

Instability of misoprostol tablets outside the blister

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Conflicts of Interest : Exelgyn, Nordic Pharma, HRA Pharma, Bayer Schering

CYTOTEC® 200 µg
misoprostol

60 Comprimés Sécables



Material and methods :

N= 420 Cytotec® tablets stored outside blister
at 25° C, 60%RH
vs controls

Pharmaco technical methods

according european Pharmacopea

- Mass uniformity
- Friability
- Hardness
- Diameter and thickness

Water content

Karl Fisher Metrohm: 787 KF Titrino



Analytical studies

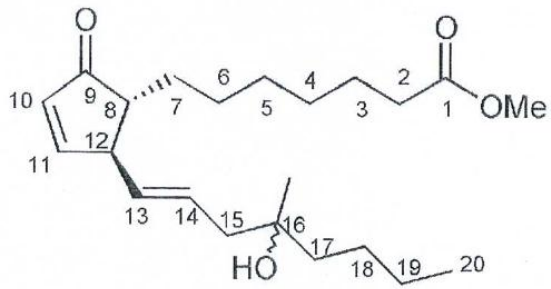
HPLC LaChrom Elite VWR 13

- Misoprostol dosage
- Decomposition products dosage :
type A, type B and 8 epi misoprostol

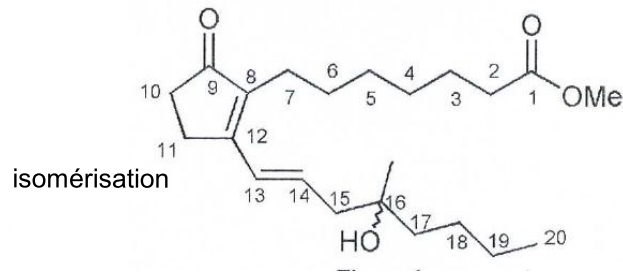


dehydration

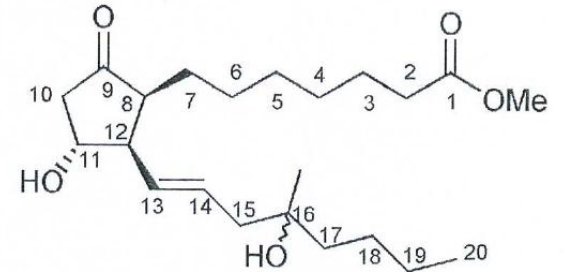
isomérisation



Type A misoprostol



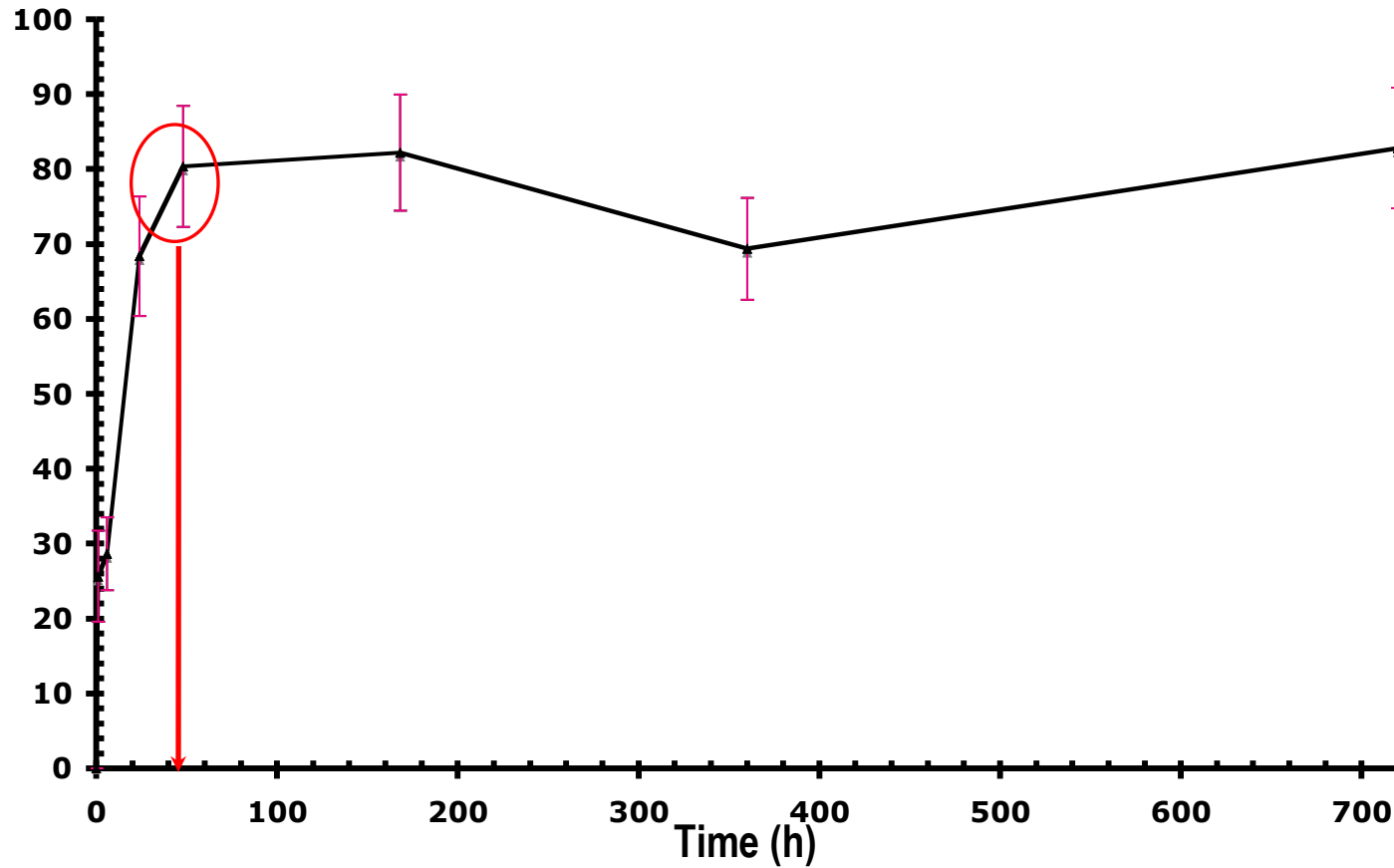
Type B misoprostol



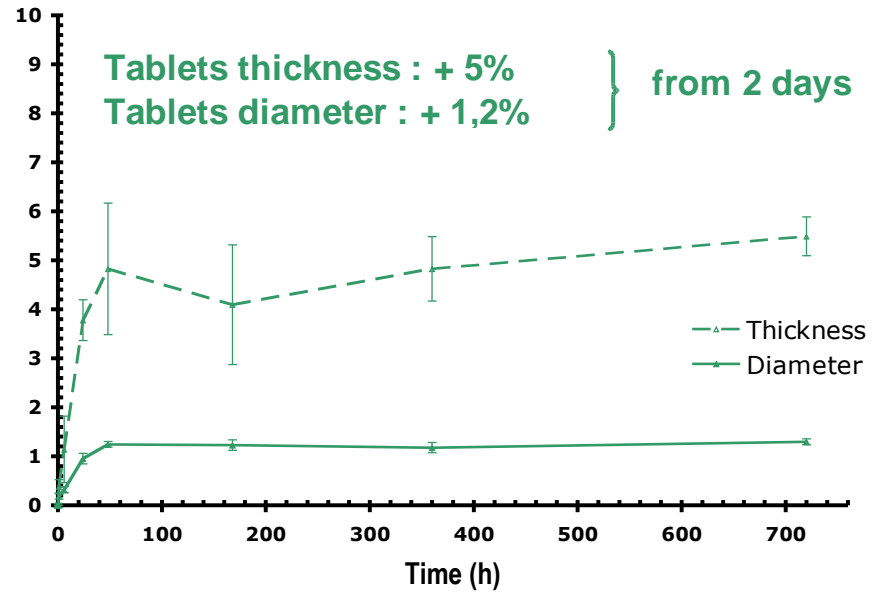
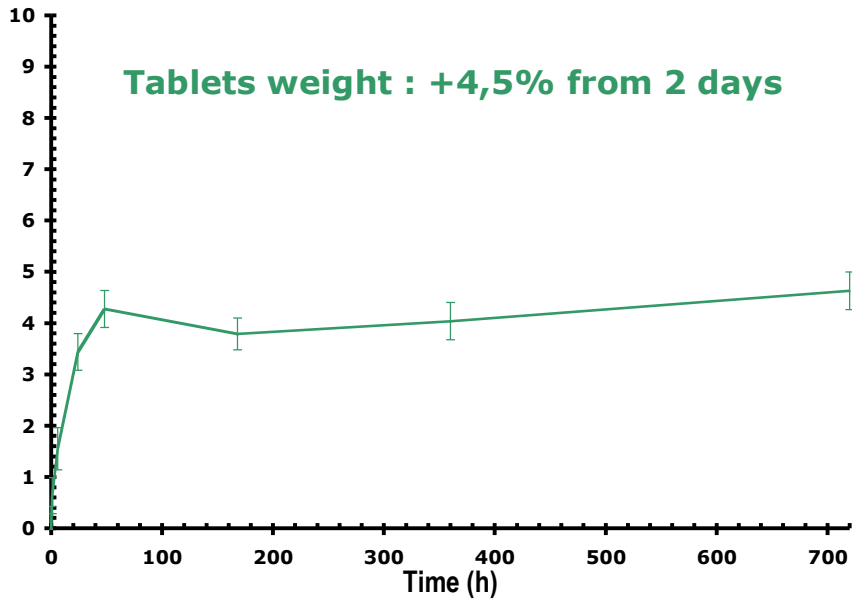
8 épi misoprostol

Non active products

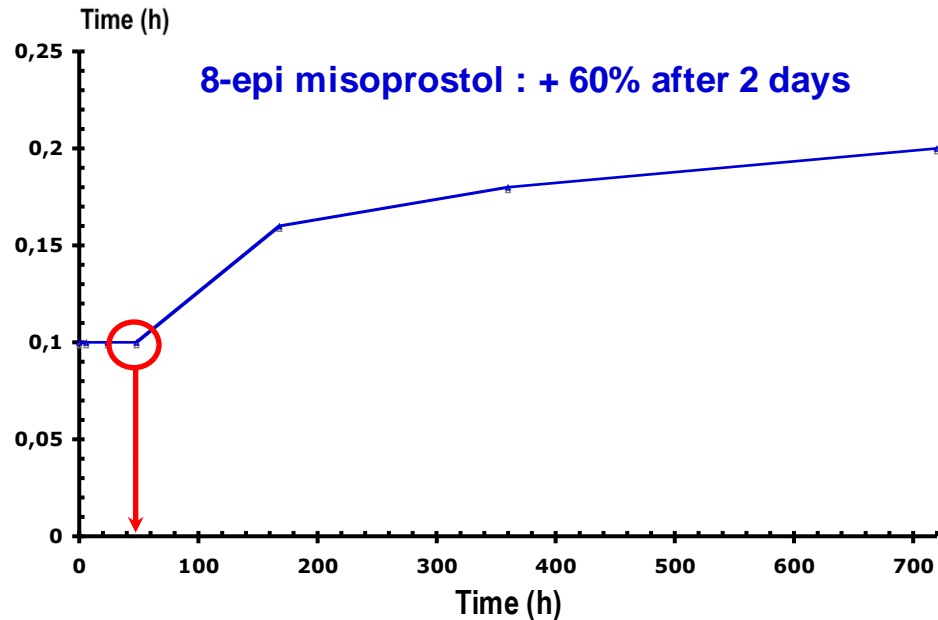
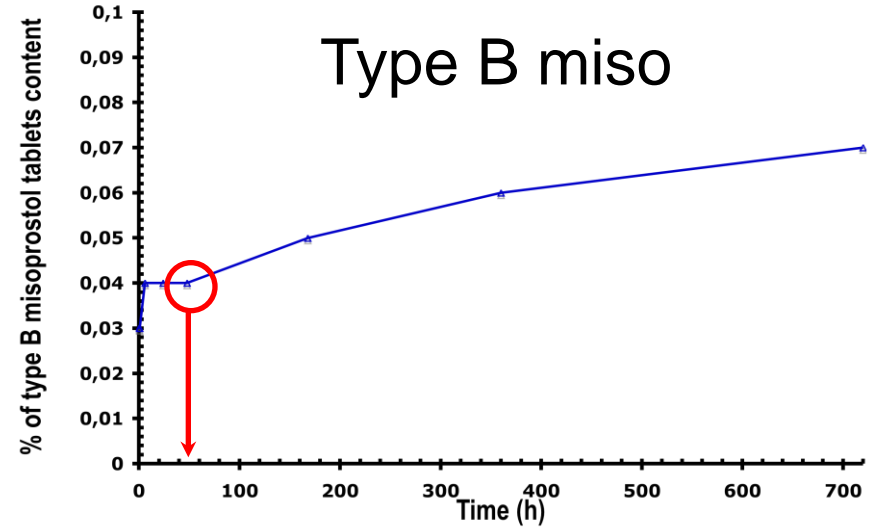
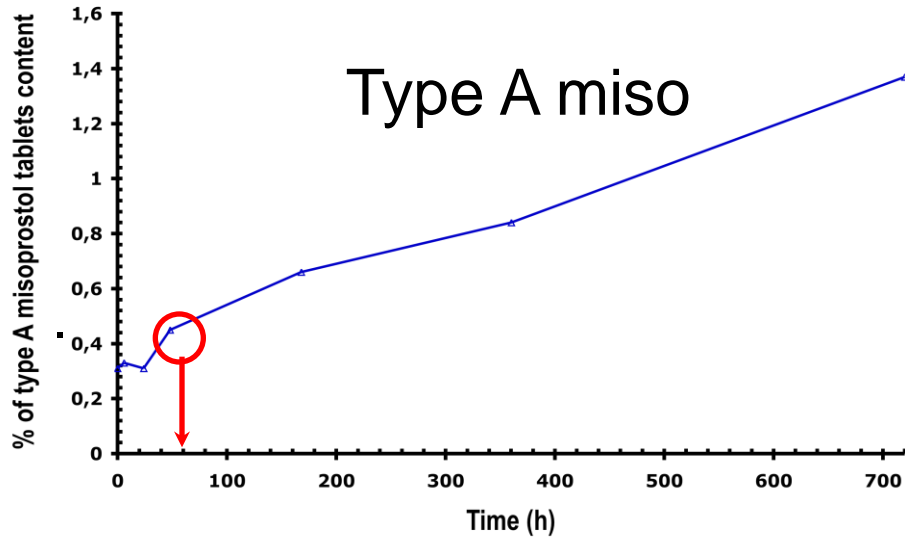
Water content



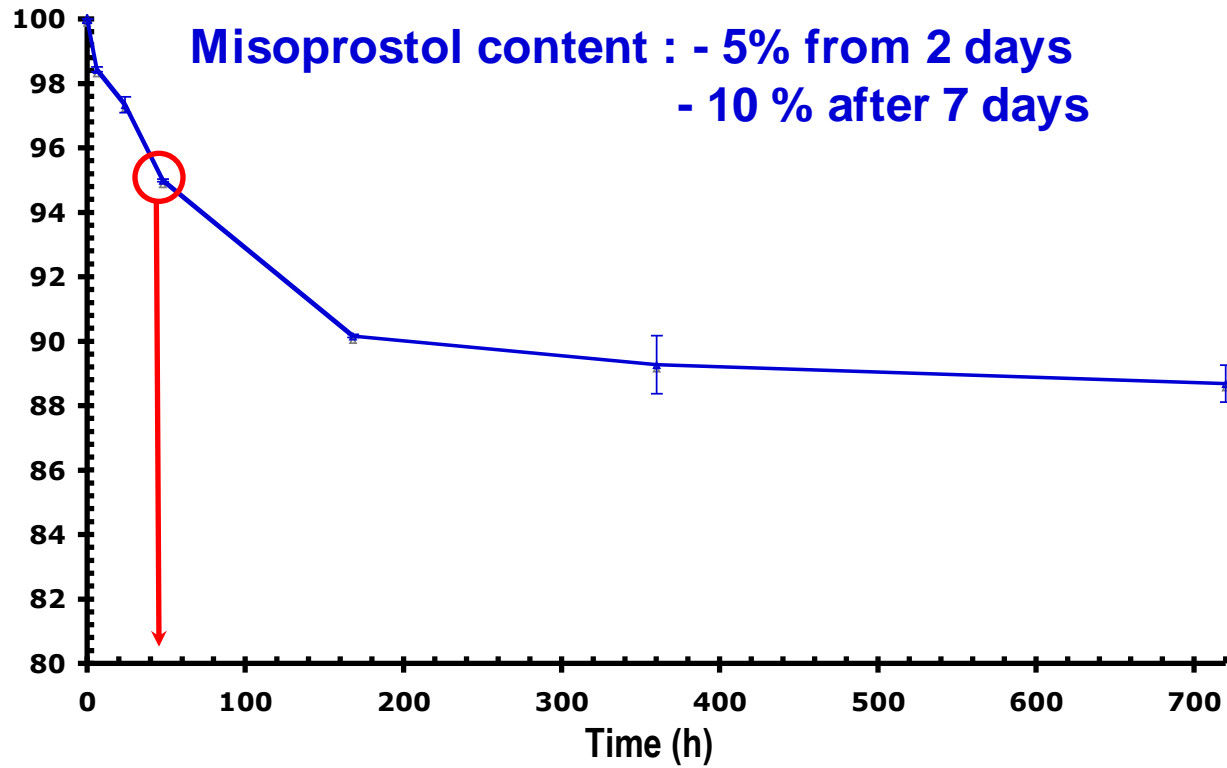
Pharmaco-technical results



Degradation products



Misoprostol dosage



**Special caution must be
taken in delivering
Cytotec® tablets**



