

क्रमांक: एफ(310)/चि0व्य0/डी.एम.एस./2022-23/5000-08

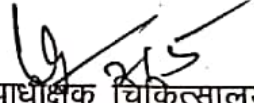
दिनांक: 02.05.2023

कार्यालय - आदेश

संस्थान चिकित्सालय की व्यवस्था हेतु दिनांक 31.12.2022 को श्रीमान कुलपति महोदय की अध्यक्षता में बनाई गई कार्यवृत्त (एम.ओ.एम.) समिति के सदस्यों द्वारा एक्सपायरी एवं नियर एक्सपायरी औषधियों के मानक संचालन प्रक्रिया (एस.ओ.पी.) बनाये जाने के संबंध में दस्तावेज तैयार किया गया है। जिसकी अनुपालना संबंधित द्वारा अनुलग्नक-ए में वर्णित नीति-नियमों के अनुसार लागू किया जाता है।

उक्त आशय की स्वीकृति श्रीमान कुलपति महोदय ने पत्रावली के पैरा संख्या 2/एन पर दिनांक 28.04.2023 को प्रदान कर दी है।

संलग्न- अनुलग्नक-ए


उपाधीक्षक चिकित्सालय

प्रतिलिपि- आवश्यक कार्यवाही हेतु प्रेषित

1. श्रीमान अधीक्षक महोदय, चिकित्सालय रा0आ0सं0, जयपुर
2. समस्त विभागाध्यक्ष.....
3. आवासीय चिकित्साधिकारी, रा0आ0सं0/ सेठ सू0 बम्बईवाला चिकि0
4. प्रभारी, रसायनशाला/बहिरंग/सेटेलाईट चिकि0
5. मैट्रन/असिस्टेंट मैट्रन, रा0आ0सं0, चिकि0


उपाधीक्षक चिकित्सालय

अनुसंधान

NATIONAL INSTITUTE OF AYURVEDA
DEEMED TO BE UNIVERSITY (De Novo), JAIPUR

**SOP FOR HANDLING THE NEAR EXPIRY DRUGS AND
EXPIRED DRUGS AT NATIONAL INSTITUTE OF
AYURVEDA**


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1. POLICY FOR HANDLING NEAR EXPIRY DRUGS

1.1 Purpose

To establish a policy for handling and maintaining the near expiry medications in OPD, IPD wards, OTs, Emergency Unit of all Hospitals under NIA, Pharmacy store and various departmental stores with an aim to minimize loss/wastage of medicine and ensure patient safety.

1.2 Responsibility

1. Pharmacy Incharge
2. Pharmacy Manager
3. Pharmacists
4. Nursing ward incharge of various units/wards/OT of all hospitals of NIA
5. Hospital medicine store Incharge

1.3 Definitions

- **"Date of Expiry of Potency"** means the date that is written on the label of packing as the date upto which the substance may be expected to retain a potency nor less than or not to acquire a toxicity greater than that required or permitted by the prescribed test. (Annexure 1: Expiry of Ayurveda Drugs)
- **Near Expiry drugs (NEDs):** Drugs that are three month ahead of their expiry date

1.4 Procedure

- 1.4.1 Expiry date shall be written on all drugs delivered to hospital from NIA pharmacy (NageswarRasayanashala) and the same shall be recorded in the stock register by the Pharmacist Incharge of the Hospital medicine store. All available medicine shall be made updated at AHMIS after stock entry.
- 1.4.2 Expiry date must be checked at the time of reception of drugs by the Pharmacist incharge/Nursing incharge/store incharge of concerned wards/units/ departments.
- 1.4.3 Pharmacist/Nurse will check expiry of drugs before dispensing or medication administration and if the drug is found expired or near expiry, will immediately initiate the action mentioned in the policy.
- 1.4.4 The drug store in the hospital, pharmacy, OPD and all departmental medicine stores must follow the First In-First Out (FIFO) system of inventory management to minimize the stock of near expiry drugs except in the case where stock received later has a shorter expiry date.



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- 1.4.5 Incharge of various stores must arrange the drugs on separate shelves which will expire in next three months.
- 1.4.6 All the efforts must be taken by concerned Pharmacist Incharge, Nursing Incharge and medicine store Incharge to see that drugs found of near expiry can be transferred/issued to other departments i.e. intra/inter departments for utilization of drugs within the expiry date.
- 1.4.7 If near expiry drugs are not in a position to be consumed, the same drug should be returned to the NIA pharmacy store before 1 month of expiry. It is the responsibility of pharmacist/nurse/medicine store incharge of all units to return all NEDs before one month of expiry back to the store.
- 1.4.8 While returning the NEDs back to the NIA pharmacy, they shall be properly packed, labelled.
- 1.4.9 Once NEDs are received in the pharmacy, the pharmacy Incharge may replace it with manufacturer/vendor/supplier(in case of allopathic drugs) or arrange best possible means for usage of drugs in accordance with the recommendations of the committee constituted for the purpose or according to set guidelines.
- *usage shall be on drug to drug basis. For example Certain bhasma can be reused after giving one set of levigation/Bhavana and incineration/Putra, while kwathā churna may be processed further in to syrup form etc.
- 1.4.10 If the NED is urgently needed and there is no replacement of stock in the pharmacy store, then the pharmacist/nursing incharge shall use it under last day of expiry.

1.5 Records

- 1.5.1 Record of the NEDs must be maintained in the stock register of particular department /store as the case may be.
- 1.5.2 DMS office shall be informed about the list of NEDs (to be expired in 3 months, 1 month) interdepartmental transfer of NEDs, replacements, and list of NEDs that are being returned back to the pharmacy store.

1.6 Activity

- 1.6.1 Quarterly inspection must be conducted by the concerned Pharmacist/Nurse/Store incharge of the respective units and report shall be submitted to DMS office.
- 1.6.2 Half yearly review by Pharmaco-therapeutic committee/Management of Medication (MOM) Committee to assess the number of drugs reaching near expiry and action taken there of during the year.



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2. POLICY FOR DISPOSAL OF EXPIRED DRUGS

2.1 Purpose

To establish a policy for handling expired drugs and their disposal as per Biomedical Waste management act 2016.

2.2 Responsibility

- Pharmacy Manager
- Pharmacy Incharge
- Officer in charge of Biomedical Waste management of Hospital

2.3 Procedure

2.3.1 All Expired drugs from the various departments and hospitals of NIA shall be returned to the NIA Pharmacy with proper documentation, packing, labelling and colour coding.

2.3.2 The information about expired medicines must be recorded in a separate register maintained for the same. The following details are to be documented

- Name of the drug
- Formulation(Churna/kwathachurna/vati/syrup etc)
- Batch no
- Manufacturing date
- Date of expiry
- Total Quantity
- Name of the returning department/Unit

2.3.3 All expired drugs should be stored preferably in a separate room ear marked for the purpose. In the absence of a separate room drugs shall be stored in a separate cupboard, which shall be always under lock with a sign board "**Expired drugs not for use**". The room/cupboard shall be under supervision of pharmacy incharge.

2.3.4 The Pharmacy Incharge and all the departments and units shall inform the Pharmacotherapeutic committee/Management of Medication (MOM) Committee and DMS office about the details of expired drugs for disposal on monthly basis.

2.3.5 After approval from Drug Committee, the Pharmacy In charge shall inform the DMS office about the list of expired drugs to be sent for disposal to Bio Medical Waste Management In charge.

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2.3.6 The decision to dispose off the expired drug through Biomedical waste management system to send the drug for bio composting (in case of drugs of herbal origin like powders and coarse powders) shall be taken by the Pharmaco-therapeutic committee/Management of Medication (MOM) Committee.

2.3.7 All the expired drugs should be transported in pilfer proof containers/boxer propely labelled and sealed in accordance with the rules of Bio Medical Waste management

2.4 Records

2.5.1 The following records shall be maintained

- Expiry drug register in all Units/Wards/OT/Departments
- Expiry drug register in Pharmacy
- Drug disposal register at Bio Medical Wate Management Department.



Annexure 1: Expiry of Ayurvedic Medicines

(Rule161B. Drug and Cosmetic Rules 1945: Shelf life or date of expiry of medicines.)

Sl. No.	Dosage form	Shelf life or date of expiry with effect from the date of manufacture
(1)	(2)	(3)
(i)	Anjana	
	(a) Anjana made from Kasthaushadhi	1year
	(b) Anjana made from Kasthaushadhi along with Rasa/Uprasa/Bhasma	2years
	(c) Anjana made only from Rasa/Uprasa/Bhasma	3years
(ii)	Arka	1year
(iii)	Asava Arista	10 years
(iv)	Avaleha, Khanda, Paka, Guda	3years
(v)	Churna, Kwatha Churna, Lepa Churna, Danta Manjan (Churna)	2years
(vi)	Dhoopan	2years
(vii)	Dravaka, Lavana, Kshara	5years
(viii)	Ghrita	2years
(ix)	Guggulu	5years
(X)	Gutika/Vati	
	(I) Gutika or Vati containing Kasthaushadhi along with Rasa/Uprasa/Bhasma/Guggulu (including Lepa Gutika and GhanVati)	5years
	(II) Gutika or Vati containing only Kasthaushadhi (including Lepa Gutika and GhanVati)	3years
	(III) Gutika/Vati containing only Ras/Uprasa/Bhasma except Naga, Vanga and Tamra Bhasma	10 years
(xi)	Karna/Nasa bindu	2years
(xii)	Kupipakva Rasayana	10 years
(xiii)	Malahar	3years
(xiv)	Mandura-Lauha	10 years
(xv)	Naga Bhasma, Vanga Bhasma and Tamra Bhasma	5years
(xvi)	Netra bindu	1year
(xvii)	Parpati	10 years
(xviii)	Pishti and Bhasma except Naga, Vanga and Tamra Bhasma	10 years
(xix)	Pravahi Kwatha	3years
(xx)	(I) Rasayoga Containing only Rasa/Uprasa/Bhasma except Naga, Vanga and Tamra Bhasma	10years

	(II) Rasayoga Containing Rasa/Uprasa/Bhasma along with Kashaushadhi/Guggulu	5years
(xxi)	Sattva (derived from medicinal plant)	2years
(xxii)	Sharkar/Panak/Sharbat	3years
(xxiii)	Shveta parpati	2years
(xxiv)	Taila	3years
(xxv)	Varti	2years

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