



OXYBUTININ TRANSDERMAL PENETRATION FROM BIOADHESIVE FILMS

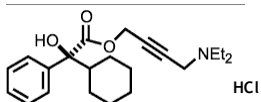
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OBJECTIVE

To evaluate the performance in vitro of a new transdermal system (Patch-non-Patch)(1) containing oxybutinin (oxy) in comparison with a commercial transdermal product.

fw:393.95
pKa: 7



PnP preparation

Components (%wet weight)	8%	1%
PVA 49000 30%	62	62
Plastoid E35H®	27	27
Sorbitol 70%	4	4
Oxybutinin	3.2	0.3
Water	3.8	6.7

Characteristics:

Transparent
Thin (80-90 µm)
Flexible
Water-based
Non-occlusive
Not self-adhesive

METHODOLOGY

Tested Patches	Oxybutinin Content	
	µg/cm ²	µg/mg
OXYTROL	923	
PnP 1%	85.6 ± 3.4	11.0 ± 0.4
PnP 8%	870.1 ± 164.6	79.4 ± 3.2

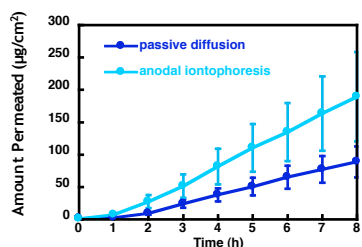
Permeation experiments

- Franz-type diffusion cell
- Rabbit ear skin
- Receptor solution: saline (0.9% NaCl)
- Donor: PnP Oxytro™ (Watson Pharma) Oxybutinin HCl 2 mg/ml
- HPLC analysis

RESULTS

Passive Diffusion and Anodal Iontophoresis

Oxybutinin conc: 2 mg/ml
pH = 6



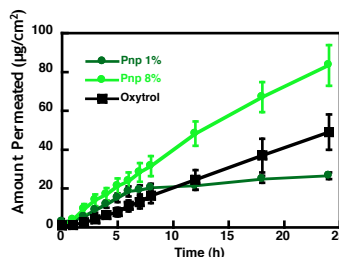
Anodal iontophoresis
Saline bridges
0.5 mA/cm²; 8 hours; pH 6

Very slight increase in the amount permeated.

	P (cm/h)	J (µg/cm ² h)	Lag time (h)
Passive Diffusion	$7 \cdot 10^{-3} \pm 1.9 \cdot 10^{-4}$	14.25 ± 3.98	1.4 ± 0.5

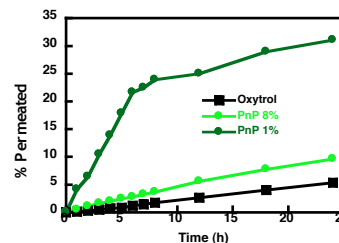
Good permeation properties

Oxybutinin patches

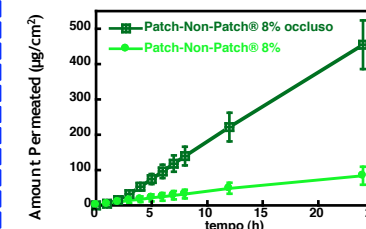


PnP 1% : after 8 hours, the permeation leveled off, due to the depletion of the drug reservoir

PnP 8% : higher permeation profile and higher efficiency (see % permeated) compared to Oxytrol



Patch non patch and occlusion



Application of an occlusive backing on the surface of the 8% PnP.

The occlusion of the system increased of 5 times the transdermal permeation of oxybutinin from PnP 8%.

REFERENCES

- (1) Film for dermal and transdermal administration of drugs, P. Colombo, P.L. Catellani, C. Padula, P. Santi, G. Colombo WO 02/30402
- (2) Moser K., Kriwet K., Froehlich C., Kalia Y.N., Guy R.H., Pharm. Res. 2001 (18) 1006-1011

CONCLUSION

- Oxybutinin has good permeation properties
- Iontophoresis did not significantly increase the permeated amount.
- The 1% PnP gave rise to an initial permeation comparable to the one of Oxytrol® then the permeation leveled off, due to the depletion of the drug reservoir.
- The new bioadhesive film 8% was able to generate permeation profile comparable to the marketed product OXYTROL with higher efficiency.
- The occlusion of the 8% PnP film greatly increased the permeation of oxybutinin.