Hepatoprotectant (APAP and other agents)

OCR Number: OCR 4554

Description:

- OCR4554 is an approved drug used by countless patients world-wide (WW).
- Acetaminophen (APAP) sales
  - Dozens of companies have OTC sales
  - Tylenol’s 20.3% market share and $850M WW/yr
- Large percentage of population have vulnerable livers and would benefit from safer APAP (Figure 1).
- APAP overdose among most common WW
  - FDA has long wrestled with safety vs. efficacy for APAP
  - US: 56,000 ER visits/yr
  - 100 unintentional deaths/yr
  - 51% of all US liver poisonings in 2003
  - Used in suicide attempts
- OCR4554 in combination with APAP reduces mortality in vivo (Figure 2).


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