

CLASSIFICATION OF HEMODIALYSIS PRODUCTS AS DRUGS

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This Bureau Circular is issued to the public and our clients regarding the classification of hemodialysis solutions. In line with this, we wish to quote p. 851 of Martindale The Extra Pharmacopeia 30th Edition with regards to dialysis solutions.

"Dialysis solutions are solutions of electrolytes formulated in concentration similar to those of extracellular fluids. Dialysis solutions are used in the management of renal failure and poisoning; they allow the selective removal of toxic substances, eletrolytes and excessive body fluid from the blood. In hemodialysis, the exchange of ions between the solution and the patient's blood is made across a synthetic semipermeable-membrane. In peritoneal dialysis, the exchange is made across the membranes of peritoneal cavity."

The so-called exchange of ions in hemodialysis across a synthetic semipermeable membrane is a mechanical and biochemical process. The hemodialysis solution supplements and replaces the electrolytes required by the body while removing the accumulated toxic substances/fluids which ordinarily would have been excreted by normally functioning kidneys. By the nature of this exchange and the systematic replacement of ions, hemodialysis products as stated in the accompanying annex shall be classified as DRUGS.

All HEMODIALYSIS SOLUTIONS previously registered under Device shall be reclassified as DRUGS accordingly.

This directive shall take effect immediately.

Adopted: 10 April 2003

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