Life Cycle Assessment (LCA) and Comparison of Five Sterile Injectable Platforms

Poster Presenter:
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Introduction

Third Party, Peer-Reviewed Life Cycle Assessment (LCA) quantifies the environmental impact of five sterile drug delivery solutions, compares results to determine if there is a statistically significant difference in the potential environmental impact of options, and identifies key drivers of sustainability and future opportunities for designs, configurations, and locations.

Five Product Alternatives

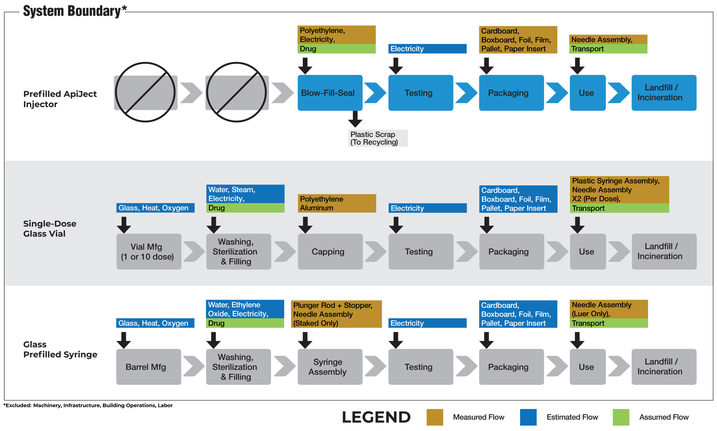
- Single-dose glass vial with plastic syringe and two hypodermic needles for drug drawing and drug administration
- Multi-dose glass vials with (per dose) plastic syringe and two hypodermic needles for drug drawing and drug administration
- Glass prefilled syringe with luer needle assembly
- Glass prefilled syringe with staked needle assembly
- Blow-Fill-Seal (BFS) container and needle assembly (Prefilled ApiJect Injector)

International Organization for Standardization, Geneva

- ISO, 2006a. ISO 14040:2006 Environmental management - Life cycle assessment - Principles and framework.
- ISO, 2006b. ISO 14044:2006 Environmental management - Life cycle assessment - Requirements and guidelines.

Methodology and Analysis

- Utilized ISO standard for LCA (14040), defining standard phases to any analysis: (1) Goal and Scope (2); Life Cycle Inventory Analysis; (3) Life Cycle Impact Assessment; and (4) Interpretation.
- Evaluation was based on the delivery of a single-dose of 1 millimeter (mL) of drug, set as the functional unit of comparison for the study.
- Shelf-life, durability during transit, ease of use, and clinical efficacy were assumed to be equivalent based on design specifications and expert judgement.
- Use stage was assumed to be equivalent among all options.
- Drug wastage was chosen as a representative data set from Parvatker et al. (2019).

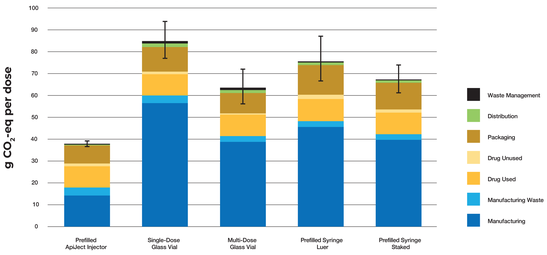


*Excluded: Machinery, Infrastructure, Building Operations, Labor

- Modeling scenarios tested process, location, and transportation assumptions.
- Data assessment quality included: reliability, completeness, temporal correlation, geographic correlation, and technological correlation.
- Analysis included all operational material and energy flows. No universal cut-off thresholds were applied.

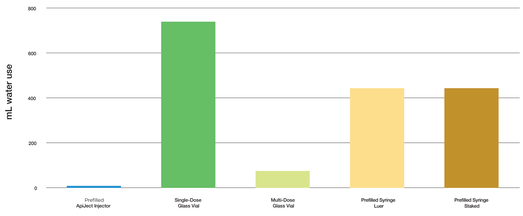
Life Cycle Impact Assessment Results

Carbon Footprint Results



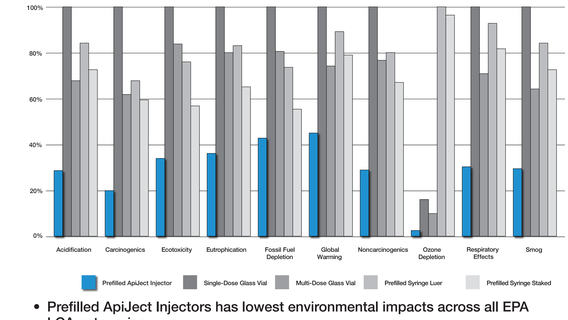
- Prefilled ApiJect Injector results of 38 g CO_2e/dose are lowest among options
- Biggest drivers are lightweighting and avoided sterilization

Direct Water Use Results



- Compared to Prefilled ApiJect Injector, other options use 12x-116x more water
- **Biggest drivers are avoided washing and sterilization**

Overall Environmental Impact Results



- Prefilled ApiJect Injectors has lowest environmental impacts across all EPA LCA categories

Conclusion

This peer-reviewed, independent study finds a substantial difference in the environmental impact comparing the Prefilled ApiJect Injector and other injection formats.

- Blow-Fill-Seal has lower environmental footprint than glass options in all stages of production.
- Compared to the Prefilled ApiJect Injector result of 38 g CO_2-eq per dose:
  - The estimated single-dose glass vial with plastic syringe impacts are ~125% higher per dose.
  - The glass prefilled syringe with needle assembly impacts are ~100% higher per dose.
  - The multi-dose glass vials with plastic syringe impacts are 65-75% higher per dose.
- Single dose glass vials use more than 100x the water than the Prefilled ApiJect Injector - 2 gallons versus 2 ounces per dose.
- The Prefilled ApiJect Injector uses less total plastic than the glass-based injection alternatives.
- The Prefilled ApiJect Injector is designed to improve product safety by preventing microbial contamination risks associated with multiple withdrawals from a vial.
- A typical single-dose glass vial requires 750 mL of direct water for cleaning and sterilization for a single 1 mL dose. In contrast, the Prefilled ApiJect Injector requires approximately 6.4 mL of water for the manufacturing process.
- The Prefilled ApiJect Injector has the lowest impact in all 10 Life-Cycle Assessment categories set by the EPA.

Acknowledgments

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*The Prefilled ApiJect Injector and its components are not cleared by the FDA or other regulatory bodies.