of Documentation

(a) MSR

Reviewed?	No		
Reference		Date	

(b) Flow chart, control plan, work inspection instructions

Reviewed?	No		
Reference		Date	

(c) FMEA

Reviewed?	No		
Reference		Date	

(d) Customer specification

Reviewed?	No		
Reference		Date	

8) Congratulate The Team