Ruxolitinib Phosphate Cream – Compounding Worksheet (1.5% w/w Free-Base Equivalent)

Purpose: Provide ready-to-use batch calculations and mixing guidance for compounding ruxolitinib phosphate topical cream at 1.5% w/w (expressed as ruxolitinib free-base equivalent). Calculations account for phosphate salt mass (CAS 941678-49-5).

Key Facts (Quick Reference)

- **API:** Ruxolitinib phosphate (≈73% free-base content by mass).
- **Target label strength:** 1.5% w/w (expressed as ruxolitinib free base).
- **Salt correction:** Free-base fraction ≈ 0.73 → Required salt = desired free base ÷ 0.73.
- **Typical commercial reference:** 1.5% cream (free-base equivalent).
- **Solubility:** Phosphate salt is freely soluble in water; soluble in ethanol/methanol/DMSO; less soluble in non-polar solvents.

Recommended Bases (SpecializedRx)

1) VersaCream™ PRO (vanishing cream base): High-penetrating O/W cream with excellent API carrying capacity, including salt forms. Good first-line choice for ruxolitinib phosphate.
2) PentraCream™ Anhydrous (hybrid transdermal): High carrying capacity; elegant vanishing feel; useful where enhanced penetration is desired.
3) VersaPenn™ AL (anhydrous lipid cream/lotion): Phospholipid-rich; for lipophilic or complex dermal delivery.
4) HelixGel™ (anhydrous water-washable ointment): Occlusive but water-washable; consider if cream is not suitable.

Formulation Calculations (Corrected for Phosphate)

Formula: Salt needed (g) = Total batch (g) × 0.015 (free-base target) ÷ 0.73 (free-base fraction of salt).

Batch Example: 30 g Jar (1.5% w/w free-base equivalent)

Component	Quantity (g)	Notes
Ruxolitinib phosphate	0.616	≈73% free-base content; corrects to 1.5% label strength
Chosen cream base (e.g., VersaCream™ PRO)	29.384	q.s. to final weight
Optional co-solvent (minimal, if needed)	q.s. (see method)	Only if needed for uniformity; avoid excess water in anhydrous bases

Batch Example: 60 g Jar (1.5% w/w free-base equivalent)

Component	Quantity (g)	Notes

Ruxolitinib phosphate	1.233	≈73% free-base content; corrects to 1.5% label strength
Chosen cream base (e.g., VersaCream™ PRO)	58.767	q.s. to final weight
Optional co-solvent (minimal, if needed)	q.s. (see method)	Only if needed for uniformity; avoid excess water in anhydrous bases

Suggested Method (General)

1. Preparation. Verify prescription and calculations; assemble materials; weigh accurately.
2. Levigation / Pre-wetting. If using VersaCream™ PRO, levigate the API directly into a small portion of base. If using anhydrous bases and a small aqueous pre-solution is required, use minimal purified water or appropriate co-solvent; then geometrically incorporate into base.
3. Geometric incorporation. Add remaining base in portions until homogeneous. Scrape and fold to uniformity.
4. pH / appearance. Confirm uniform appearance; avoid visible grittiness. Adjust process (not formula) if needed.
5. Packaging & Labelling. Dispense to suitable jar/s; label with strength as ruxolitinib free-base equivalent (1.5% w/w). Include beyond-use date per USP <795> and storage instructions.

Quality & Documentation

• Record lot numbers, weights, and calculations.
• Aim for potency range 90–110% of target.
• Consider content uniformity checks on initial lots.
• Follow USP <795> BUD guidance for non-aqueous creams unless base manufacturer provides validated stability data.

Safety & Regulatory Notes

• Prescription-only medicine; compound only against a valid prescription.
• Use appropriate PPE and controls during weighing and mixing.
• Express strength as ruxolitinib (free-base equivalent) and document salt correction on the worksheet.