



Republic of the Philippines
Department of Health
BUREAU OF FOOD AND DRUGS
Filinvest Corporate City
Alabang, Muntinlupa City



10 April 2003

BUREAU CIRCULAR
No. 05 s. 2003

RE : CLASSIFICATION OF HEMODIALYSIS PRODUCTS AS DRUGS

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 Pharmacopoeia 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, electrolytes 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 systemic 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.

(Sgd) Prof. LETICIA-BARBARA B. GUTIERREZ, M.S.
Director

RSN	PRODUCT NAME	BRAND	DS	DF	APPLICANT COMPANY	TYPE	REG. NO.	OLD RSN	MANUFACTURER	DISTRIBUTOR	eval & date decked 1	return ed to pool stora ge	eval & date decked 2	STAT 1	STAT 2
02A-0903	Acid Concentrate for Hemodialysis 1K+	Biasol AC-21	Potassium Chloride 2.75g, Calcium Chloride 6.13g, Sodium Chloride 174.35mg, Glacial Acetic Acid 8.85g, Magnesium Chloride 1.75g, Dextrose Anhydrous 73.66g	Solution	Baxter Healthcare Phils. Inc.	I		1 bot./5L	Baxter Healthcare Phils. Inc.		DJM 11.13.02		DJM 11.13.02		
02A-0904	Acid Concentrate for Hemodialysis 2K+	Biasol AC-23	Potassium Chloride 5.49g, Calcium Chloride 7.15g, Sodium Chloride 174.35mg, Glacial Acetic Acid 8.85g, Magnesium Chloride 1.75g, Dextrose Anhydrous 73.66g	Solution	Baxter Healthcare Phils. Inc.	I		1 bot./5L	Baxter Healthcare Phils. Inc.		DJM 11.13.02		DJM 11.13.02		
02A-3142	Hemodialysis Acid Concentrate	Solucid AC 10	Each liter conc. Contains: 216.20g Sod. Chloride, 6.47g Calcium Chloride, Dihydrate, 5.30g Potassium Chloride, 2.65g Magnesium chloride Hexahydrate, 8.55g Glacial Acetic Acid & 77.50g Dextrose Monohydrate	Haemodialysis Solution	Euromed Labs., Phils. Inc.	I		1 container/5 L	Euromed Labs., Phils. Inc.		CTC 01.27.03	Return ed 02.03.03 - class ified as devic e	CTC 01.27.03		
02A-3143	Hemodialysis Acid Concentrate	Solucid AC 07	Each liter conc. Contains: 216.20g Sod. Chloride, 6.47g Calcium Chloride, Dihydrate, 5.30g Potassium Chloride, 2.65g Magnesium chloride Hexahydrate & 8.55g Glacial Acetic Acid	Haemodialysis Solution	Euromed Labs., Phils. Inc.	I		1 container/5 L	Euromed Labs., Phils. Inc.		CTC 01.27.03	Return ed 02.03.03 - class ified as devic e	CTC 01.27.03		
02A-3144	Hemodialysis Acid Concentrate	Solucid AC 09	Each liter conc. Contains: 216.20g Sod. Chloride, 6.47g Calcium Chloride, Dihydrate, 5.30g Potassium Chloride, 2.65g Magnesium chloride Hexahydrate, 8.55g Glacial Acetic Acid & 77.50g Dextrose Monohydrate	Haemodialysis Solution	Euromed Labs., Phils. Inc.	I		1 container/5 L	Euromed Labs., Phils. Inc.		CTC 01.27.03	Return ed 02.03.03 - class ified as devic e	CTC 01.27.03		

RSN	PRODUCT NAME	BRAND	DS	DF	APPLICANT COMPANY	TYPE	REG. NO.	OLD RSN	MANUFACTURER	DISTRIBUTOR	eval & date decked 1	return ed to pool stora ge	eval & date decked 2	STAT 1	STAT 2
02A-3145	Hemodialysis Acid Concentrate	Solucid AC 08	Each liter conc. Contains: 216.20g Sod. Chloride, 6.47g Calcium Chloride, Dihydrate, 5.30g Potassium Chloride, 3.60g Magnesium chloride Hexahydrate, 8.55g Glacial Acetic Acid	Haemodialysis Solution	Euromed Labs., Phils. Inc.	I		1 container/5 L	Euromed Labs., Phils. Inc.		CTC 01.27.03	Return ed 02.0 3.03 - class ified as devic e	CTC 01.27.03		
02A-3081	Hemodialysis-1A Liquid Conc.	HD-1A Liquid Conc.		Concentrate	B.Braun Medical Supplies Inc.	I		1 x 5L	B.Braun Medical Supplies Inc.	Zuellig Pharma Corp.	JGP 01.24.03		JGP 01.24.03		
02A-3113	Hemodialysis-3A Liquid Conc.	HD-3A Liquid Conc.	Sodium chloride 161.43g, Potassium Chloride 5.500g Calcium Chloride 2H2O 6.77g, Magnesium Chloride 6H2O 3.74g, Glacial Acetic Acid 8.85g & Water for Inj. To 1000mL	Concentrate	B.Braun Medical Supplies Inc.	I		1 canister x 10L	B.Braun Medical Supplies Inc.	Zuellig Pharma Corp.	CTC 01.27.03	Return ed 02.0 3.03 - class ified as devic e	CTC 01.27.03		
02A-3112	Hemodialysis-4A Liquid Conc.	HD-4A Liquid Conc.	Sodium chloride 161.0g, Potassium Chloride 5.500g Calcium Chloride 2H2O 7.0g, Magnesium Chloride 6H2O 3.7g, Glacial Acetic Acid 8.8g & Water for Inj. To 1000mL	Concentrate	B.Braun Medical Supplies Inc.	I		1 canister x 5L	B.Braun Medical Supplies Inc.	Zuellig Pharma Corp.	JGP 01.24.03		JGP 01.24.03		
01A-0699	Acetate Concentrate for Hemodialysis	Hemosol DK-20		Solution	Baxter Healthcare Phils. Inc.	I		97F-486	Baxter Healthcare Phils. Inc.		LSP 09.25.01	return ed to stora ge 10.0 3.01 not reap	LSP 09.25.01		

01A-2191	Liquid Bicarbonate Concentrate for Hemodialysis			Solution	Baxter Healthcare Phils. Inc.	X/I	DR-XY27164	99A-1440	Baxter Healthcare Phils. Inc.		SOO 10.11.01		SOO 10.11.01	CPR 10.22.01	
01A-3163		Biasol AC-22 Hemodialysis Concentrate		Solution	Baxter Healthcare Phils. Inc.	X/I			Baxter Healthcare Phils. Inc.		JPM 11.26.01		JPM 11.26.01	CPR 01.31.02	
01A-3164		Biasol AC-20 Hemodialysis Concentrate		Solution	Baxter Healthcare Phils. Inc.	X/I			Baxter Healthcare Phils. Inc.		JPM 11.26.01		JPM 11.26.01	CPR 01.31.02	
00A-1458	Haemodialysis Solution with 3.5% Dextrose				Euromed Labs., Phils. Inc.	CM	DR-XY3380		Euromed Labs., Phils. Inc.		GM 08.07.00		GM 08.07.00	CPR 08.09.00	Revalida ted 05.07.01
00A-1543	Haemodialysis Solution without Dextrose (392.60/50L, 1570.00/20L)				Euromed Labs., Phils. Inc.	CM	DR-XY3381		Euromed Labs., Phils. Inc.		GM 08.07.00		GM 08.07.00	CPR 08.09.00	Revalida ted 05.07.01