short period (2 months) and the PIs refused were not collected.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of interest No conflict of interest

3PC-029 STUDY OF PSMA11-68GA ADSORPTION ON MEDICAL DEVICES USED FOR RADIOSYNTHESIS AND MEDIA FILL TEST

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Background and importance PSMA-11 labelled with gallium-68 (PSMA11-68Ga) is a diagnostic radiopharmaceutical. Labelling is performed in a Trasis Mini all-in-one synthesiser. Sterile excipients, solvents and devices are necessary to produce a sterile and pyrogen-free injectable solution.
Aim and objectives The aim of this study was device evaluation. Two aspects were investigated: the sterility of the final preparation and the absorption of PSMA11-68Ga on the device.
Material and methods Device adsorption evaluation: radioactivity was measured with an ISOMED 2010 activity meter. PSMA11-68Ga labelling was performed and five syringes of 5 mL were filled with 1 mL from the preparation vial every 30 min after the end of the preparation. The weight activity (MBq/mg) of the preparation vial and syringes was calculated, measuring the activity and weight of each of them. At the end of the labelling process, the PSMA11-Ga68 preparation was totally filled in the preparation vial. The residual activity of different parts of the device were measured: the elution vial, the five syringes, the extraction cartridge, the synthesiser garbage, the vented filter, and three additional syringes were measured after three rinses with sodium chloride within 1 hour to 5 hours after elution. Finally, the activity of the elution vial at the end of the elution step and the activity of the final preparation vial at the end of the labelling process were compared on nine syntheses.

Final preparation sterility: media fill tests (MFT) were performed on three syntheses, replacing the excipients and solvents with tryptone-casein-soybean solution. A fertility test was performed with concentrated bacterial strains in accordance with the European Pharmacopoeia.
Results The weight activity difference between the final preparation vial and the five syringes were between 4% and 7%. Residual activities in the syringes, the vented filter, the waste garbage, the extraction cartridge and the three additional syringes were between 0.2% and 5% of the elution activity. The activity variation between the elution and final preparation vials were between –4% and +5%. The MFT did not show microbiological contamination after 14 days of incubation at 37°C. The fertility test was positive after 24 hours of incubation.
Conclusion and relevance These results show that the adsorption of PSMA11-68Ga on medical devices used for synthesis appeared to be limited. The MFT performed show that the manufacturing process was aseptic.

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3PC-030 DIFFERENT SUBSTRATES FOR ORODISPERSIBLE FILMS: YOU HAVE THE CHOICE!

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Background and importance Orodispersible films (ODF) are thin layers of a polymer that can be loaded with an active ingredient (API). This could be realised during the film-forming process or afterwards. Different polymers produce different film properties (eg, dissolution behaviour). So, you have the choice!
Aim and objectives Films of different compositions and heights were produced and investigated. The aim was to estimate whether the resulting films are appropriate candidates for further processing.
Material and methods Four formulations were chosen based on: (1) polyvinyl alcohol (PVA), (2) hydroxypropylmethylcellulose (HPMC), (3) HPMC with microcrystalline cellulose (MCC) and (4) starch.

The ODF based on starch was a commercial product, an 'edible paper'. ODF were produced with solvent casting and different heights. After drying, pieces were investigated for appearance, residual moisture and dissolution time.
Results The dried films differed in resulting thickness. Edible paper was the thickest followed by the mixture of HPMC and MCC, then PVA and finally HPMC. The very thin films of HPMC were difficult to handle.

All the films look different: PVA is white and very flexible. HPMC is colourless and flexible also. It becomes sticky when it comes into contact with water. When MCC is mixed with HPMC the films are white and too brittle to handle. Edible paper is green (colourant added) and also brittle, but is easy to handle.

Residual moisture depends especially on the formulation. PVA has ~1%–2%, HPMC MCC ~5%, starch ~7% and HPMC ~7%–10%.

Dissolution time depends on both the formulation and the height of the films. Starch takes more than 15 min and HPMC up to 3 min. Both formulations become sticky when they come into contact with water. The others predominantly show times under 1 min.
Conclusion and relevance Investigations revealed the different characteristics of the resulting films. The stickiness and prolonged dissolution time could be useful for mucoadhesial formulations. Mixture with MCC shortens the dissolution time but increases the brittleness. This formulation could be optimised. PVA and starch exhibit the easiest handling.

Incorporation of API should be possible for all formulations that were casted when API is dissolved. If the API is to be loaded after film production (eg, via inkjet printing) PVA and starch are promising candidates.

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3PC-031 PHYSICOCHEMICAL STABILITY OF DILUTED 'THIOTEPA RIEMSER' INFUSION SOLUTIONS IN PREFILLED 5% GLUCOSE INFUSION BAGS

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