DRUGS CONTROL ADMINISTRATION
Government of Telangana

Cir. No.10/DCA-Peshi/2023. **Dated : 11/08/2023**

CIRCULAR MEMO

Sub: Testing of Aluminium in purified water, raw materials used for preparation of Dialysis Solutions and in the final product Haemodialysis Solutions – Strict enforcement – Instructions – Issued – Reg.

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It is observed that, in patients with chronic renal failure, aluminium appears to be of proven toxicological importance. Aluminium toxicity primarily results from exposure to aluminium in dialysis fluid. In such patients the accumulation of aluminium in tissues causes dialysis dementia/dialysis encephalopathy, osteomalacia and microcytic anemia.

Aluminium contamination of dialysis fluid/dialysate may occur from the water used to prepare dialysis fluid and also from the chemical concentrate used in the preparation of the dialysis fluid.

(1) As per Para 1.3 of Part I of Schedule-M of Drugs Rules, Purified Water used in the production shall comply with pharmacopoeial specifications.

Water used to manufacture dialysis fluids shall comply with the following additional requirement.

As required in accordance with the Indian Pharmacopoeia monograph of 'Purified Water' (IP-2022 Volume III), the purified water intended for use in the manufacture of dialysis solution shall comply with the additional requirement with respect to "Aluminium" content - Not More Than 10 ppb determined by AAS/ICP/IC techniques.

(2) Testing of the raw materials shall be carried out in accordance with the specifications prepared and maintained as per the pharmacopoeial standards.

Raw materials such as Sodium Chloride, Magnesium Chloride used in the preparation of dialysis fluids shall comply with the following additional requirement:

As required as per the Indian Pharmacopoeia monographs of 'Sodium Chloride' & 'Magnesium Chloride' (IP-2022 Volume III):

Sodium Chloride intended for use in the preparation of dialysis solution shall comply with the additional requirement with respect to "Aluminium" content - Not More Than 0.2 ppm determined by fluorimetry technique.

Magnesium Chloride intended for use in the preparation of dialysis solution shall comply with the additional requirement with respect to "Aluminium" content - Not More Than 1 ppm determined by fluorimetry technique.

(3) Limit of Aluminium in the Haemodialysis Solutions should be NMT 10µg/L, determined by Atomic Absorption Spectrometry (AAS), as per British Pharmacopoeia which shall be complied with Rule 124 of Drugs Rules.

The above regulatory requirements regarding testing of Aluminium in purified water, raw materials used for preparation of Dialysis Solutions and in the final product Haemodialysis Solutions shall be enforced strictly and shall be verified during routine inspections of Manufacturing sites of dialysis fluids by the Drugs Inspectors.

All the Assistant Directors and Deputy Directors are requested to monitor adherence of the above said requirements by the Manufacturers.

Please acknowledge the receipt of Circular Memo.

Kamaleswar Rao 11/8

DIRECTOR GENERAL

To
All the Drugs Inspectors in the State.

Copy to :
All the Assistant Directors in the State.
All the Deputy Directors in the State

Copy submitted to :
The Drugs Controller General (India), CDSCO, New Delhi for information.