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Compatibility of Lactated Ringer's Injection With 94 Selected Intravenous Drugs During Simulated Y-site Administration

Margaux Vallée[1], Isabelle Barthélémy[2], Mihaela Friciu[3], Élaine Pelletier[4], Jean-Marc Forest[4], France Benoit[5], and Grégoire Leclair[3]

Abstract

Objective: To test the compatibility of intravenous (IV) lactated Ringer's injection (LR) with 94 injectable (IV) drugs during simulated Y-site administration. **Methods:** Ninety-four IV drugs were investigated for compatibility with LR (Baxter). Each sample was prepared in duplicate and performed at room temperature. Two observers performed visual evaluation independently immediately upon mixing and then 15 minutes, 1 hour, 2 hours, 3 hours, and 4 hours after admixture. Another observer performed a particle counting test on 1 of the 2 duplicates of each admixture that did not immediately show incompatibility and then after 4 hours by a light obscuration particle count test. **Results:** Of the 94 tested drugs, 86 were found to be compatible with LR. A total of 8 drugs were found to be physically incompatible. Of these incompatible drugs, 7 were directly identified visually and 1 was confirmed by the light obscuration particle count test. **Conclusion:** Lactated Ringer's injection was physically compatible for 4 hours with 86 tested drugs during simulated Y-site administration. Eight drugs, ciprofloxacin, cyclosporine, diazepam, ketamine, lorazepam, nitroglycerin, phenytoin, and propofol, were found to be incompatible and should not be administered with LR.

Keywords
lactated Ringer's injection, compatibility, Y-injection site

Introduction

Lactated Ringer's injection (LR) is a sterile, nonpyrogenic solution that may be used for intravenous (IV) irrigation, washing, and rinsing and also acts as a diluent for infusion of drugs. Lactated Ringer's injection contains sodium chloride (Na^+ 130 mEq/L), potassium chloride (K^+ 4 mEq/L), calcium chloride (Ca^+ 3 mEq/L), chloride (Cl^- 109 mEq/L), and lactate (28 mEq/L) in water for injection.[1]

Questions about drug compatibility are recurrent, and bringing up available information is an essential part of pharmacist assignment. Lactated Ringer's injection is widely used in Sainte-Justine University Teaching Hospital, especially for patients receiving many other IV drugs by Y-site administration. Compatibility data about LR are scarce, and there is a need to evaluate the Y-site injection compatibility of LR with other IV drugs.

The purpose of this study was to determine Y-site injection compatibility of LR with 94 IV drugs using visual evaluation and light obscuration particle counting.

Methods

Lactated Ringer's injection (lot W5I17C2) was provided by Baxter in 250 mL bags. A selection of 94 drugs was tested with LR. Details about the tested drugs and concentration are provided in Table 1. Tested IV drugs were reconstituted according to the manufacturer's recommendation when required.

Ninety-four drugs were tested in 1:1 admixture with LR in testing glass tubes at room temperature and under normal

[1]Pharmacist, Hôpitaux universitaires de Genève, Switzerland
[2]Daniel Vermette Pharmacy, Montréal, QC, Canada
[3]Faculté de pharmacie, Université de Montréal, QC, Canada
[4]CHU Sainte-Justine, Montréal, QC, Canada
[5]CHSLD Vigi Yves-Blais, Mascouche, QC, Canada

Corresponding Author:
Jean-Marc Forest, CHU Sainte-Justine, 3175, Chemin de la Côte-Sainte-Catherine, Montréal, QC H3T 1C5, Canada.
Email: jean-marc.forest.hsj@ssss.gouv.qc.ca

Table 1. Drugs Tested for Physical Compatibility With Lactated Ringer's Injection (Baxter) in Simulated Y-site Injection Administration After Visual Inspection and Light Obscuration Particle Count Test.

		Particle count test			Visual		
	Drug name	Concentration mg/mL (or as specified)	Manufacturer	Lot	Concentration mg/mL	Manufacturer	Lot
1	Acetazolamide sodium	100	Sterimax	01000A15 01000B15A	100	SteriMax	01000B11
2	Acetylcysteine	200	Alveda Pharma	14055056	200	Alveda Pharma	9075059
3	Acyclovir sodium	50	PPC	6008872	50	PPC	6002138
4	Albumin, human (Alburex-25)	250	CSL Behring	4309900011	250	CSL Behring	4309900011
5	Amikacin sulfate	250	Sandoz	EZ9666	250	Sandoz	BR9068
6	Aminophylline	25	Hospira	54-375-DK	50	Omega	OK472
7	Amiodarone hydrochloride	50	Sandoz	FJ2260	50	Sandoz	BR5023
8	Amphotericin B liposomal	4	Astellas	20160416074	4	Bristol-Myers Squibb	93070TB31
9	Amphotericin B deoxycholate	5	Bristol-Myers Squibb	51940TB24	5	Bristol-Myers Squibb	51940TB24
10	Ampicillin sodium	100	Novopharm	FF7340 DS8980	100	Novopharm	BP1879
11	Atropine sulfate	0.4	Alveda Pharma	50587	0.4	Alveda Pharma	434
12	Azithromycin	500	Sterimax	7602823 7602657	500	Pfizer	Z065606
13	Bretylium tosylate	50	Sandoz	EF9361	50	Sandoz	AY2120
14	Bupivacaine hydrochloride	0.5%	Hospira	48-198-DK	20 mL	Hospira	48-198-DK
15	Caffeine citrate	10	Sandoz	EM6977	10	Sandoz	BR2092
16	Calcium gluconate	100	Fresenius Kabi	6010000	100	PPC	6001828
17	Calcium chloride	100	Hospira	52-393-DK 42-315-DK	100	Hospira	89458DK
18	Caspofungin acetate	5	Merck	2195750	5	Merck	2070040
19	Cefazolin sodium	100	Hospira	117F003	100	Hospira	117B004
20	Cefotaxime	100	Sterimax	4CS1513CA 4CS1512CA	100	Sanofi	91846
21	Cefoxitin	100	Novopharm	0001D5	100	Hospira	123B002
22	Ceftazidime	100	PPC	105394C	100	PPC	103573C
23	Ceftriaxone sodium	100	Hospira	H101HC4 H103HC4	100	Hospira	120B001
24	Cefuroxime	100	Sterimax	157012.1	100	PPC	8309
25	Chlorpromazine hydrochloride	25	Sandoz	EF2262 DL5599	25	Sandoz	AY5529
26	Ciprofloxacin	2	Hospira	50672	2	Hospira	4777201
27	Clindamycin phosphate	150	Sandoz	FJ8765	150	Sandoz	CS5861
28	Cloxacillin sodium	100	Sterimax	2CL1531CA	100	Novopharm	BP5356
29	Cyclosporine	50	Novartis	S0076 S0070	50	Novartis	S0065
30	Dexamethasone sodium phosphate	4	Sandoz	FM3580	4	Sandoz	F20120216057
31	Dexmedetomidine hydrochloride	0.1	Hospira	67-294-DK 63-198-DK	0.100	Hospira	67-294-DK 63-198-DK
32	Dextrose 50%	500	Hospira	50-239-DK	500	Hospira	03399DK
33	Diazepam	5	Sandoz	350085 429070	5	Sandoz	BP9416
34	Digoxin	0.25	Sandoz	FG7843	0.05	Sandoz	BK4807
35	Dimenhydrinate	10	Sandoz	FL9838 ES0313	10	Sandoz	CB8792

(continued)

Table 1. (continued)

		Particle count test			Visual		
	Drug name	Concentration mg/mL (or as specified)	Manufacturer	Lot	Concentration mg/mL	Manufacturer	Lot
36	Diphenhydramine hydrochloride	50	Sandoz	4K152 EJ5196	50	Sandoz	CC6193
37	Dobutamine hydrochloride	12.5	Hospira	57-245-DK 61-123-DK	12.5	Sandoz	BT5348
38	Dopamine hydrochloride	3,2	Baxter	P331496	3.2	Baxter	2BO846
39	Enalaprilat	1.25	Sterimax	143177.1	1.25	Sandoz	CB8013
40	Epinephrine hydrochloride	1	Erfa	F5E195	1	Hospira	107388E10
41	Erythromycin lactobionate	50	Amdipharm	44-906-TB-24	50	Amdipharm	88324TB26
42	Esmolol hydrochloride	10	Baxter	115376Z	10	Baxter	071310Z
43	Fentanyl citrate	0.050	Sandoz	FU61144	0.050	Sandoz	CD0281
44	Fluconazole	2	Sandoz	EG3097	2	Sandoz	BX9809
45	Furosemide	10	Omega	5J082	10	Sandoz	BY8329
46	Gentamicin sulfate	10	Sandoz	EZ8736 EW0069	40	Sandoz	BU6761
47	Granisetron hydrochloride	1	Omega	4M838	1	Omega	4M838
48	Haloperidol lactate	5	Sandoz	GB9093 FS6939 FM6054	5	Sandoz	GB9093 FS6939 FM6054
49	Heparin sodium	1000 IU/mL	Sandoz	FU4871	1000 IU/mL	PPC	6000130N
50	Hydralazine hydrochloride	20	Sterimax	PLNG1518 PLNK1438 PLNK1440	20	Novartis	00501B10
51	Hydrocortisone sodium succinate	50	Novopharm	0480514 4160115	50	Novopharm	9650310
52	Hydromorphone hydrochloride	10	Sandoz	FA1043	10	Sandoz	CC7651
53	Hydroxyzine hydrochloride	50	Sandoz	EF1703	N/A	N/A	N/A
54	Insulin regular (Humulin R)	100 IU/mL	Lilly	C358890H C358890K	100 IU/mL	Lilly	C001867D
55	Isoproterenol hydrochloride	0.2	Sandoz	FM8982	0.2	Sandoz	BU3292
56	Ketamine hydrochloride	50	Sandoz	FB4018 FK2313	50	Sandoz	BX2917
57	Labetalol hydrochloride	5	Sandoz	FD6396	5	Sandoz	BW9642
58	Lidocaine hydrochloride	1%	Alveda Pharma	15262021	1	AstraZeneca	10410
59	Linezolid	2	Pfizer	3770714	2	Pfizer	3770714
60	Lorazepam	4	Hospira	53275EV 52170EV	4	Sandoz	CZ3827
61	Magnesium sulfate	500	Fresenius Kabi	6010611	500	PPC	6101127
62	Mannitol	250	Hospira	60-222-DK	250	Hospira	01485DK
63	Meropenem	50	Sterimax	2694106	50	AstraZeneca	JD947
64	Methylprednisolone sodium succinate	62.5	Novopharm	6000215 4450915	62.5	Pfizer	G00030
65	Metoclopramide hydrochloride	5	Sandoz	EM2979 EL7926 EL4390 EG3207 FG3415	5	Sandoz	BY4533
66	Metronidazole	5	Hospira	58-011-JT	5	Hospira	7811853
67	Midazolam hydrochloride	5	Fresenius Kabi	6009861	5	PPC	CB8867
68	Milrinone lactate	1	Sandoz	FH8172	1	Sandoz	CB2379
69	Morphine sulfate	50	Sandoz	FC1902	50	Sandoz	BR8368

(continued)

Table 1. (continued)

		Particle count test			Visual		
	Drug name	Concentration mg/mL (or as specified)	Manufacturer	Lot	Concentration mg/mL	Manufacturer	Lot
70	Multivitamins (Multi-12/K1 pediatric)		Sandoz	FL5796 (vial 1) FL6371 (vial 2)		Sandoz	CY0799 et CY0797
71	Multivitamins (Multi-12)		Sandoz	FL5795 (vial 1) FK1211 (vial 2)		Sandoz	CG5111
72	Naloxone hydrochloride	0.4	Alveda Pharma	30209 30522	0.4	Sandoz	BL1147
73	Nicardipine hydrochloride	0.2	Baxter	NC096925	0.2	Baxter	NC096925
74	Nitroglycerin	5	Omega	5GO44 5D948	5	Omega	1K775
75	Norepinephrine bitartrate	1	Sandoz	FD2438	1	Sandoz	BU3181
76	Octreotide acetate	0.500	Omega	5F008 5J086	0.500	Omega	S0013
77	Oxytocin	10 IU/mL	Hospira	521388E01	10 IU/mL	Hospira	054528E01
78	Penicillin G sodium	500 000 IU/mL	Fresenius Kabi	303246	100 000 IU/mL	Novopharm	CG7189
79	Phenytoin sodium	50	Sterimax	152079.1	50	Sandoz	CJ8539
80	Piperacillin sodium	200	Hospira	1P301MC3	200	Mayne Pharma	1P301MC1
81	Piperacillin sodium / Tazobactam	200	Sandoz	20160428083	200	Sandoz	BW5243
82	Potassium chloride	2 mEq/mL	Hospira	50-151-DK	2 mEq/mL	Hospira	92180DK
83	Potassium phosphate	3 mmol/mL	Sandoz	6109697	3 mmol/mL	Sandoz	BW8396
84	Propofol	10	Pharmascience	A050374	10	Novopharm	R10167B
85	Ranitidine hydrochloride	25	Sandoz	F59330 FW1356	25	GlaxoSmithKline	C566822
86	Rocuronium bromide	10	Sandoz	FS6942 FM5396	10	Hospira	12008DK
87	Salbutamol	1	GlaxoSmithKline	V972	1	GlaxoSmithKline	L061
88	Sodium bicarbonate	1 mEq/mL	Hospira	54-178-EV	1 mEq/mL	Abbott	11138DK
89	Sodium nitroprusside	25	Hospira	531303A	25	Omega	1K775
90	Tobramycin sulfate	40	Sandoz	6009024	40	Sandoz	C152865
91	Trimethoprim / Sulfamethoxazole	16/80	GlaxoSmithKline	20160422036	16/80	GlaxoSmithKline	1E531
92	Vancomycin hydrochloride	50	Sandoz	FF5576 FW3816	50	Hospira	096588E02
93	Verapamil hydrochloride	2.5	Sandoz	FM1440	2.5	Sandoz	CM0627
94	Voriconazole	10	Sandoz	FY0203	10	Sandoz	FY0203

room light. Each drug available in a breakable glass ampoule was passed through a 5-µm filter as it was introduced into the testing glass tube.

Step 1: Visual evaluations were performed independently by 2 observers in accordance with the established procedure previously reported several times.[2-8] Visual simulated Y-site injection evaluation was accomplished by the 2 observers by mixing 1 mL of LR with 1 mL of the tested drug in glass tube and then switching the order of drug mixing for the second observation. Each admixture was visually observed immediately upon mixing and then at specified time points: 15 minutes, 1 hour, 2 hours, 3 hours, and 4 hours. Visual compatibility was defined as the absence of any color change or visible particle matter, gas bubble, substantial haze, or precipitate by a naked eye.

Step 2: Another second observer performed the light obscuration particle count test using the LS-20 Liquid Particle Counter (Lighthouse Worldwide Solutions, Medford, OR). At

the beginning of the experiment, the particle count test was controlled by a standardized solution (Pharm-Trol Particle Count Control solution; Thermo Scientific, Saint-Laurent, QC, Canada, lot 44035) with a specific concentration of 15 μm particles. This allowed us to ascertain that the accuracy of the particle counter is in agreement with the United States Pharmacopeia (USP) Reference Standard for the duration of the observations. Furthermore, on each day of observation, a control solution made of 10 mL of LR and 10 mL of sterile water for injection passed both the visual test and the particle count test immediately upon mixing and after 4 hours. Then each admixture was tested in sterile plastic syringes by mixing 10 mL of LR with 10 mL of the tested drug. In the absence of visual incompatibility, the particle content of the first admixtures was immediately analyzed and that of the second was quantified by a final particle count test at 4 hours. Admixtures that were visually incompatible were immediately discarded without particle count test evaluation. Drug admixtures were considered compatible if the average number of particles did not exceed USP <788> Test 1.B guidelines.[9] In this study, volumes are less than 100 mL, and the limit allowed for particulate matter does not exceed 6000 particles ≥10 μm and 600 particles ≥25 μm per container. Thus, with a container volume of 20 mL, 5 mL per test, the average number of particles equal to or greater than 10 μm does not exceed 300 particles and no more than 30 particles equal to or greater than 25 μm to be considered compatible. Each measure was in triplicate, 3 times 5 mL, with 4 mL as a prime.

Results

A total of 94 admixtures were visually inspected in step 1, and 77 of them demonstrated no evidence of visual incompatibility immediately and throughout the 4-hour period. Seventeen drugs were described as being possibly or definitively incompatible with LR when inspected visually by 2 different observers. Table 2 illustrates the details associated with the 17 admixtures that could possibly be visually incompatible.

In step 2, just before the light obscuration particle count test, 7 admixtures showed precipitation (ciprofloxacin, cyclosporine, diazepam, ketamine, lorazepam, phenytoin, propofol) and were discarded without particle count test evaluation because there is evidence of incompatibility. All the other 10 admixtures that were suspected to be visually incompatible and did not clearly precipitate were analyzed by the particle count test, including all the other 77 certain results by visual inspection, to determine whether they were really compatible or not. For 86 drugs, measurement of the number of particles ≥25 and ≥10 μm was within specification limit immediately upon admixture and after 4 hours. Only for 1 drug, nitroglycerin, particle counting and sizing confirmed the incompatibility suspected (Table 3).

In summary, all the incompatible drugs are listed in Table 4, with the corresponding reason.

Table 2. Incompatibilities of Lactated Ringer's Injection With Other Drugs After Visual Inspection by the 2 Observers in Step 1.

	Drug name	Notes
1	Amiodarone	Uncertain
2	Caspofungin	Uncertain
3	Ciprofloxacin	Incompatible
4	Clindamycin	Uncertain
5	Cyclosporine	Precipitate
6	Diazepam	Immediate precipitate
7	Insulin (human regular) (Humulin R)	Uncertain
8	Ketamine	Incompatible
9	Lorazepam	Incompatible
10	Methylprednisolone	Uncertain
11	Multivitamins (adult) (Multi-12)	Uncertain
12	Multivitamins (pediatric) (Multi-12/K1 pediatric)	Uncertain
13	Nitroglycerin	Uncertain
14	Penicillin G	Uncertain
15	Phenytoin	Incompatible
16	Propofol	Precipitate
17	Verapamil	Uncertain

Table 3. Incompatibilities of Lactated Ringer's Injection With Other Drugs After Step 2 With Light Obscuration Particle Count Test.

	Drug name	Notes
1	Nitroglycerin	>30 × 25 μm particles/mL at $T = 0$

Discussion

Lactated Ringer's injection is widely used as a drug diluent. Until now, no study has evaluated specifically the compatibility of LR with drugs used in clinical practice. This study tested the compatibility of LR with 94 injectable drugs.

The simulated Y-site injection model used in this study is based on the model described by Allen et al in 1977. They established that when mixing 2 solutions in a Y-administration set, the concentration ratio will be 1:1.[10] As admitted, if 2 drugs are compatible at high concentration, they will also probably be compatible at lower concentrations.[11] This hypothesis reflects the condition in Y-site administration that is used by nurses during drug administration.

Results by visual control show that 10 drugs are possibly incompatible with LR, whereas 7 are incompatible after visual test. Visual control can only detect particles greater than 50 μm, whereas the light obscuration particle count test assesses particle within the range of 1 to 50 μm and permits to comply with USP <788> Test 1.B.[9] This could explain the difference seen between the results of the 2 testing methods. This is why the results obtained with the particle count

Table 4. Incompatibilities of Lactated Ringer's Injection With Other Drugs After All Analyses.

	Drug name	Incompatibility reason
1	Ciprofloxacin	Directly by visual inspection
2	Cyclosporine	Directly by visual inspection
3	Diazepam	Directly by visual inspection
4	Ketamine	Directly by visual inspection
5	Lorazepam	Directly by visual inspection
6	Nitroglycerin	Especially with light obscuration particle count test
7	Phenytoin	Directly by visual inspection
8	Propofol	Directly by visual inspection

test are more reliable than those obtained by visual control. However, when admixture leads to an obvious precipitation, the particle count test is not processed, thus becoming useless.

Precipitate formation occurred when propofol was mixed with LR. Because propofol is an opaque white emulsion, particle count test could not be performed due to its dense turbidity. Propofol would require an alternative approach to physical compatibility other than particle count test evaluation.

Concerning cyclosporine and nitroglycerin, the present results are not congruent with published data.[12-14] These 2 drugs are listed as compatible with LR in some visual studies[12,13] where physical compatibility was evaluated only by the absence of changes in measured haze or turbidity, particulates, or color found. The light obscuration particle count test was required to detect an incompatibility like in this study. Cyclosporine needs to be diluted to a concentration of 5 mg/mL or less using sterile water before testing with light obscuration particle count test because the 50 mg/mL solution is too viscous for particle count test analysis and even more diluted for clinical practice.[2,14] The dilution factor used could explain the difference between other data because a drug could be incompatible at high concentration but be compatible, almost for 4 hours, after being diluted. Nitroglycerin incompatibility with LR could be detected by the light obscuration particle count test, depending on techniques used by other authors, which could explain the conflicting result.

Surprisingly, compatibility results were found with drugs such as ceftriaxone, amphotericin B (Fungizone), and piperacillin sodium/tazobactam that are supposed to be incompatible according to published data.[14-18] Several factors may explain these differences as contact time, methods, concentrations, diluents, manufacturers, and excipients. Lack of recent studies for these drugs makes the result obtained with a modern particle counting test confident to be trusted.

All other results of this study are consistent with the results of previous compatibility studies and demonstrate the value of the light obscuration particle count test to assess compatibility between 2 drugs and complete visual inspection, eliminating hazardous results. Lactated Ringer's injection and each other drug were tested at 1 concentration, and it is possible that the incompatible combinations might be compatible when mixed at lower concentrations.

Conclusion

Lactated Ringer's injection was compatible with 86 of the drugs tested and was found to be directly incompatible by naked eye with ciprofloxacin, cyclosporine, diazepam, ketamine, lorazepam, phenytoin, and propofol and additionally by light obscuration particle count test with nitroglycerin. The light obscuration particle count test to assess compatibility between 2 drugs completes visual inspection, eliminating hazardous results.

Declaration of Conflicting Interests

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ORCID iD

Jean-Marc Forest https://orcid.org/0000-0001-8451-5471

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