3PC-039 OPTIMISATION OF MIXING AN ORAL POWDER MIXTURE OF CODEINE PREPARED IN THE HOSPITAL PHARMACY FOR FILLING INTO HARD CAPSULES

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Background and importance Codeine mixed with calcium salts filled into capsules is used to treat chronic diarrhoea in transplant, oncological and geriatric patients, and in patients with irritable bowel disease. At least 11 500 hard capsules are regularly prepared from a manually blended powder mixture in the hospital pharmacy per month. Turbula 2F2 blender has been introduced into the hospital pharmacy to optimise the mixing process.

Aim and objectives To establish optimal blending time and speed for mixing of codeine with the Turbula 2F2 blender and to verify homogeneity by determining the amount of codeine in the samples, a validated spectrophotometric analytical method was used.

Material and methods The total amount of prepared mixture was 245.7 g containing 4.5 g of codeine phosphate (1.83%). The optimal rotation speed of Turbula was established as 49 rounds per min (RPM) based on visual analysis with colourant instead of codeine.

A 2 litre polyethylene container for homogenisation was used. Calcium carbonate was premixed with colloidal silica, and codeine and tricalcium phosphate added. Five samples for analysis were taken from different places in the container after 5, 10, 15 and 20 min of mixing. Expression of relative standard deviation (RSD) was used to evaluate the homogeneity of codeine in the mixture.

Results The results are summarised in table 1.

Conclusion and relevance Based on the results, the optimal time of 10 min was estimated for mixing of the codeine mixture at 49 RPM. The use of the Turbula 2F2 mixer was beneficial in reducing pharmacy staff exposure to powder particles of hazardous drugs and in reducing the risk of cross contamination in the laboratory.

Abstract 3PC-039 Table 1

Time of mixing at 49 RPM	Sample No	Content of codeine (%)	RSD
5 min	1	1.84	2.47
	2	1.79	
	3	1.77	
	4	1.79	
	5	1.89	
10 min	6	1.75	1.91
	7	1.72	
	8	1.74	
	9	1.72	
	10	1.81	
15 min	11	1.59	3.82
	12	1.73	
	13	1.76	
	14	1.62	
	15	1.64	
20 min	16	1.58	5.47
	17	1.69	
	18	1.74	
	19	1.49	
	20	1.67	

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-040 GALENIC VALIDATION OF A DEXAMETHASONE 0.01% MOUTHWASH SOLUTION TO PREVENT EVEROLIMUS RELATED STOMATITIS

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Background and importance Stomatitis is a common adverse drug reaction of the mTOR inhibitor everolimus. Rugo *et al* (2016) reported that the use of a dexamethasone mouthwash solution prevented everolimus related grade >2 stomatitis in patients with hormone receptor positive and HER2 negative metastatic breast cancer. No commercial presentation is available in our country, and so we carried out galenic validation of a formulation for these patients.

Aim and objectives The aim of this study was to develop a dexamethasone 0.01% stable solution for mouth washing to prevent stomatitis in patients started on everolimus treatment.

Material and methods We designed two formulations based on the components of a commercial oral preparation manufactured in USA by Roxane Laboratories. We added EDTA to explore if this affected stability (table 1).

Abstract 3PC-040 Table 1

Dexamethasone phosphate 4 mg/mL injectable ampule (Kern Pharma)	10 mg/2.5 mL
Preservative water containing methylparaben (9%) and propylparaben (2.2%)	qs 100 mL
Citric acid solution 25%	qs pH 3–5
Sodium edetate*	10 mg

qs, quantum sufficit.
*Only added in one solution.

For assignment of the microbiological validity period, we used the risk matrix from Good Manufacture Practices of Hospital Pharmacy. We preserved both solutions under room temperature and refrigeration conditions, always protected from light. We checked for organoleptic characteristics (cleanness, colour, odour, flavour) and pH every week for 30 days.

Results We obtained transparent, homogenous solutions free of visible and rare particles. Physicochemical stability was guaranteed as we used a pre-existing formulation to develop our preparation. Furthermore, organoleptic characteristics were constant and pH remained stable between 3 and 5. We selected the formula without EDTA because its manufacture was easier. We assigned a beyond use date of 30 days, keeping the formulation refrigerated and protected from light.

Conclusion and relevance This formulation was simple to prepare. It can be used in other hospitals for the same purpose and has filled a therapeutic void. Clinical effectiveness might be investigated to confirm the utility of this magistral formula.