

Formato 3

RAPID ALERT NOTIFICATION OF A QUALITY DEFECT / RECALL

IMPORTANT -- DELIVER IMMEDIATELY

Reference Number: MX/03/2020

(add letter head of sender):

1. To : (see list attached, if more than one)			
2. Product Recall Clas of Defect:		I <input checked="" type="radio"/> II	3. Falsification / Fraud (specify): Falsification /Adulterated
4. Product: Sprycel 50 mg		5. Marketing Authorisation number: 104M2007 SSA IV For use in humans / animals (Select as required):	
6. Brand / Trade name: Sprycel 50 mg		7. INN o generic name: Dasatinib	
8. Dosage form: Tablets		9. Strength: 50 mg	
10. Batch number (and bulk , if different): 2G6026H, 2G6085D, KC0134		11. Expiry date:	
12. Pack size and presentation: Box with 60 tablet of 50 mg		13. Date manufactured:	
14. Marketing Authorisation holder: BRISTOL-MYERS SQUIBB DE MÉXICO, S DE R.L. DE C.V			
15. Manufacturer: Not known because it's a counterfeit product Contact person: Telephone:		16. Recalling firm (if different) Contact person: Telephone:	
17. Recall number assigned (if available):			
18. Details of defect / Reason for recall: The product does not have the active principle and presents differences between primary and secondary packaging			
19. Information on distribution including exports (type of costumers, e.g. hospitals): Distributed in pharmacies and hospitals, There is no knowledge of exports.			
20. Action taken by issuing Authority: Alert publication on the web site, surveillance in market for to avoid the marketing and use, and international notification			
21. Proposed action: Aplication of security measures like product assurance			
22. From (issuing Authority): Federal Commission for the Protection from Sanitary Risk		23. Contact person: alertas@cofepris.gob.mx Telephone:+ 52 55 5080 52 00 ext. 11256, 11257 y 11183	
24. Signed Norberto López Santos Emergency Manager		25. Date: May, 13 2020	26. Time: 17:00