

4. Contact that can give further information of any clinical incident.			
Name:			Position/Status:
Organisation:			
Address			
Telephone No:	Work:	Fax:	
E-mail address:			
5 Has manufacturer/supplier been informed?		YES/NO	
6. Other action taken by reporter:			
7. Company Contact			
Name:			Position/Status:
Company:			
Address			
Telephone No:	Work	Ext	Fax:
e-mail address:			
8. The following details should be obtained/confirmed with the licence holder			
Site of manufacture			
Date of distribution			
Batch size			
Distribution (including other countries)			
Other similar defects			
Retained sample to be tested / examined.			
Name of QP(s) responsible for batch release			
9. Comments of Duty Medicines Inspector:			
Initials:	Date:	Time:	
10. Comments of Duty Medical Assessor (where applicable)			

11. The following details should completed when available		
Cross ref. to other file(s)	Ref no:	
Defect confirmed?	Y/N	
Recall required?	Y/N	
Drug Alert to be issued?	Y/N	
12. Drug Alert/Recall Details		
Class	1 / 2 / 3	
Date		
Reference Number	EL	
Level	Wholesaler /Hospital Pharmacy/Community Pharmacy / Patient	
Distribution (In addition to miscellaneous list)	Hospital Only / Hospitals & Pharmacies	
Rapid Alert issued	Y/N	
13. Company Reports		
Initial report received	Y/N	Date:
Interim report received (if required)	Y/N	Date:
Closing report received	Y/N	Date:
14. Administrative details		
Communication to Competent Authority in Country of Manufacture	Date	
File opened	Date:	
Acknowledgement sent to reporter	Date:	
Closing letter sent to:	Reporter	Date
	Company	Date
File closed	Date	
Database updated	Date	
15. Additional notes		