



## Oxytocin in a heat-stable fast-dissolving tablet for PPH prevention and/or management

### Oxytocin innovation meets two out of three product requirement specifications

Oxytocin is the recommended drug of choice to prevent PPH, however it requires refrigeration and typically is given intravenously or as an intramuscular injection, which are both challenging in LMIC settings. Innovative fast dissolving sublingual tablets could be a heat-stable and needle-free solution but needed long-term stability and preclinical studies to determine an appropriate dose.

#### Long shelf life and rapid absorption

PATH developed a robust oxytocin sublingual fast-dissolving tablet using safe, nontoxic excipients and demonstrated its short-term stability under elevated storage-temperature conditions of 40°C/75% relative humidity, with <5% loss in oxytocin content after 1 year. The rigorous research conducted by the D<sub>3</sub>AWN team successfully demonstrated that oxytocin in a sublingual fast-dissolving tablet formulation maintains thermostability for 2 years at elevated temperature and humidity. We also determined in an animal model that oxytocin is rapidly absorbed in blood via the sublingual route within 5 minutes.

#### Repurposing heat-stable oxytocin formulation

However, the oxytocin in sublingual fast dissolving tablet did not meet the threshold for a clinically relevant level of oxytocin in blood needed to prevent postpartum hemorrhage. Even increasing the dose of oxytocin in the sublingual fast dissolving tablet could not achieve bioequivalence, which was set as the go/no-go criteria for advancing the needle-free heat stable oxytocin tablet. The team is considering other uses of the oxytocin tablet such for treatment of postpartum depression.



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### OXYTOCIN IN SUBLINGUAL FAST-DISSOLVING TABLETS PIPELINE STATUS

Research ► Translation

► Development ► Implementation

Exit from portfolio

