



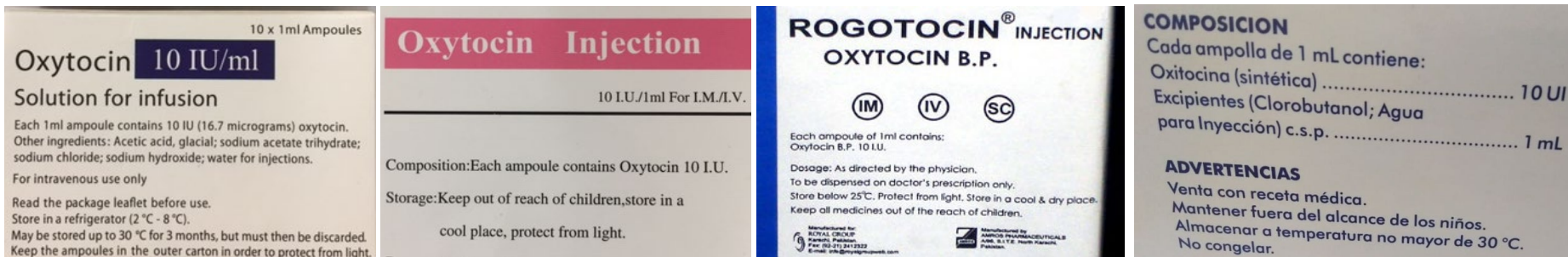
Oxytocin Injection - Stability and Storage

What do we know?

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Differences in Labelling of Oxytocin Injection Products - What does it mean?

- Reportedly over 300 oxytocin injection products supplied into global markets from around 100 suppliers
- The labelled storage conditions on these products vary, including many that do not specify refrigerated storage

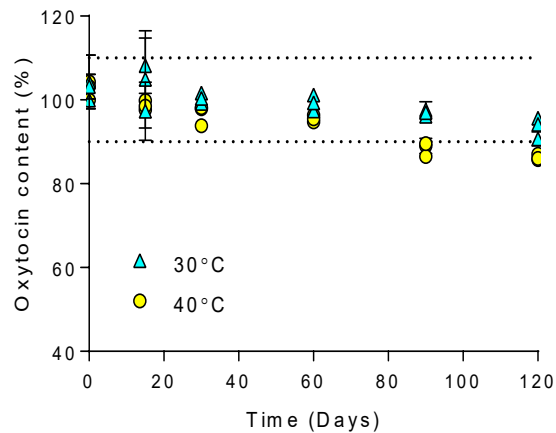


- This causes confusion among stakeholders involved in the procurement, supply and storage of oxytocin injection:
 - Can/should oxytocin injection be stored outside of the refrigerator?
 - Are some oxytocin injection products more stable than others?
- Monash University/UNFPA conducted a study to investigate the stability of oxytocin injection products with differently labelled storage conditions

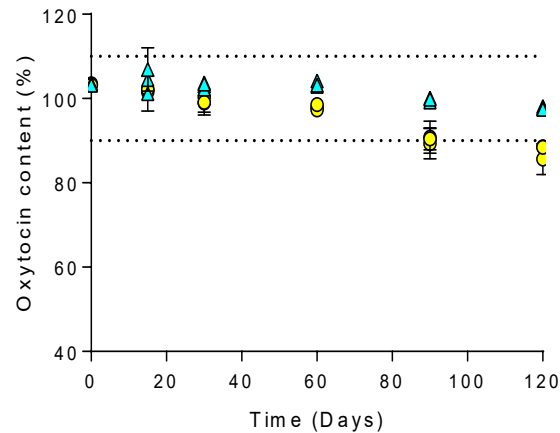
Stability of Oxytocin Injection Products labelled for storage at 2-8°C

- Product samples were obtained from three manufacturers
- All manufacturers were EU-based and the products were SRA-approved
- All products were oxytocin 10IU/mL ampoules labelled for storage at 2-8°C
- Accelerated stability testing conducted for 120 days at 30°C & 40°C

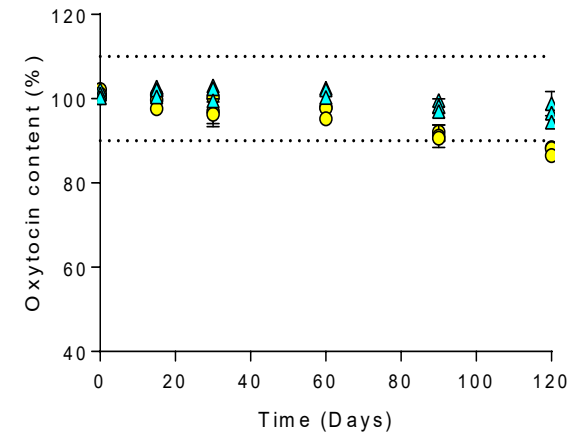
Supplier 1



Supplier 2



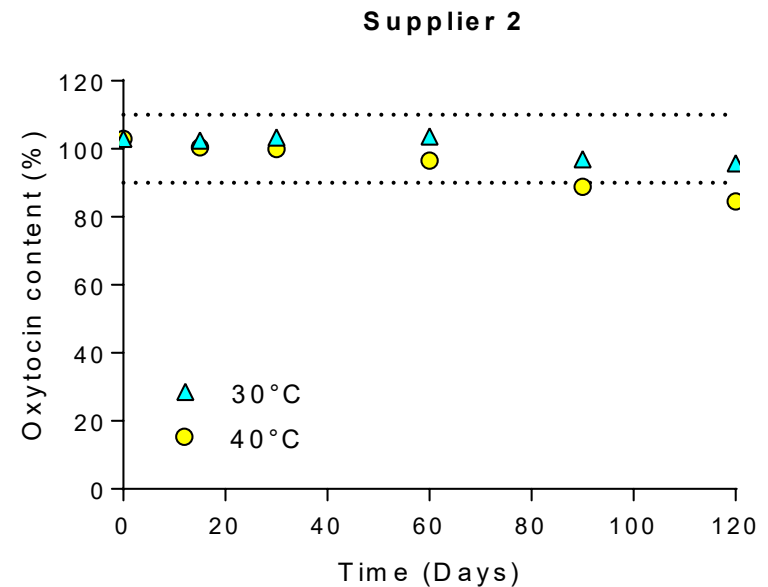
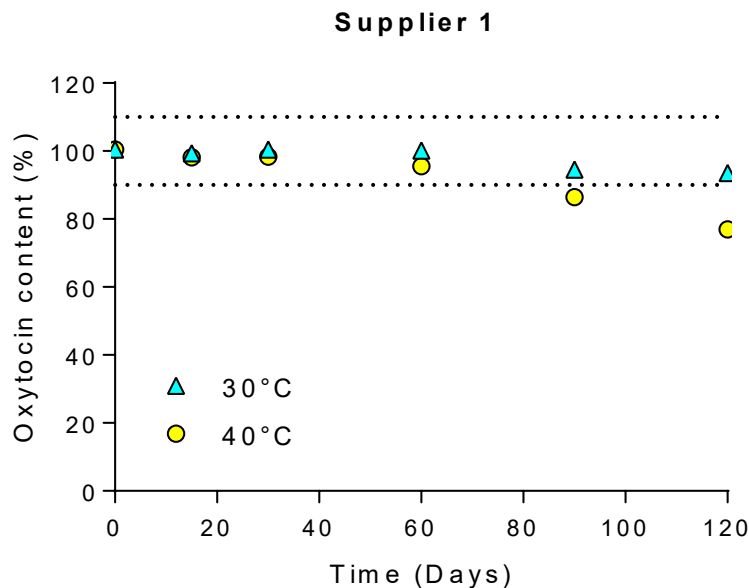
Supplier 3



Stability of Oxytocin Injection

Products labelled for storage outside of the refrigerator

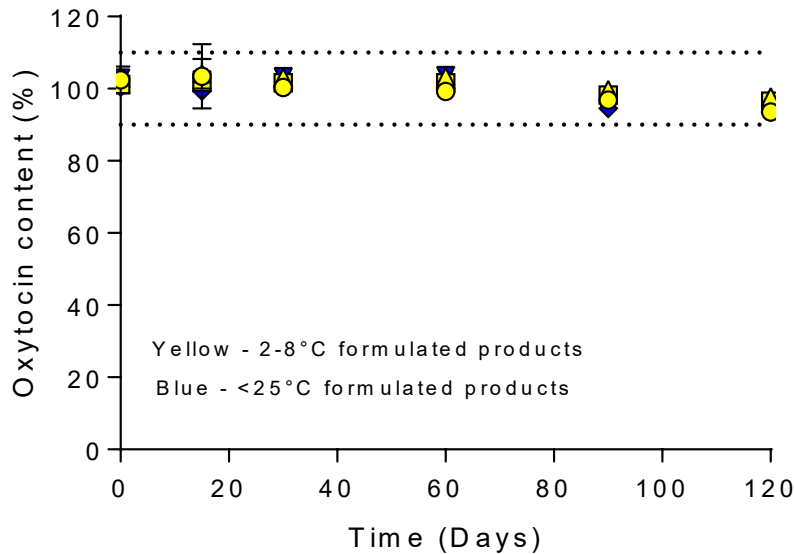
- Product samples were obtained from two manufacturers
- One EU-based and one South American manufacturer
- All products were oxytocin 10IU/mL ampoules labelled for storage at $<25^{\circ}\text{C}$
- Accelerated stability testing conducted for 120 days at 30°C & 40°C



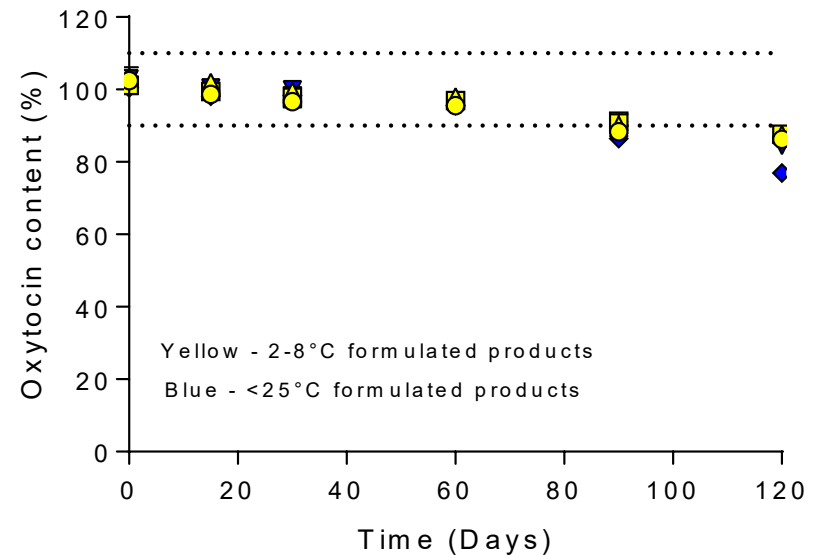


Stability of Oxytocin Injection Comparison of Products

Storage at 30°C



Storage at 40°C



NO DIFFERENCE IN STABILITY AT 30°C & 40°C



So which products should you buy/use?

- International (WHO) guidelines require that the storage requirements of pharmaceutical products be dependent on the climate of the country in which it will be used
- In all countries with hot climates (climatic zones III & IV - 121 countries), if products are to be stored outside of the refrigerator, the product must demonstrate stability **for the duration of its shelf-life** (usually a minimum of 2 years) at 30°C*
- Oxytocin injection products are NOT stable for 2 years at 30°C and therefore should NOT be stored outside of the refrigerator in these countries
- All products procured for use in these climates should be labelled for storage in refrigerated conditions
- Products labelled for storage outside of the refrigerator generally have shorter shelf-lives (2yrs vs 3/4yrs)

*https://www.who.int/medicines/areas/quality_safety/quality_assurance/StabilityConditionsTable2UupdatedMarch2015.pdf?ua=1



Key Messages

- There are NO heat stable oxytocin injection products
- Irrespective of labelling, the stability of oxytocin injection products is similar between manufacturers
- Products labelled for storage outside of the refrigerator generally have a shorter shelf-life than those labelled for storage at 2-8°C
- In countries with high ambient temperatures, only product labelled for refrigerated storage should be procured/used and it should be maintained in the cold chain throughout supply and storage