

Supplementary Material

Pharmaceutical Development of Film-coated Mini-tablets with Losartan Potassium for Epidermolysis Bullosa

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Table S1. Composition of mobile phase for purity analysis via HPLC

Mobile phase			
buffer	1.25 mg/mL potassium dihydrogen phosphate and 1.5 mg/mL di-sodium hydrogen phosphate in water (pH approximately 7.0)		
solution A	acetonitrile and buffer (15:85)		
solution B	acetonitrile		
	time [min]	solution A [%]	solution B [%]
gradient elution	0	80	20
	10	40	60
	11	80	20
	20	80	20

Table S2. Flow properties of F 8 and its single components, mean \pm sd, n=3, LP = losartan potassium, SMCC = silicified microcrystalline cellulose

Material/powder	Hausner ratio	Flowability (Ph.Eur. 10)*
F 8	1.35 \pm 0.01	poor
LP	1.50 \pm 0.01	very poor
SMCC 50	1.27 \pm 0.02	passable

*Rating by mean of Hausner ratio

Table S3. Particle size characterization and Hausner ratio of granules (F 10A, 10B, 10C), mean \pm sd, n=3

	D ₁₀ [μ m]	D ₅₀ [μ m]	D ₉₀ [μ m]	Hausner ratio	Flowability (Ph. Eur. 10)*
F 10A (2 kN/cm)	59 \pm 1	634 \pm 12	1135 \pm 4	1.41 \pm 0.01	poor
F 10B (4 kN/cm)	75 \pm 1	799 \pm 8	1183 \pm 4	1.35 \pm 0.02	poor
F 10C (6 kN/cm)	101 \pm 13	832 \pm 12	1204 \pm 4	1.33 \pm 0.02	passable

*Rating by mean of Hausner ratio

Table S4. Purity of the coated mini-tablets (F 10C) stored at 40 °C / 75 % r.h. and 25 °C / 60 % r.h. in different packaging conditions (openly, in polyethylene bags (PE) and in sealed aluminium foil (Alu)). For better overview only results at initial timepoint and after 6 months storage are shown (3rd month timepoint not shown), MT = mini-tablets, ND = not detected, < 0.1 % = impurities detected but not included in calculations

Coated MT of F 10 C	6 months 25 °C / 60 % r.h.				6 months 40 °C / 75 % r.h.		
Purity	Initial	Openly	PE	Alu	Openly	PE	Alu
1H Dimer	ND	ND	ND	ND	< 0.1 %	< 0.1 %	< 0.1 %
2H Dimer	ND	ND	ND	ND	ND	ND	< 0.1 %
Other single impurities	ND	ND	ND	ND	< 0.1 %	< 0.1 %	ND
Sum of unknown impurities	ND	< 0.1 %	0.10 %	< 0.1 %	0.11 %	0.13 %	0.13 %
Sum of total impurities	ND	< 0.1 %	0.10 %	< 0.1 %	0.11 %	0.13 %	0.13 %

Table S5. Purity of the coated mini-tablets (F 11) stored at 40 °C / 75 % r.h. and 25 °C / 60 % r.h. in different packaging conditions (openly, in polyethylene bags (PE) and in sealed aluminium foil (Alu)). For better overview only results at initial timepoint and after 6 months storage are shown (3rd month timepoint not shown), MT = mini-tablets, ND = not detected, < 0.1 % = impurities detected but not included in calculations

[illegible]