Complaint Number: 101617

Report 8D

Generated By: Christine Hulme
Generated On: 22 Nov 2011

I. COMPLAINT INFORMATION

Origination Date	17 Oct 2011		
Sales Name	Daniel Eng	Sales Office	Dunstable
Telephone	+44 1636 821494	Fax Number	+44 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

PO70000556606
Material number 1114206
Batch number 1012060.
Visual inspection of 200 samples.
68 showed black spots either on stiffner and/or the body-side liner.
12 showed serious folds on the body side liner.

Actions Requested From The Customer

3) Containment Actions

II. EVALUATION AND ACTION

Sample/photo Received	No				
Date					
Process Owner	Christine Hulme				
Team Leader	tobrien				
Is Complaint Valid?	Yes	Return The Goods		Dispose The Goods	

Comments

1) Analysis

8 samples returned.
Findings are as follows:
1. 200 micron particle embedded in body side liner paper.
2. 200 micron particle embedded in body side liner paper
3. 200 micron particle embedded in body side liner paper & fold in body side liner paper.
4. Coarse cell in PE foam side of pull tab
5. 100 micron particle embedded in body side liner paper & coarse cells in PE foam side of pull tab.
6. Fold in body side liner paper
7. Fold in body side liner paper
8. 4 x 100 micron particles embedded in body side liner paper & coarse cells in PE foam side of pull tab.

Author	Terry O'Brien	Date	28 Oct 2011

2) Root Causes

Embedded particles in paper. Our supplier has indicated that paper is a natural substance, with coloured imperfections embedded in the paper itself.

Fold in body side liner is caused by a 'kick' in the processing of the plaster. As there is only partial adhesive coverage on the device side of the plaster the device side liner can lift and get caught in tooling. We now use modified tooling which has reduced incidents of kicking but not completely eliminated this issue.

Coarse cell structure in PE foam - We have sent sample to our supplier for review and comment. PE supplier has responded 16/11/2011. Cells in foam can vary between 0.1 and 0.7mm (up to 1mm).

Author	Terry O'Brien	Date	28 Oct 2011

3) Possible Solutions

Author		Date	

4) Implemented Perm Corrective Actions

Author		Date	
Estimated Date		Implementation Date	
Validation Date			

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?	Yes		
Reference	TBA	Date	

(c) FMEA

Reviewed?	No		
Reference		Date	

(d) Customer specification

Reviewed?	No		
Reference		Date	

8) Congratulate The Team