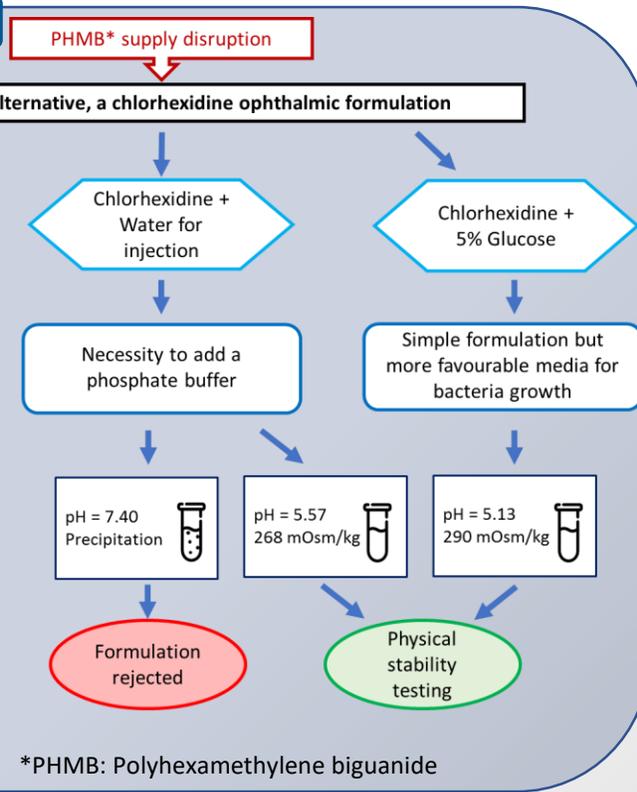


Physical stability of 0.02% chlorhexidine digluconate eye drops in 5% glucose or phosphate buffer at refrigerated and room temperature

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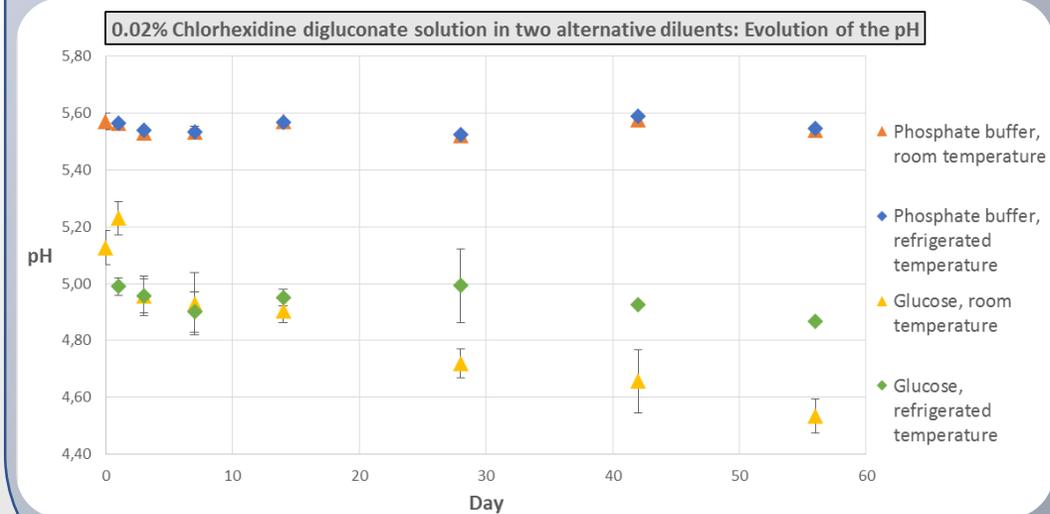
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Introduction



Results

Osmolality at D0 (mOsm/kg) Mean ± standard deviation		Subvisible particles count/mL at D0 Mean ± standard deviation	
Phosphate buffer	5% glucose	Phosphate buffer	5% glucose
268 ± 1.73	290.33 ± 4.51	3-10µm: 124.89 ± 22.70	62.18 ± 14.73
		15-30µm: 15.64 ± 4.71	4.76 ± 1.81
		50-100µm: 0.62 ± 0.30	0.04 ± 0.04



No colour change or macroscopic particles were detected

Subvisible particles values did not increase for both diluents during storage at ambient temperature but did increase slightly when stored at 5 ± 3°C

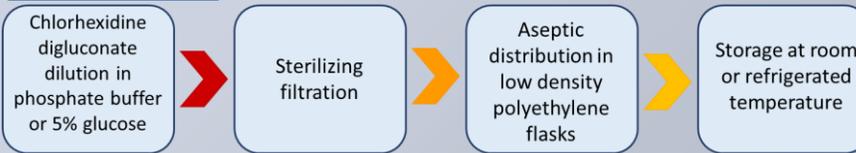
Turbidity stayed below 1.3 FNU

pH maximal variation compared to D0 was 0.90% with phosphate buffer and 11.54% with 5% glucose

Osmolality maximal variation compared to D0 was 6.59%

Sterility was preserved

Methods



Tested parameters (n=3):



Test schedule: D0, D1, D3, D7, D14, D28, D42, D56

Discussion and conclusion

0.02% chlorhexidine digluconate solutions did not present any physical instabilities when stored at ambient or refrigerated temperature in phosphate buffer or 5% glucose for 56 days. This is not unexpected, as neither of these diluents contain chloride anions which are incompatible with chlorhexidine. As glucose solutions are a more favorable media for bacteria growth and presented a pH decrease during the study, the best diluent and storage condition seems to be the phosphate buffer with an ambient temperature storage. This preliminary study would need to be completed by a full physicochemical study before any overall conclusions can be made.