Two phases: pre-implementation (1 month) and post-implementation (1 month) of the RM.

All preparations of parenteral antineoplastic drugs in the HPD were included in the analysis.

Standard local protocols for preparation and storing of remaining starting material (vials) were followed in both phases.

All remaining vials that exceeded the expiry date were stored separately and the amount of product within was measured. Finally, the cost for all discarded products was calculated in each phase and compared.

Results Expiry dates were reduced in only six drugs (9%) after modifying stability according to the RM.

The number of preparations in the anti-neoplastic preparation unit was 1479 in the pre-implementation phase and 1434 in the post-implementation phase.

Previous to the implementation of the RM, 1.01% of the cost of drugs prepared in the HPD was due to discarded product after storing dates were exceeded. After the implementation of the RM, this was 0.97%.

Conclusion The implementation of a risk matrix in the preparation of parenteral anti-neoplastic drugs has no significant economic impact in terms of discarded product.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.
HOT-MELT RAM EXTRUSION 3D PRINTING: A SMART OPTIMISATION OF INTRACAMERAL CEFUROXIME

The dose of oxybutynin was maintained in one patient with the initial dose and, in another, rose to 0.1 mg/kg/8 hour (the maximum 0.2 mg/kg/8 hour).

Pharmaceutical care was performed by the explanation of the doses in milliliters adjusted to the weight and monitoring of possible adverse effects. Strawberry essence was incorporated into the suspension to improve flavour.

Since birth, the number of catheters has decreased, with an improvement in the patient’s symptoms. Regarding safety, no adverse reactions attributable to the drugs have been observed.

Conclusion Both oral suspensions were appropriated for the pathology of our patients, which continue in treatment. They are well tolerated, for an age range not included in the bibliography, with good response. Pharmaceutical care was given from the beginning to the family and the paediatric service.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

BACKGROUND

Orodispersible films (ODF) have been proposed as a valid alternative to conventional oral dosage forms to personalise the therapies and to improve patient adherence, especially in special populations (e.g., dysphagics, paediatrics, geriatrics). Since manufacturing technologies used by the industries (e.g., the solvent-casting technique) cannot be easily applied in a pharmacy setting, alternative methods have been proposed for compounding. 3D-printing permits the preparation of ODF of different strengths and geometries that fulfil the Ph.Eur. specifications concerning the uniformity of dosage units.

PURPOSE

To demonstrate the feasibility of the preparation of ODF by hot-melt ram extrusion 3D printing.

MATERIAL AND METHODS

This novel technology consists of three simple operations. First, maltodextrins, drug and other excipients (e.g., colourants, flavours, sweeteners) are mixed in a mortar and wetted with the plasticiser (i.e., glycerine). Then, the mixture is fed into the chamber of the ram-extruder and heated. ODF are individually printed using an 18G needle on the packaging material foil and sealed without further manipulation. The critical formulation attributes and process variables were investigated to define the processability space and their impact on the disintegration time and tensile properties of the ODF. The paracetamol (PAR) was used as a model drug to assess the drug-loading capacity of the ODF and the dissolution profile.

RESULTS

Preliminary results allowed to the optimization of the process parameters (heating temperature, 85°C; maximum print rate, 50 mm/s; filling angle, 120°) and composition (maltodextrins/glycerine: 80/20 w/w) to obtain homogeneous ODF. The compounded ODF (6 cm²; thickness 150–250 μm) disintegrated in less than 1 min and showed acceptable tensile properties for product handling. Different doses of PAR (12.5, 25, 37.5% w/w) were loaded to such basic composition without altering the ODF performances. The CV% of PAR assay remains lower than 5%. The PAR dissolution profile of printed ODF (t80 <6 min) overlapped that obtained by ODF prepared by the solvent-casting technique.

CONCLUSION

The overall results suggested that hot-melt ram extrusion 3D printing can be used in a pharmacy setting to prepare well-accepted orodispersible dosage forms and to personalise the drug dose according to the needs of the patient.

REFERENCE AND/OR ACKNOWLEDGEMENTS


No conflict of interest.