



## Customer Complaint Submission Form

*For submission of your request into our system, it is REQUIRED that all details are completed. Our goal is "Timeliness and Quality of Response".*

PLEASE TYPE OR USE BLACK INK

Date of Submission: _____		
<b>A: CUSTOMER INFORMATION</b>		
Company Name: _____		Contact Name: _____
Address: _____		Phone: _____
		Fax: _____
Report/Complaint #: _____		E_mail: _____
<b>B: BACKGROUND INFORMATION</b>		
Describe Exact Details of Problem/Defect:          		
<b>Type of Actions Requested:</b> <input type="checkbox"/> Notification/No Response Needed <input type="checkbox"/> Investigation <input type="checkbox"/> CAPA (Corrective Action Plan) <input type="checkbox"/> Credit <input type="checkbox"/> Return <input type="checkbox"/> Other _____	<b>Where Detected:</b> <input type="checkbox"/> Incoming <input type="checkbox"/> Post Processing <input type="checkbox"/> After Assembly <input type="checkbox"/> Field Complaint <input type="checkbox"/> Other _____	<b>Processing by Your Company:</b> <input type="checkbox"/> Washed Only <input type="checkbox"/> Washed and Sterilized <input type="checkbox"/> Sterilized Only <input type="checkbox"/> None – Used as Received  If Sterilized, Type: <input type="checkbox"/> ETO <input type="checkbox"/> Steam <input type="checkbox"/> Gamma <input type="checkbox"/> Other  Siliconized?: <input type="checkbox"/> Yes <input type="checkbox"/> No
Describe Exact Details of Processing (Times, Temperatures, etc.):    		
<b>C: INSPECTION DETAILS</b>		
Specification # on File: _____	Accept/Reject (AQL): _____ # Inspected: _____	Utilized Inspection Standard:  <input type="checkbox"/> ANSI <input type="checkbox"/> MIL <input type="checkbox"/> ISO/DIN <input type="checkbox"/> Other _____
Defect Out of Specification: _____	# Detected: _____ Incident Rate %: _____	
Name of QA/Manufacturing contact who can provide more details on defect: _____	Phone: _____	E_mail: _____
<b>D: SUSPECT PRODUCT</b>		
<u>Customer Detail</u> SKU #: _____ PO #: _____ Quantity Received: _____ Quantity Rejected (if applicable): _____ If Field Complaint – What is the Product Name: _____	<u>West Detail</u> Item #: _____ Master Lot #: _____ Formulation: _____ Sub Lot #: _____ West Order #: _____ Carton #: _____	
Other Product Details/Comments:   		
<b>E: SAMPLE INFORMATION</b>		
- Are defect samples available for evaluation? <input type="checkbox"/> Yes <input type="checkbox"/> No If Yes, please provide samples to West. # of Samples Submitted With Defect: _____ # of Samples Submitted Without Defect (Control): _____	- Have samples been in drug contact? <input type="checkbox"/> Yes <input type="checkbox"/> No  <p style="text-align: center;"><b>If Yes, You Must Provide a MSDS</b></p>	
Provide Control Lot #: _____	<i>For Internal Use Only:</i> _____ <i>Date:</i> _____	

**Submit Completed Form To: Linda Fetterman**  
**West Pharmaceutical Services**  
**101 Gordon Drive,**  
**Lionville, PA 19341-0645**  
 Telephone: 610-594-3363 Fax: 610-594-3016  
 E\_mail: [Linda.Fetterman@westpharma.com](mailto:Linda.Fetterman@westpharma.com)



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## **Submission Form Guidelines**

### **Section A: CUSTOMER INFORMATION**

- Enter all corresponding contact details.
- *Contact Name & Address*
  - Identify the person who will be the primary contact and address for the final report.
- *Report/Complaint Number*
  - Provide your company's reference number (if available) for the filed complaint. All correspondence to your company will also reference this number.

### **Section B: BACKGROUND INFORMATION**

- Describe in detail the product problem and/or defect. Include full descriptions, the date the issue was encountered and facts that brought your company to the conclusion that West's product is suspect. If available and relevant, also enclose any supporting documentation such as inspection sheets, laboratory reports and process flows, and appropriate photos or video.
- *Type of Actions Requested*
  - Check the actions that are being requested from West and are to be addressed in the final report.
- *Where Detected*
  - Check the applicable location where the problem or defect was encountered.
- *Processing by Your Company*
  - Check the applicable processing steps that were performed by your company on the suspect product.
- *Describe Details of Processing*
  - If processing steps such as washing, sterilization or siliconization were performed by your company, describe in detail the manufacturer/model of the processing equipment, process times and temperatures, dosage level (i.e. 2.5mRads) and trade name of processing aides. If there were any recent changes to the described processing steps, please include details of the changes.

### **Section C: INSPECTION DETAILS**

- In order for West to complete a full assessment of the defect level on suspect product, please complete all details for conditions of inspection, the inspection standards used and the determined incidence rate percent.
- *Specification Number on File*
  - Provide the specification number on file and that was used to assess or inspect the product.
- *Defect Out of Specification*
  - Provide a description of the specification requirement that has not been met for this product.

### **Section D: SUSPECT PRODUCT**

- The following West product details can be obtained from the Certificate of Conformance, carton labels or the packing slip that accompany each shipment.
  - *Master Lot Number* (One lot number assigned to the entire shipment) For example: M173246
  - *Sub Lot Number* (Plant specific lot number(s) to fill order quantity) For example: J3279
  - *Carton Number* (Individual carton number for each sub lot) For example: 1

### **Section E: SAMPLE INFORMATION**

- In order for West to make a full assessment if the suspect product is defective, it is crucial that samples be submitted for analysis and investigation. Please enclose representative samples as part of your submission.
- *Defect Sample*: Product that clearly shows evidence of a defect or problem.
- *Control Sample*: Product that clearly does not show evidence of a defect or problem.
- *Provide Control Lot Number*
  - Identify the sub lot number from which the control product was obtained.
- If the samples being submitted to West were in contact with a drug product, a copy of a MSDS for the drug product is required as part of the submission.