

THE EXPOSURE OF DRUGS TO EXCESSIVE TEMPERATURE DURING THE MAIL-ORDER PHARMACY PROCESS

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Popularity of Mail-Order Pharmacy demands the answer to one question; **Is it Safe?**

A PRELIMINARY STUDY

- The goal of this initial project is to assess viability of a large-scale study.
- This study will determine if drugs are subject to excessive heat and freezing temperatures during the mail-order pharmacy shipping process?
- We will not be performing laboratory studies to determine effects of extreme temperatures on drugs in this portion of the study.
- Do mail-order pharmacies need to adjust their current processes to ensure safety?

MAIL-ORDER PHARMACY

- Mail Order has increased in popularity as of recent due to convenience.
- The novel prescription service has now become required by many private insurance plans.
- Chronic prescriptions, Cold-chain drugs, and OTCS are all shipped via Mail-Order pharmacy services operated through health plans.

CURRENT FEDERAL MAIL-ORDER SHIPPING REGULATIONS

Non-Cold Chain Drugs

- 20-25°C or (68-77°F) during Storage
- 15-30°C or (59-86°F) during Shipping
- Brief Exposure up to 40°C or (104°F) provided the mean temperature does not exceed 25°C or (77°F).

CURRENT FEDERAL MAIL-ORDER SHIPPING REGULATIONS

Cold Chain Drugs

- 2-8°C or (36-46°F) during Storage
- 0-15°C or (32-59°F) during Shipping
- Transient spikes over (25°C or 77°F) for no more than 24 hours.

HOW DID WE COLLECT OUR DATA

- Simulated mail-order prescriptions will be shipped with temperature tracking devices.
- The temperature of simulated mail-order prescription packages will be logged every 5 minutes throughout the entire shipping process.

SIMULATED PACKAGES

- The simulated packages are packaged in two systems:
- **Bubble-lined manilla envelope** for non-cold chain drugs.
- **Styrofoam cooler with five frozen cold packs** to mimic cold chain drug packaging.
- (The supplies used for both systems are the same brands that mail-order pharmacies currently use to ship prescriptions.)

We reached out to every major mail-order pharmacy requesting exact packaging. We did not receive a response on all inquires.

SIMULATED SHIPPING

- Considering most mail-order pharmacies operate out of coastal regions in the U.S., the simulated packages were shipped to locations varying in distance from the hub.
- The range of shipping distances spanned from **100 to 952 miles**.
- The **United States Postal Service** was used as the shipping service. To ensure fast delivery, every package was sent using **“Priority Mail Express”** shipping.

TEMPERATURE TRACKING

- The temperature tracking would be enabled upon drop-off at the post office and disabled upon delivery to an expecting team-member. The temperature tracker used is a **“LogTag Temperature Analyzer”** by **MicroDAQ**.
- **-40°C to 85°C Temperature Measurement Range with $\pm 0.5^\circ\text{C}$ Accuracy**



[TRIX-8 LogTag Temperature Recorder and Data Logger \(microdaq.com\)](http://microdaq.com)

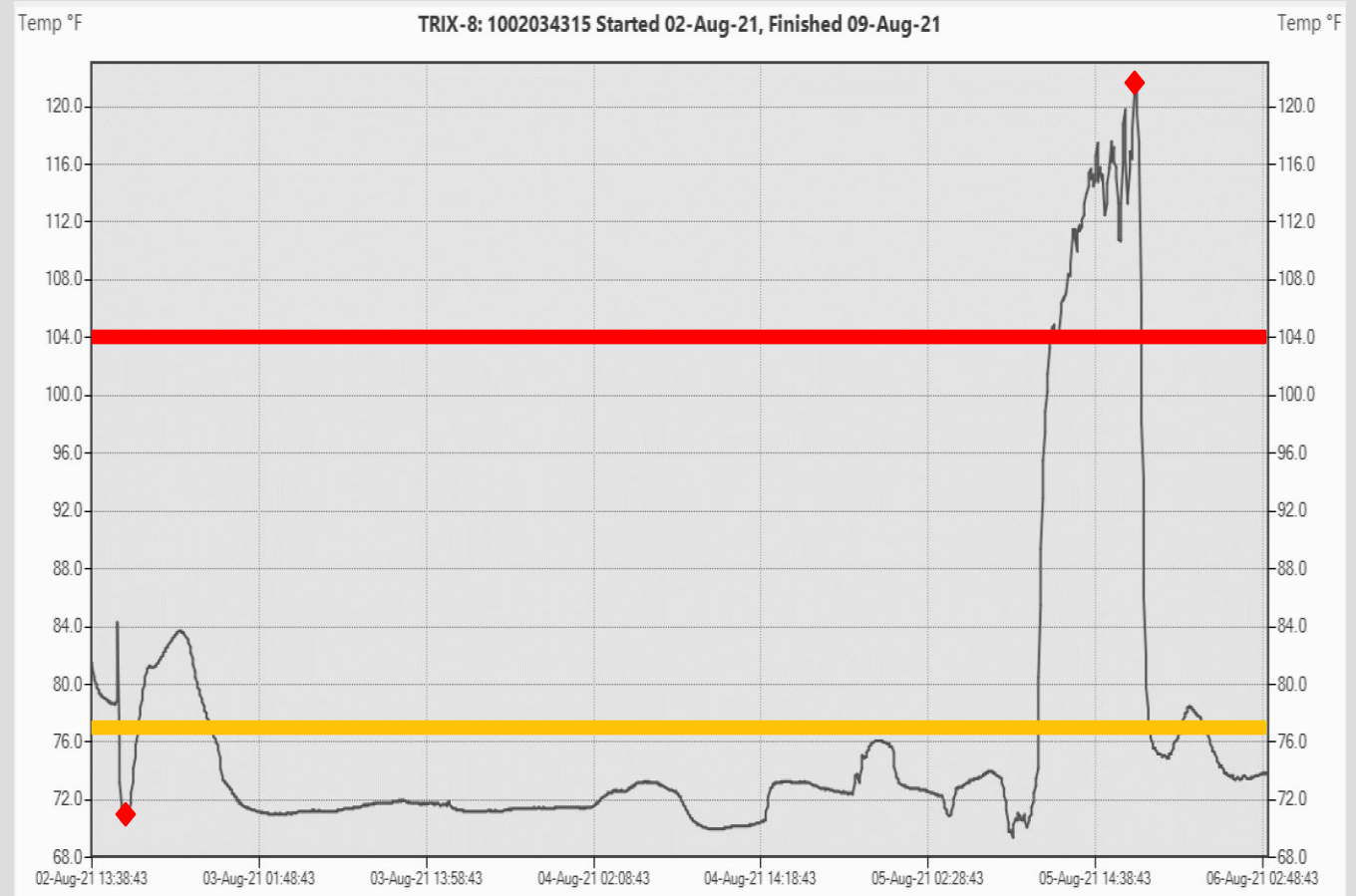
TEMPERATURE TRACKING

- A “**FAILED**” package would be noted if a non-cold chain simulated drug reached a temperature of 40°C or **104°F**.
- If the package simulated a cold chain system, a sustained temperature above 15°C or **59°F**, or a spike above 25°C or **77°F** would also deem a “**FAILED**” notation.

PRELIMINARY FINDINGS

NON-COLD CHAIN MEDICATION

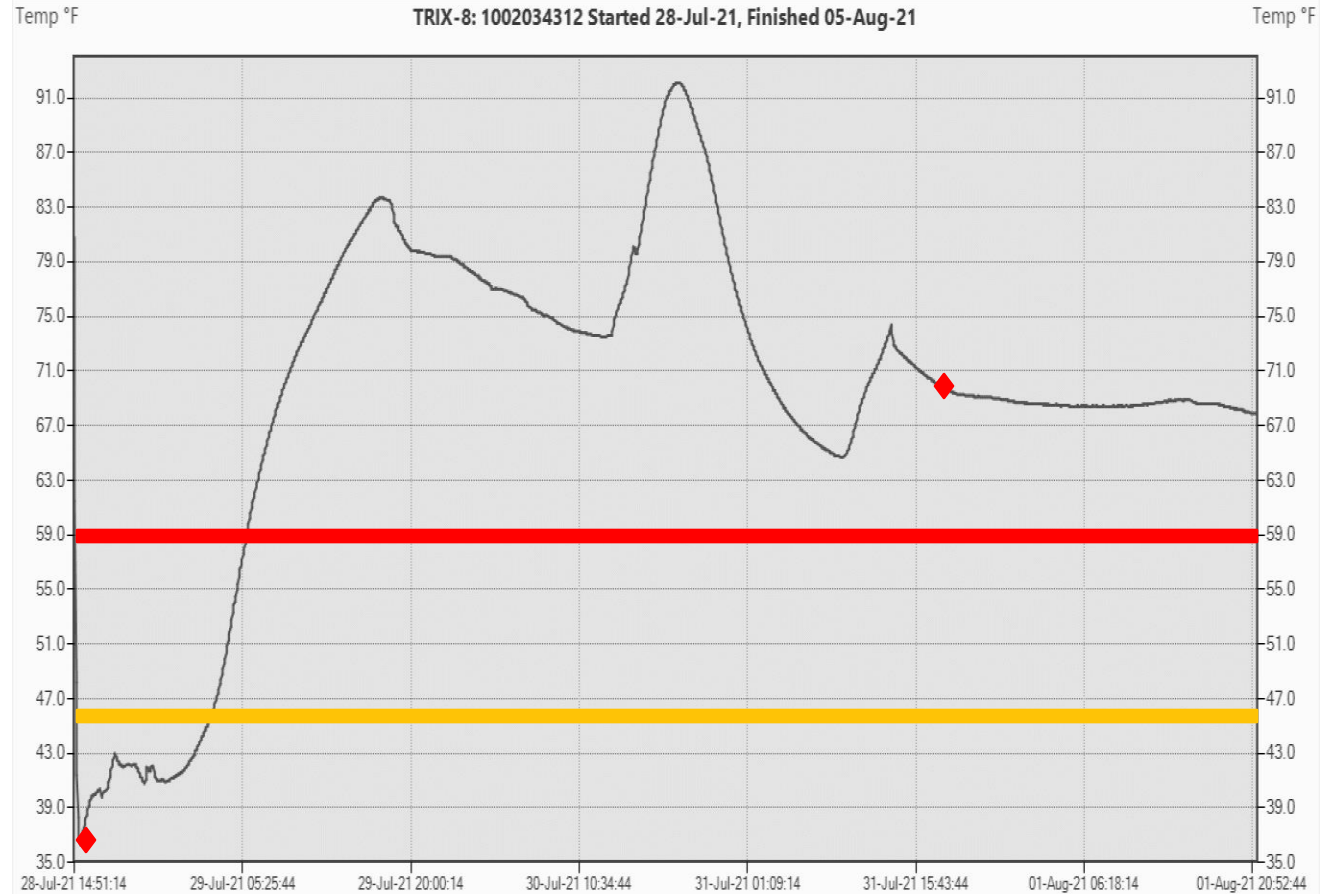
- Above Excessive Temperature for:
10 hours and 20 minutes
- Maximum Temperature Reached:
121.8°F
- 5 days 23 hours 42 minutes:
Transit Time



PRELIMINARY FINDINGS

COLD CHAIN MEDICATION

- Above Regulated Cold-Chain Temperature for:
43 hours and 55 minutes
- Maximum Temperature Reached:
92.1°F
- 3 days 2 hours 40 minutes:
Transit Time



DISCUSSION

- Consistent data would support a hypothesis that drugs are subject to excessive temperatures during the mail-order pharmacy shipping process.
- Temperatures gathered reveal simulated prescription packages are exposed to unsafe temperatures for extended periods of time while enroute.
- **80% of simulated packages reached temperatures deemed “Excessive” or “Unsafe” by the FDA (Food and Drug Administration) and the USP (United States Pharmacopeia).**

DISCUSSION

- Are mail-order pharmacy patients receiving drugs that are unsafe?
- Most cold chain medications denature and lose stability when placed in environments similar to those portrayed by the collected data.
- Why do most mail-order pharmacies not provide a **Temperature Alert Card** with all prescription packages to alert the patient if their prescription has reached excessive temperatures?

PHASE II

- We achieved our goal of determining the viability of a large-scale study.
- Phase 2 of this Research Project will begin in May 2022.

REFERENCES

- 1. 21 CFR 211.150 of the GMPs addressing distribution procedures; 21 CFR 211.150 of the GMPs addressing distribution procedures;
- 2. 21 CFR sections 203 and 205 on good practices for holding drugs; 21 CFR sections 203 and 205 on good practices for holding drugs;
- 3. NDA/ANDA labeling requirements; and application and GMP requirements regarding stability and expiration dates. NDA/ANDA labeling requirements; and application and GMP requirements regarding stability and expiration dates.
- 4. USP General Chapter <1079> Good Storage and Shipping Practices; USP General Chapter <1079> Good Storage and Shipping Practices
- 5. USP General Chapter <1118> Monitoring Devices -Time, Temperature and Humidity; USP General Chapter <1118> Monitoring Devices -Time, Temperature and Humidity
- 6. USP General Chapter <1150> Pharmaceutical Stability; USP General Chapter <1150> Pharmaceutical Stability

QUESTIONS

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