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The "Drill & Fill" Method

C. PHILIPPE^{1,2}, **D. HAEUSLER**^{1,2}, **L.-K. MIEN**^{1,2}, **K. KLETTER**¹,
R. DUDCZAK¹, **W. WADSAK**^{1,3}, **H. VIERNSTEIN**², **M. MITTERHAUSER**^{1,2,4}

¹ Dept of Nuclear Medicine, Medical University of Vienna, Austria

² Dept of Pharmaceutical Technology and Biopharmaceutics, University of Vienna, Austria

³ Dept of Inorganic Chemistry, University of Vienna, Austria

⁴ Hospital Pharmacy of the General Hospital of Vienna, Austria

E-Mails: cecile.philippe@meduniwien.ac.at (C. Philippe), helmut.viernstein@univie.ac.at (H. Viernstein), markus.mitterhauser@meduniwien.ac.at (M. Mitterhauser)

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Aim: The "Drill&Fill"-Method is a suitable method to radiolabel compact dosage forms, such as tablets, and further to investigate their compartment in the human organism. Therefore, a hole is drilled into the tablet and filled with radioactive liquid. The hole is sealed with antiabsorbable glue. Hence, the radioactivity labels the tablet and allows its visualisation in the body using scintigraphy. The aim of the study was the evaluation and validation of a "Drill&Fill"-method for enteric coated tablets for a clinical study of dosage modification. Thereby the mandatory conditions were:

- The drill loss must be $\leq 3.0\%$ and $\leq 32\text{mg}$, respectively.
- No damaging of the coating through the drilling and filling.
- A uniform radiolabelling should be warranted.
- The labelled tablets must not differ from the not labelled tablets in the dissolution test.
- A suitable amount of radioactivity had to be determined to allow the visualisation of the tablet in the human body over 36 hours (study design: 3 tablet/day, max. radiation dosage/day: 10MBq)

Material & Methods: The tablet's dimension was 18x 9x 5mm and it had a weight of approximately 1 gram. Drill: The hole was drilled using an electric drill (Proxxon®). Fill: The drill hole was filled with 99m-Tc-DTPA using a Hamilton syringe. Subsequently the drill hole was sealed with cyanacrylate glue (Pattex® Blitz Sekundenkleber) and air-dried. Thereafter, the activity of the tablet was assessed in a PTW Curiemeter 2. The method was validated on the basis of 80 tablets.

Results: For ideal filling conditions the drill hole had to be 12mm deep with a diameter of 1.5mm. The drill loss was $28.78\text{mg} \pm 0.4$ and $2.64\% \pm 0.04$, respectively. The volume of 99m-Tc-DTPA in the hole was $21.92\mu\text{l} \pm 2.1$. The glue was air dried for 90 minutes in order to assure a complete drying-out of the glue. The activity after drying was $2.77\text{MBq} \pm 0.4$. The dissolution test showed no difference between drilled and intact tablets.

Conclusion: All required conditions could be achieved. The "Drill&Fill"-Method is a fast and easy method for labelling tablets. It is suitable for showing the residence and disintegration of the tablet.