

Stability of ampicillin sodium 20% in 0.9% sodium chloride and aqua for injection

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Background:

Sodium ampicillin antibiotic is not stable in the aqueous solutions. which should be reconstituted with aqua for injection or 0.9% sodium chloride before used.

The β -lactam ring of sodium ampicillin is easily to decomposite or degradate by hydrolitic reaction to form penicillic acids.

Nurses in the ward of neonatology department Dr. Soetomo Hospital prepared sodium ampicillin injection by reconstituted 1 g sodium ampicillin in the vial with 5 ml 0.9% sodium chloride or aqua for injection before administrated.

After administrated to the patients. the remains of the sodium ampicillin solution usually stored in the refrigerator or room temperature before administrate to the next schedule.

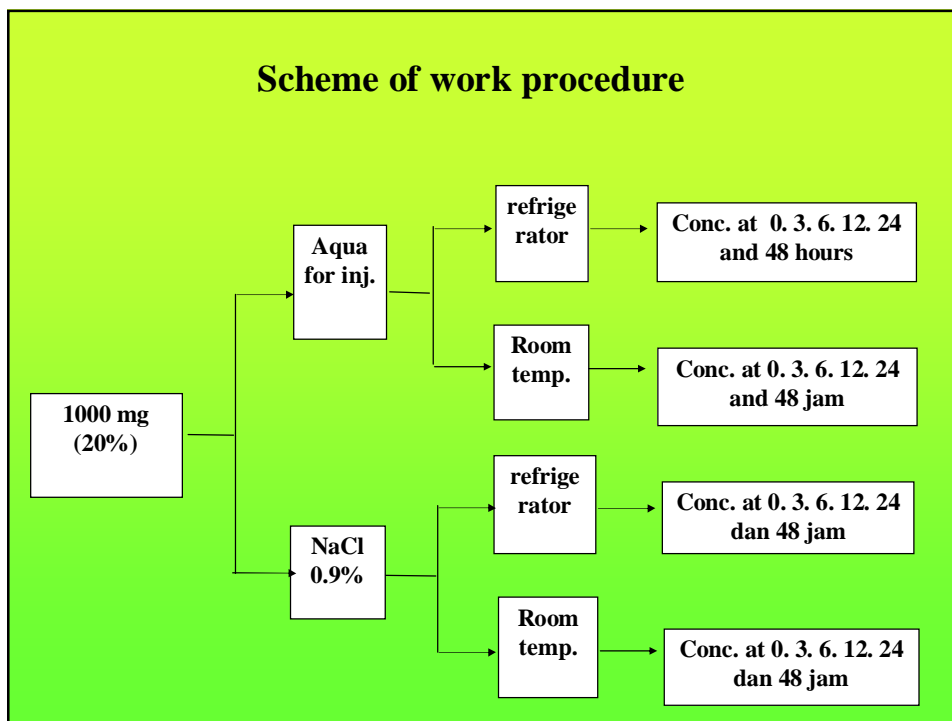
Objective:

The objective of this study was to determine the effects of solvents (0.9% sodium chloride and aqua for injection) and temperatures (room ($28 \pm 2^{\circ}$ C) and refrigerator ($2 \pm 2^{\circ}$ C)) on stability.

Method:

Triplicate test samples were prepared by reconstituting the sodium ampicillin injection. 10 g with 50 ml 0.9% sodium chloride and water for injection. The test solutions were packaged in vials. Samples were stored in room ($28 \pm 2^\circ \text{C}$) and refrigerator temperature ($2 \pm 2^\circ \text{C}$). Each sample was assayed by spectrophotometry and its pH recorded for 48 hours (0. 3. 6. 12. 24 and 48 hours).

Scheme of work procedure



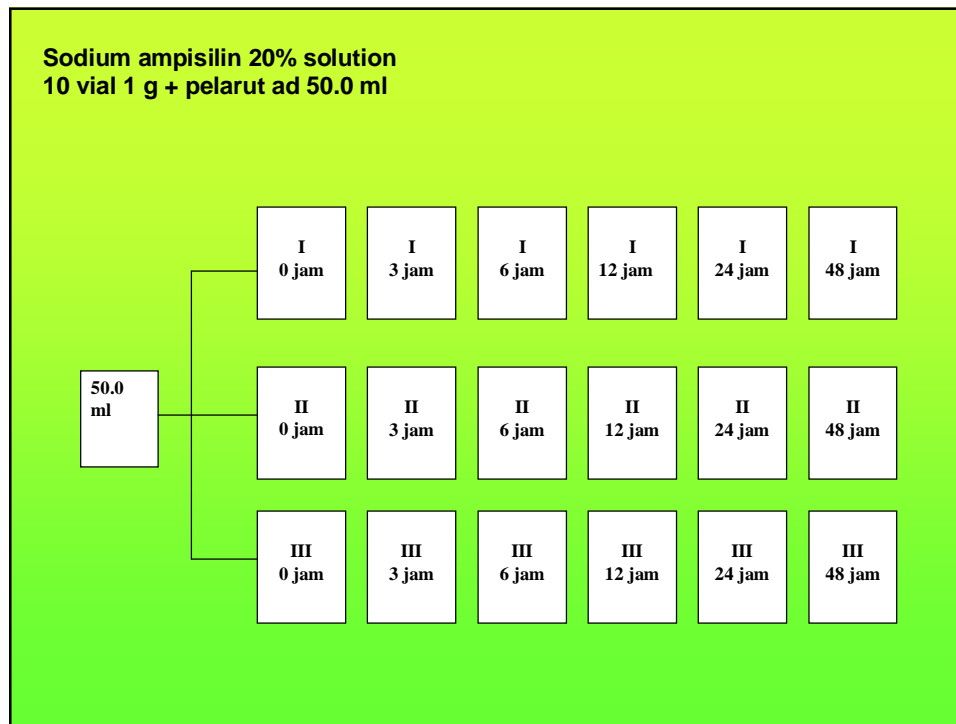
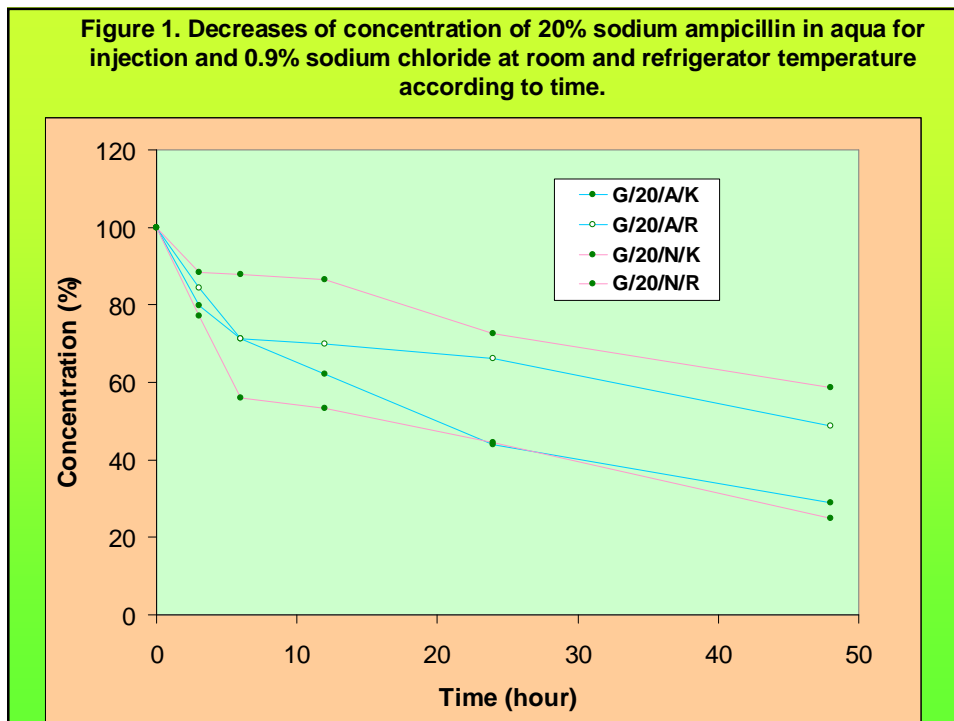


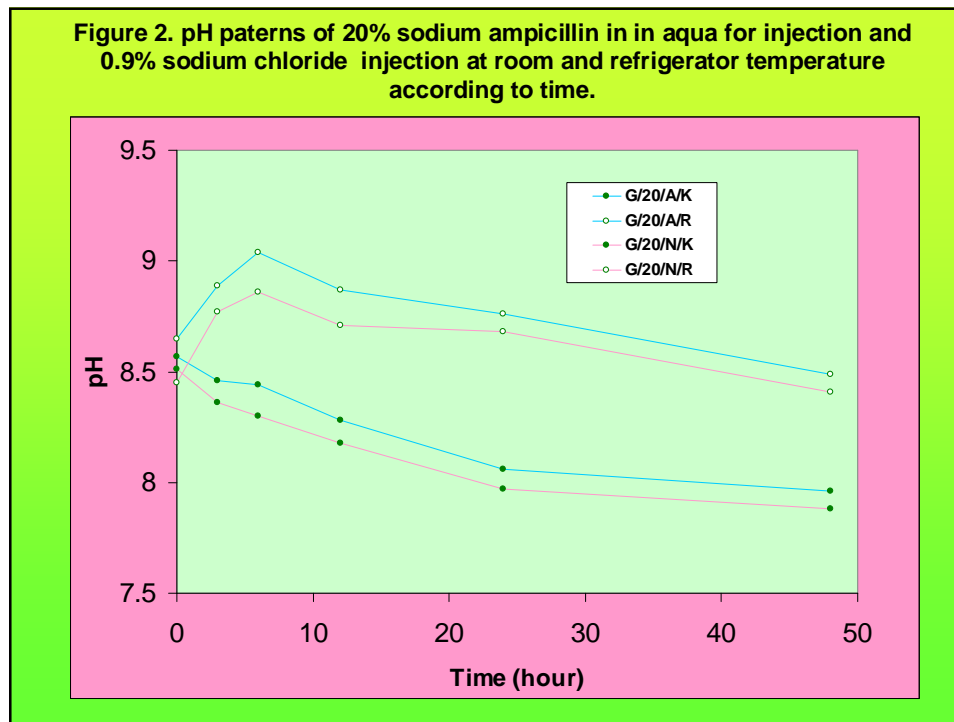
Table 1. Percent degradation of 20% sodium ampicillin in aqua for injection at room and refrigerator temperature.

Time (hour)	Room temperature					Refrigerator temperature				
	pH	Concentration (%)			Average (%)	pH	Concentration (%)			Average (%)
		I	II	III			I	II	III	
0	8.57	100.0	100.0	100.0	100±0	8.65	100.0	100.0	100.0	100±0
3	8.46	79.7	78.7	80.7	79.7±1.0	8.89	86.0	81.6	85.6	84.4±2.4
6	8.44	73.1	70.1	71.0	71.4±1.5	9.04	68.1	72.6	73.6	71.4±2.9
12	8.28	63.8	61.3	61.1	62.1±1.5	8.87	68.0	71.4	70.8	70.0±1.8
24	8.06	44.2	41.8	46.3	44.1±2.3	8.76	61.9	67.3	69.6	66.2±4.0
48	7.96	30.5	27.2	29.4	29.0±1.7	8.49	48.4	48.7	49.0	48.7±0.3

Table 2. Percent degradation of 20% sodium ampicillin in 0.9% sodium chloride injection at room and refrigerator temperature.

Time (hour)	Room temperature					Refrigerator temperature				
	pH	Concentration (%)			Average (%)	pH	Concentration (%)			Average (%)
		I	II	III			I	II	III	
0	8.51	100.0	100.0	100.0	100±0	8.45	100.0	100.0	100.0	100±0
3	8.36	78.0	78.1	75.6	77.2±1.4	8.77	87.0	88.3	89.6	88.3±1.3
6	8.30	54.7	57.0	56.6	56.1±1.2	8.86	86.5	88.2	89.2	87.9±1.4
12	8.18	52.9	54.6	52.3	53.3±1.2	8.71	85.7	86.9	86.5	86.4±0.6
24	7.97	44.7	44.1	44.3	44.4±0.3	8.68	71.2	72.9	74.0	72.7±1.4
48	7.88	24.8	24.0	25.7	24.8±0.9	8.41	57.8	59.2	59.2	58.7±0.8





Result:

The Result indicated that the stability of the drug is definitely temperature dependent.

Sodium ampicillin solution in 0.9% sodium chloride and aqua for injection is stable not more than 3 hours (77.2% potency versus 79.7% respectively) in room ($28 \pm 2^\circ \text{C}$) temperature and (88.3% potency versus 84.4% respectively) in refrigerator temperature ($2 \pm 2^\circ \text{C}$).

Result:

The stability of Sodium ampicillin solution in 0.9% sodium chloride and aqua for injection after 48 hours were 24.8% potency versus 29.0% respectively in room temperature ($28 \pm 2^\circ \text{C}$) and 58.7% potency versus 48.7% respectively in refrigerator temperature ($2 \pm 2^\circ \text{C}$).

Conclusion:

The result shows that the stability of the drug neither depends on solvent and temperature in first 3 hours.

The degradation of ampicillin is rapid, resulting greater than 10% loss in less than 3 hours.

Recommendation:

For ward pharmacist and nurses.

Pharmacist and nurses should use the sodium ampicillin injection solution either in 0.9% sodium chloride and water for injection not more than three hours after reconstitution and should store it in refrigerator temperature.