Drying of Opzelura® (Ruxolitinib) Cream 1.5%: Implications for Clinical and Real-World Use

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Haydar Abdalghafor, PhD, Janel Torsiello, PharmD, Daniel Sturm, PharmD, Adnan Nasir, MD, PhD, Russell Elliott, MA, DPhil, FRSC, Ahmad Naim, MD
Incyte Corporation, Wilmington, DE, USA

Objective

- Determine the drying time of ruxolitinib cream post-application to provide guidance for the use of topical cosmetic products relative to ruxolitinib cream application

Conclusions

- **Ruxolitinib cream dried rapidly under optimal conditions, reaching a stable film in approximately 10 minutes**
- **While additional studies are needed to confirm the extent and time of ruxolitinib cream absorption into human skin following topical delivery, preclinical minipig data[1] and phase 2 clinical itch relief findings[2] highlight the effective delivery of ruxolitinib to target tissues**
- **These findings indicate that ruxolitinib cream may provide drying times supporting its use as a convenient treatment for inflammatory skin conditions**

Introduction

- Rapid absorption, cutaneous localization at high concentrations, and short drying time are important clinical attributes of a topical therapy to ensure clinical efficacy and convenience for patients
- Opzelura® (ruxolitinib) cream 1.5%, a topical JAK1/JAK2 inhibitor, is FDA approved for the inflammatory skin conditions atopic dermatitis and vitiligo
- A published preclinical study comparing ruxolitinib concentrations following topical versus oral administration in minipigs showed substantially higher concentrations of ruxolitinib in dermal and epidermal tissues after wiping off ruxolitinib cream 10 minutes post-application compared with oral ruxolitinib, suggesting rapid absorption of ruxolitinib into the skin with topical administration[1]
- In addition, a phase 2 open-label clinical study showed initial itch reduction within 15 minutes after first application of ruxolitinib cream in patients with atopic dermatitis, suggesting rapid absorption of ruxolitinib into human skin[2]
- Understanding drying time is needed to help inform patients and caregivers how to use cosmetic products (eg, sunscreen, moisturizers, makeup) without compromising the effectiveness of a medical topical therapy

Methods

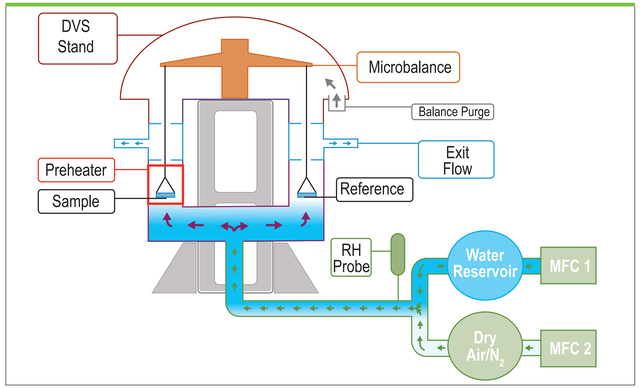
Study Design

- Controlled laboratory study using a DVS system to model the time needed for ruxolitinib cream to dry after applying a clinical dose of 1.5–2 mg/cm^2 to approximate real-world conditions (**Figure 1**)
- Multiple doses of ruxolitinib cream ranging from 5–20 mg/cm^2 were manually spread on the DVS quartz pan and tested at 32°C with 50% RH
  - The conditions selected represent the FDA-defined skin temperature and RH of a comfortable work environment

Analyses

- The data recorded from the DVS analysis represented the amount of water lost, expressed as the percentage of mass from the dose applied vs time
- These data were then used to calculate the speed of evaporation

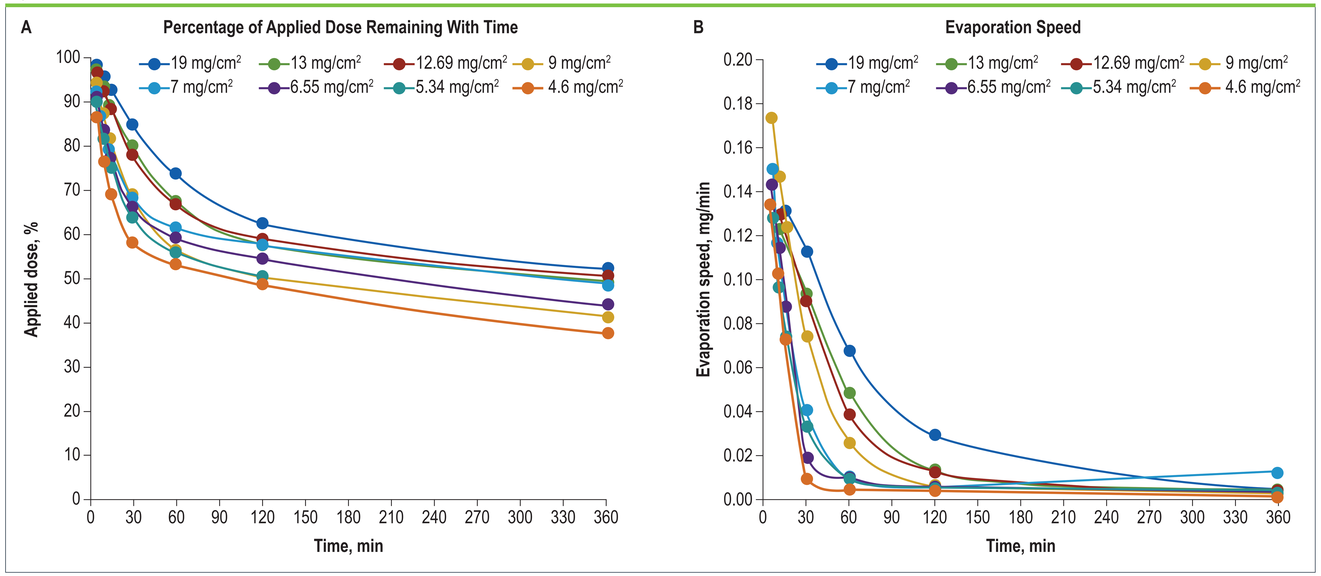
Figure 1. Schematic Presentation of DVS System



Results

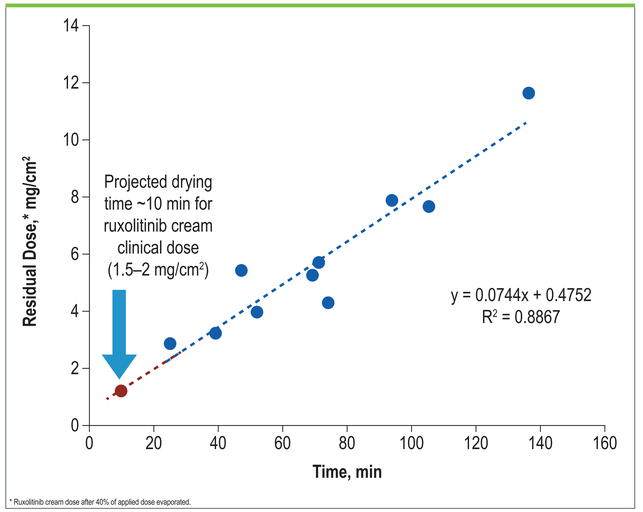
- Drying was rapid until approximately 40% of the mass of the applied product was lost, suggesting that loss of 40% of the sample mass (equivalent to 82% of the water added during manufacturing) results in a dry sample (**Figure 2**)

Figure 2. Ruxolitinib Cream Evaporation Trends Across Multiple Doses



- The time needed for the different doses to lose 40% of the applied dose was used to project the time needed for lower doses to dry to a stable film
- It was projected that ruxolitinib cream 1.5–2 mg/cm^2 (clinical dose) would require approximately 10 minutes to dry to a stable film (**Figure 3**)

Figure 3. Correlation Between Residual Dose and Time Needed to Lose 40% of Applied Dose Mass



Abbreviations

DVS, dynamic vapor sorption; FDA, US Food and Drug Administration; JAK, Janus kinase; MFC, mass flow control; RH, relative humidity.

Disclosures

All authors are employees and shareholders of Incyte Corporation.

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2. Bissonnette R, et al. Rapid, Substantial, and Sustained Reduction of Itch in Adults With Atopic Dermatitis Applying Ruxolitinib Cream: Clinical and Translational Results From the Open-Label Phase 2 SCRATCH-AD Study. Presented at: European Academy of Dermatology and Venereology Congress; October 11-14, 2023; Berlin, Germany.

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