SAHPRA
South African Health Products Regulatory Authority

	Reference Number CASE_19

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: Adco-Napacod tablets	5. Marketing Authorisation Number: For use in humans
6. Brand/Trade Name: Adco-Napacod	7. INN or Generic Name: Paracetamol 500 mg and Codeine Phosphate 10mg
8. Dosage Form: tablets	9. Strength: 500mg/ 10mg
10. Batch number (and bulk, if different): AD0433 and AC1264	11. Expiry Date: AD0433: 02-2026 and AC1264: 06-2025
12. Pack size and Presentation: 1000s	13. Date Manufactured: AD0433: March 2021; AC1264: June 2020

14. Marketing Authorisation Holder:

Adcock Ingram Limited.
1 New Road, Midrand, 1685, SA South Africa

Contact Person: Tammy Chetty, Tammy.Chetty@adcock.com Telephone: + 27 11 635 0429/ +27 82 302 8891

15. Manufacturer:

Batch	API	Manufacturer (s)
AD0433	Paracetamol	Sri Krishna Pharmaceuticals Ltd.
	Codeine Phosphate	Sun Pharmaceutical Industries
AC1264	Paracetamol	
	Codeine Phosphate	Sun Pharmaceutical Industries

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

16. Recalling Firm (if different):

Contact Person: Not Applicable

Telephone: Not Applicable

17. Recall Number Assigned (if available): Not Applicable

18. Details of Defect/Reason for Recall:

Due to quality defect: the company received a customer complaint reporting about the discoloration of tablets and/or discoloured silica gel.

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

Adcock Ingram South Africa confirmed that the affected batches were also exported to the neighbouring country, Namibia.

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