263

Di Stasi S M[1], Giannantoni A[2], Massoud R [3], Navarra P [4], Porena M[2], Vespasiani G [1], Attisani F[1], Stephen R L[5]
1. Department of Urology, "Tor Vergata" University, Rome Italy , 2. Department of Urology, University of Perugia, Perugia, Italy, 3. Department of Clinical Biochemistry, "Tor Vergata" University, Rome, Italy, 4. Institute of Pharmacology, Chatolic University, Rome Italy, 5. Physion Laboratories, Medolla, Italy

STABILITY OF RESINIFERATOXIN STOCK SOLUTIONS

Hypothesis / aims of study
Intravesical instillation of resiniferatoxin (RTX) is proving to be a valuable adjunct in the treatment of refractory detrusor hyperreflexia. However, certain issues are yet to be resolved, especially the storage and stability of stock solutions. Researchers have reported degradation of RTX solution stored in various plastic containers. Therefore, we investigated the stability of stock solutions stored in a commonly used plastic material and in glass, under differing conditions of temperature, light and dark.

Study design, materials and methods
RTX 1 mg was dissolved in 1 ml of absolute ethanol and diluted (10 fold) in ethanol/water (50/50), so that we had RTX 1 mg in 10 ml of equal parts ethanol/water solvent as our stock solution(s). Aliquots of 250 μl were then stored in glass containers or high grade polypropylene (plastic) containers and subjected to different temperatures and light/dark conditions over times ranging from 0-144 hours. 10 μl of samples were loaded for HPLC analysis. Results were normalized by taking the value at time 0 as 100%.

Results
Normalized results are shown in the following Table.

Experimental condition: data expressed as % of the value at time 0.							
	Room temperature				4°C		-20°C	
Time (h)	Plastic Dark	Plastic Light	Glass Dark	Glass Light	Plastic Dark	Glass Dark	Plastic Dark	Glass Dark
0	100	100	100	100	100	100	100	100
3	93.30	112.71	75.50	105.61	124.34	83.22	106.51	78.41
6	86.95	68.30	86.17	89.42	114.00	92.12	109.51	82.26
12	76.37	72.91	74.79	64.48	110.89	94.00	117.24	77.78
24	89.42	78.65	69.05	60.21	104.60	91.75	112.92	71.18
48	82.50	50.85	77.82	52.45	118.10	93.14	126.09	71.87
96	60.80	41.46	65.36	42.94	130.69	103.18	101.88	84.94
144	73.11	46.41	68.79	49.23	104.06	82.65	106.91	92.94

From the analysis of these data, it clearly emerges that: (a) both room temperature and light exposure affect RTX stability and the combined effect of these factors is additive; (b) RTX degradation, if present, falls to a nadir at 48 hours; (c) At low temperatures, in the dark, plastic storage affords better stability than glass.

Interpretation of results & Concluding message
RTX stock solutions should be stored at temperature $\leq$ 4° C in the dark. The material comprising the container for RTX is of secondary importance.