EVALUATION OF THE IMPACT OF MACHINE-AIDED DEBLISTERING IN UNIT DOSE BLISTER PRODUCTION ON THE FUNCTIONALITY OF TABLET COATING

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Background and importance

Our Unit Dose blister production processes large quantities of drugs with deblistering machines (Fig.1). Damaged drugs are removed. However, it has not been studied if mechanical stress might cause unobservable damage and negative effects on functional coating.

Aim and objectives

We investigated the influence of machine-aided deblistering on the functionality of drug coating. Drugs were chosen for their high deblistering volume or critical active agent (worst case approach).

Fig.1: machine-aided deblistering of tablets; machine with bottom roll and adjustable discs operated with a manual crank

Materials and methods

Preparation:

- Thrombo ASS 100mg (TA) (Acetylsalicylic acid; enteric coating) and
- Quilonorm retard 450mg (QU) (Lithiumcarbonate; tablet film causing retardation of release)

were deblistered:

1. manually and then minimally damaged *(positive control)* Fig. 2
2. with deblistering machines Type RBP Bauer D1500[1] *(test sample)*
3. manually *(negative control)*

Fig.2: generation of tiny superficial defects on tablet film using a pointed item

Analysis: Ten tablets of each group were analysed:
1) TA+QU: Dissolution testing was performed following the methods of the European Pharmacopoeia[2] (assembly with 37°C and motion of fluid). *Requirements:* two hours of acid stage duration in 0,1M HCl followed by fast (enteric coating) or delayed (retardation) disintegration in neutral buffer solution.
2) TA: Tablets were immerged into a methyleneblue dye bath to visualise intactness of coating / damaged areas.

Results	minimally damaged TA	machine-deblistered TA	manually deblistered TA	minimally damaged QU	machine-deblistered QU	manually deblistered QU
0,1M HCl (Fig.3)	disintegration starts within seconds, complete after 1h	no disintegration after 2h	no disintegration after 2h	no disintegration after 2h	no disintegration after 2h	no disintegration after 2h
phosphate buffer pH 7	-	disintegration visible after 1h, complete after 2h	disintegration visible after 1h, complete after 2h	no disintegration after 1h, disintegration visible after 2h	no disintegration after 1h, disintegration visible after 2h	no disintegration after 1h, disintegration visible after 2h
dye bath (Fig.4)	cavities and grooves	even dying of surfaces	even dying of surfaces			

Fig.3: disintegration test TA in 0,1M HCl: minimally damaged (left), machine-deblistered (middle), manually deblistered (right)

Fig.4: TA in dye bath: minimally damaged (left), machine-deblistered (middle), manually deblistered (right)

Conclusion and relevance

Although minimal damage can lead to a loss of coating functionality, machine-aided deblistering showed no negative effects on coated tablets; Neither differences in disintegration tests nor in the dye bath were detected compared with manually deblistered tablets. These results support machine qualification and validation of this important step in our Unit Dose blister production and were examined upon a GMP inspection by the Austrian authority.

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References

(1) https://www.rbp.de/produkte/rbp-d1500/
(2) Europäisches Arzneibuch, Verlag Österreich GmbH Band 1, 2.9.3 Wirkstofffreisetzung aus festen Arzneiformen (dissolution test for solid dosage forms)