	Reference Number CASE_18

Rapid Alert Notification of a Quality Defect

1. To: The Regulatory Authority	
2. Product Recall Class & Type of Defect: Class: II Type: B	3. Falsification / Fraud (specify) Not Applicable
4. Product: Demetrin 10mg	5. Marketing Authorisation Number: G/2.6/188 For use in humans
6. Brand/Trade Name: DEMETRIN tablets	7. INN or Generic Name: prazepam
8. Dosage Form: tablets	9. Strength: 10 mg
10. Batch number (and bulk, if different): DT3236	11. Expiry Date: 28 Feb-2023
12. Pack size and Presentation: 100's	13. Date Manufactured: Not Applicable
14. Marketing Authorisation Holder: Pfizer Laboratories (Pty) Ltd, 85 Bute Lane, Sandton South Africa Contact Person: Bronwen.Swartz@pfizer.com Telephone: + 27 11 320 6363 / +27 67 416 7732	
15. Manufacturer: 15.1 Pfizer Freiburg Site, Germany	16. Recalling Firm (if different): Not Applicable Contact Person: Not Applicable Telephone: Not Applicable
15.2 Where the defect is attributed to a manufacturing site, site where defect occurred (if different from 15.1): Not Applicable	
17. Recall Number Assigned (if available): Not Applicable	
18. Details of Defect/Reason for Recall: Quality defect Due to out of specification results for dissolution reported during stability studies.	
19. Information on distribution including exports (type of customer, e.g. hospitals): *For more information about exporting or batch destination, please contact the Marketing Authorisation Holder and/ or local Regulatory Authority (SAHPRA)* portia.nkambule@sahpra.org.za / maphutheho.selikane@sahpra.org.za	
20. Action taken by Issuing Authority: Conduct a recall (Class II, Type B) https://www.sahpra.org.za/product-recalls/	
21. Proposed Action: SAHPRA is monitoring the recall.	

22. From (Issuing Authority):

South Africa Health Products Regulatory Authority (SAHPRA) Loftus Park, Building A, 402 Kirkness St, Arcadia, Pretoria, 0083, South Africa.

Portia Nkambule – Chief Regulatory Officer

Email: portia.nkambule@sahpra.org.za Tel: 27 78 802 0781

Deon Poovan – Senior Manager: Inspectorate & Regulatory Compliance

Email: deon.poovan@sahpra.org.za Tel: +27 65 683 9783

Mokgadi Fafudi – Manager: Regulatory Compliance

Email: mokgadi.fafudi@sahpra.org.za Tel: +27 66 301 1878

Signed: Digitally Signed by: Deon Poovan, Senior Manager: Inspectorate and Regulatory Compliance, 70dd9ebc-b1cb-4422-af5c-ae27ede429f1, Powered By RealSign

Date: 15/09/2022 10:23:16 AM