REPUBLIC OF KENYA

MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

RAPID ALERT NOTIFICATION OF A QUALITY DEFECT / RECALL

	Reference Number : **2025/001**
1. To: **World Health Organisation, Market Autorisation Holders, Distributors, Retailers and Consumers**	
2. Product Class of Defect: **Class 1**	3. **Substandard**
4. Product : **Flurasted 500**	5. Marketing Authorisation Number: **N/A** For use in humans
6. Brand/Trade Name : **Flurasted 500**	7. INN or Generic Name: **5-Fluorouracil**
8. Dosage Form : **Injection**	9. Strength: **500mg**
10. Batch number: **HHP24017**	11. Expiry Date: **06/2026**
12. Pack size and Presentation: **5 ampoules of each 10ml**	13. Date Manufactured: **07/2024**
14. Marketing Authorisation Holder : **Halsted Pharma Private Limited**	
15. Manufacturer : **Halsted Pharma Private Limited**	16. Recalling Firm (if different): **Halsted Pharma Private Limited**
15.1 Where the defect is attributed to a manufacturing site, site where defect occurred: **Halsted Pharma Private Limited**	
17. Recall Number Assigned (if available):	
18. Details of Defect/Reason for Recall: **Detection of particles in the injectable medicinal product.**	
19. Information on distribution including exports (type of customer, e.g. hospitals): **consumer/patients**	

20. Action taken by Issuing Authority: **Issue of mandatory recall notice for the Flurasted 500 (5-Fluorouracil) Injection Batch no. HHP2401**
21. Proposed Action : **Healthcare Professionals to Quarantine all the remaining stock and stop further distribution, sale, issuing, or use of the batch immediately.**

22. From (Issuing Authority): **Kenya Pharmacy and Poisons Board**	23. For **Feedback** Contact: pms@ppb.go.ke Telephone: **0795743049**
24. Date: **6th January 2025**	