

DETERMINATION OF THE PHYSICO-CHEMICAL STABILITY OF AMIODARONE HYDROCHLORIDE IN SYRINGES FOR INTENSIVE CARE UNIT.



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Background

The intensive Care Unit (ICU) use drug solutions within higher concentration to avoid fluid overload

Purpose

To determine the physicochemical stability of concentrated solution of amiodarone in polypropylene syringe during 28 days at $5 \pm 3^\circ\text{C}$ with protection from light.

Material and methods

- Five syringes of 50 ml, containing 25 mg/ml of amiodarone in 0.9 % NaCl were prepared and stored at $5 \pm 3^\circ\text{C}$ with protection from light during 28 days.
- Immediately after preparation and periodically during the storage, amiodarone concentrations were measured by an ultra performance liquid chromatography (UPLC).
- Spectrophotometric absorbance at different wavelengths, pH measurement, visual and microscopic observations were also performed.

Conclusion

Solutions of amiodarone 25 mg/ml in syringe of 0.9 % NaCl are physically and chemically stable for at least 28 days when stored in syringes at $5 \pm 3^\circ\text{C}$ with protection from light and may be prepared in advanced by a Centralized IntraVenous Admixture Service (CIVA).

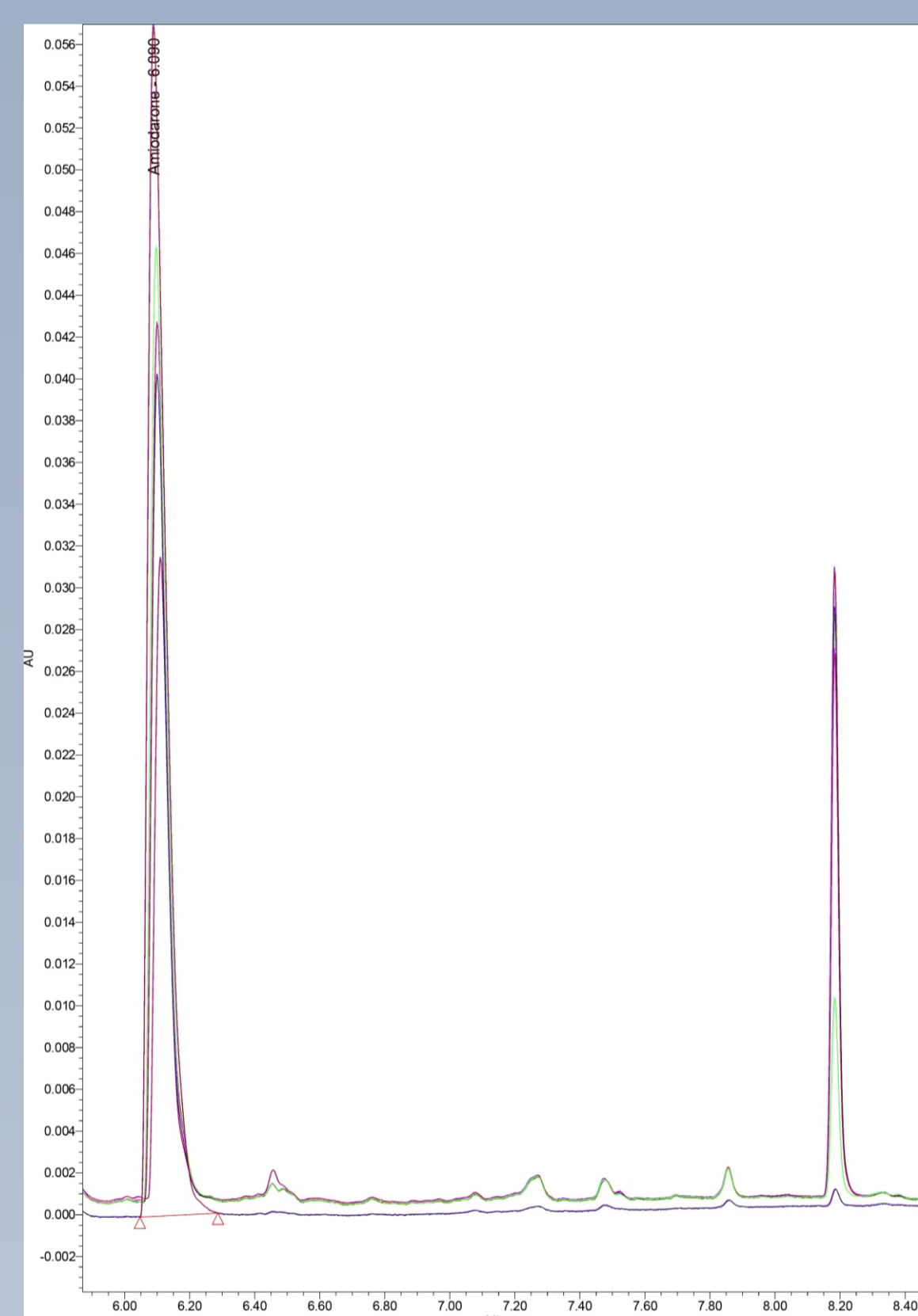
References

Simar J, Delcave C, Godet M, Decoster C, Gillet P, Bihin B, Jamart J, Galanti LM, Hecq JD. Stabilité physique du chlorhydrate d'amiodarone dans des seringues de glucose 5 % pour perfusion. Journal de Pharmacie de Belgique 2016 ;98 (1) : 24-25

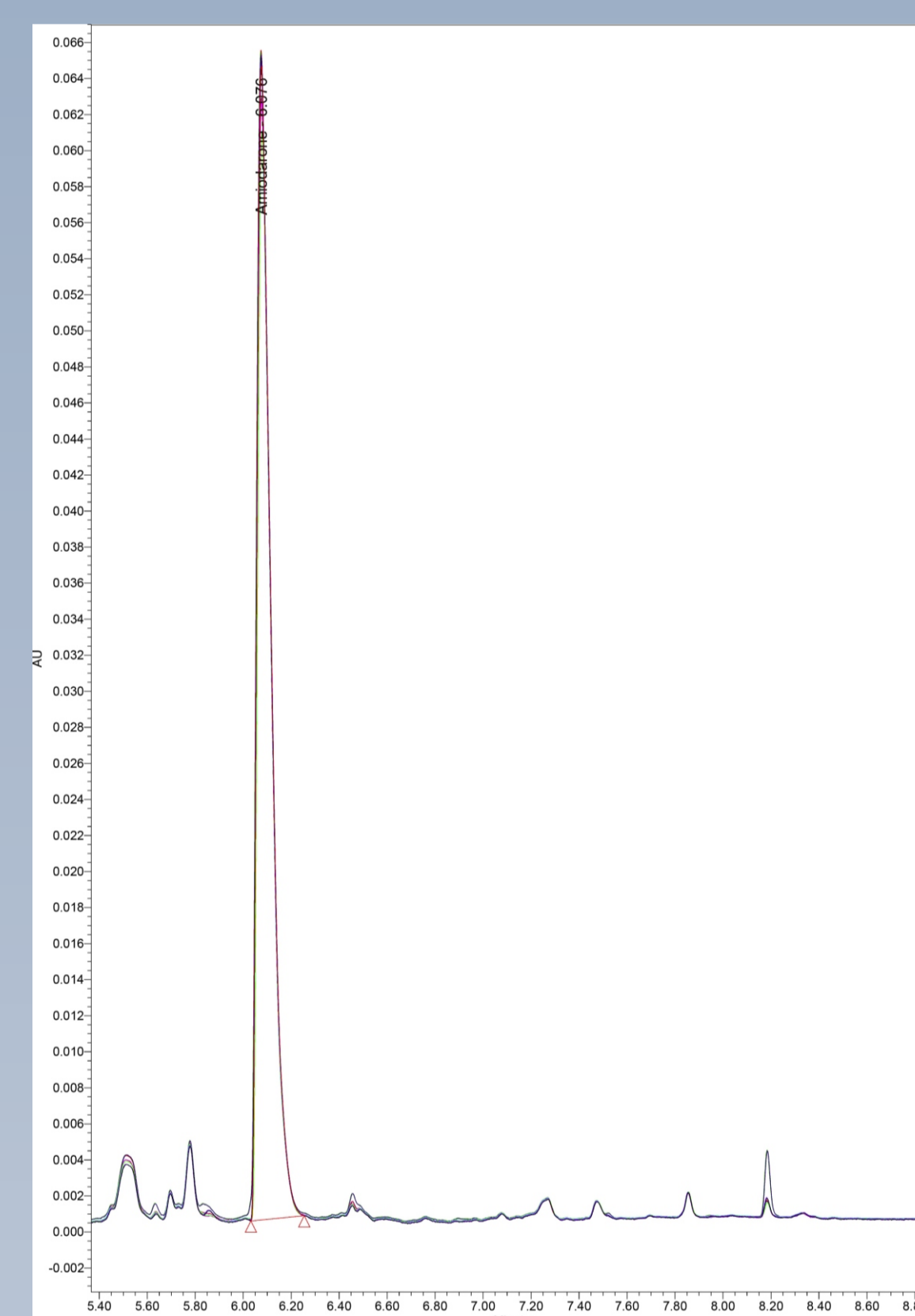
Results

- All solutions were physico-chemically stable during the whole period storage at $5 \pm 3^\circ\text{C}$:
- No color change, turbidity, precipitation or opacity, no significant pH variations or optic densities were observed in the solutions.
- Any crystals were seen by microscopic analysis.
- Solutions are considered chemically stable as the lower limit of the 95 % unilateral confidence interval on the mean remained above 90 % of the initial concentration for at least 28 days.

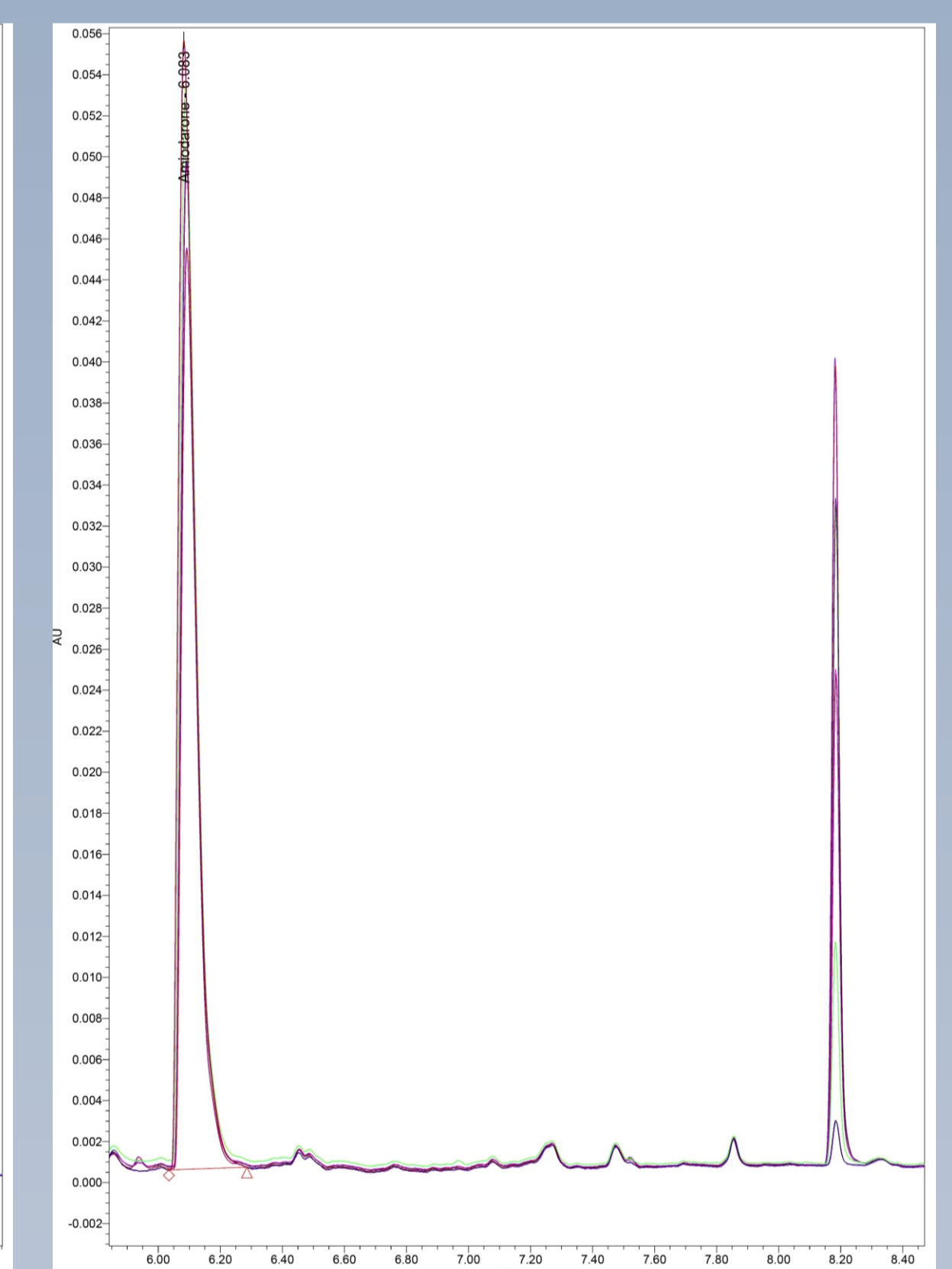
Forced degradation at neutral pH



Forced degradation at acidic pH



Forced degradation at alkaline pH



factor(j)	conc ech					conc			
	A	B	C	D	E	All	RM	p5	
0	30:81	32:45	27:95	28:13	30:87	30:04	1:9429	100:0	100:00
1	27:86	26:58	28:68	24:50	27:70	27:06	1:6165	100:2	99:82
2	30:02	31:61	27:21	32:76	31:54	30:63	2:1435	100:3	99:65
3	32:08	29:25	29:31	30:48	27:39	29:70	1:7307	100:5	99:47
6	27:41	26:52	27:54	28:02	25:75	27:05	0:9041	100:9	98:94
8	NA	NA	NA	NA	NA	NA	NA	101:2	98:59
10	25:47	24:51	23:03	26:09	22:19	24:26	1:6333	101:5	98:23
13	30:28	30:88	30:32	29:39	29:45	30:06	0:6329	102:0	97:70
15	NA	NA	NA	NA	NA	NA	NA	102:3	97:35
17	27:23	28:42	29:96	29:21	29:24	28:81	1:0371	102:6	97:00
20	28:35	30:70	30:68	29:42	30:58	29:95	1:0421	103:0	96:47
22	NA	NA	NA	NA	NA	NA	NA	103:3	96:11
24	30:31	30:27	30:10	29:21	30:88	30:16	0:6031	103:6	95:76
26	30:09	29:80	30:09	29:57	29:37	29:79	0:3203	103:9	95:41
28	28:85	29:96	30:27	29:51	29:05	29:53	0:5955	104:2	95:06