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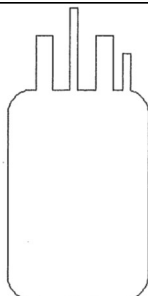
Effective Date



Document Title

FORM - Complaint report concerning octaplas or octaplasLG (Form to be used in case of breakage/ leakage of bags)

COMPLAINT REPORT Corporate R./...../.....
concerning octaplas or octaplasLG
(Form to be used in case of breakage/ leakage of bags)

TO BE FILLED LOCALLY by Complainant		
Date of complaint:		Local Complaint No:
Contact person (name), full address, telephone number, e-mail		
About product	<input type="checkbox"/> octaplas	<input checked="" type="checkbox"/> octaplasLG
Blood group:	Batch number:	Quantity of bag(s)
Description of complaint/quality defect (e.g. inner bag/outer bag):		 Please indicate position of defect, if possible
Has the product been administered to the patient? <input type="checkbox"/> YES <input type="checkbox"/> NO		
Date and signature (+Name) of complainant:		
TO BE FILLED BY MANUFACTURING SITE		
Received on:		
Licence Holder (MAH):		
Evaluation of defect / classification of quality defects according PIC/S <input type="checkbox"/> Class 1 → Information of <input type="checkbox"/> cQRB / Date <input type="checkbox"/> Class 2 → Information of <input type="checkbox"/> cQRB / Date <input type="checkbox"/> Class 3 → <input type="checkbox"/> Others (not meeting the minimal criteria of the Class 3) <input type="checkbox"/> Reported quality defect is not confirmed		
Follow up required: <input type="checkbox"/> NO, total number of breakages per batch ≤ 0.5 % <input type="checkbox"/> YES, total number of breakages per batch > 0.5 %		

Person in charge / date:.....