2% Minoxidil Topical Solution for Hair Loss Treatment

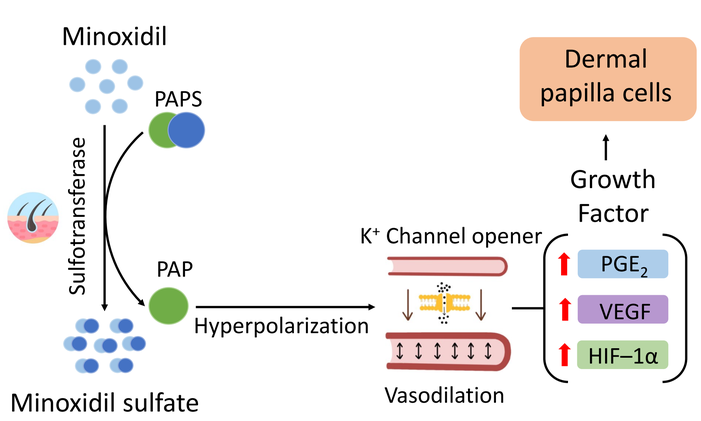
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1 ABSTRACT

The aims were to select optimal components for the formulation and to develop 2% Minoxidil topical solution by using the physical and chemical properties which match with the standard requirements, about the stability throughout its shelf life and identify the most suitable formulation for industrial-scale development in further.

2 INTRODUCTION



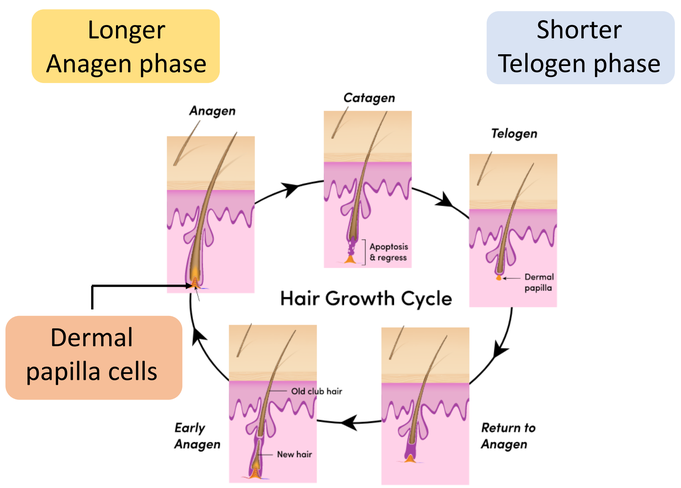
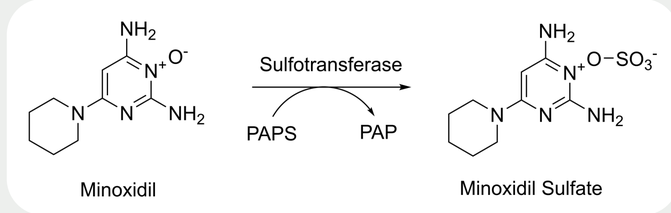


Figure 1 Minoxidil promotes proliferation of Dermal papilla cells

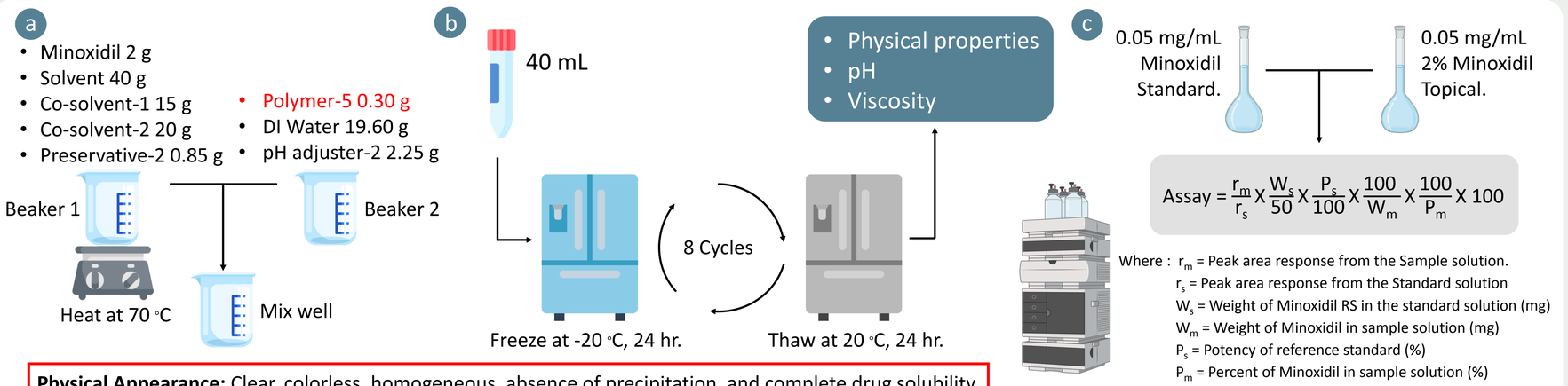


Chemotherapy-induced alopecia severely impacts the psychological well-being and self-image of cancer patients, causing up to 8% of patients to refuse chemotherapy treatment. Although Minoxidil is widely accepted for treating hair loss , most commercial products contain propylene glycol, which can cause allergic contact dermatitis and irritation on the sensitive scalps of patients. Therefore, this project aims to develop a propylene glycol-free 2% minoxidil topical solution to reduce irritation- related side effects, increase access to high-quality medication and improve the overall quality of life for cancer patients.

Regarding its mechanism of action, minoxidil acts as a prodrug that requires the sulfotransferase enzyme in the hair follicles to convert it into its active form, minoxidil sulfate. The drug then functions as a potassium channel opener, causing cellular hyperpolarization, which leads to vasodilation. This vasodilation stimulates the production of essential growth factors, including PGE_2, VEGF, and HIF-1α, which promote the proliferation of dermal papilla cells. These changes help prolong the hair growth period (anagen phase) and shorten the resting period (telogen phase), ultimately leading to new hair growth.

3 METHODOLOGY

Preliminary Formulation & Evaluation → **Formulation & Evaluation** → **Assay of Active Pharmaceutical Ingredient**



Physical Appearance: Clear, colorless, homogeneous, absence of precipitation, and complete drug solubility.
pH: 4.5 – 6 and **Viscosity:** 100 cP (55 rpm, Spindle No.1)

Figure 2 Methodology. (a) Preparation process of the optimized 2% minoxidil formulation (F5D). **(b)** Physical stability testing via freeze-thaw cycles. **(c)** Active pharmaceutical ingredient (API) assay using High-Performance Liquid Chromatography (HPLC).

4 RESULTS

Table 1 Physicochemical properties of the optimized 2% minoxidil formulation (F5D)

Formulation	F5D
Physical Appearance	Clear, colorless, homogeneous, absence of precipitation
pH	4.84 ± 0.01
Viscosity (cP) (55 rpm, Spindle No.1)	102.17 ± 1.95

Figure 3 Physical Appearance of the optimized 2% minoxidil formulation (F5D)



- **Formulation F5D** appeared clear, colorless and without precipitation. It exhibited a stable pH of 4.84 ± 0.01 and an optimal viscosity of approximately 102 cP. Furthermore, it remained highly stable after the freeze-thaw stability testing, showing no changes in its physical characteristics, pH value, or viscosity.

Assay of Active Pharmaceutical Ingredient

$$\text{Assay} = \frac{r_m}{r_s} X \frac{W_s}{50} X \frac{P_s}{100} X \frac{100}{W_m} X \frac{100}{P_m} X 100$$

Minoxidil Standard Solution.

Figure 4 Chromatogram of Minoxidil Standard Solution.

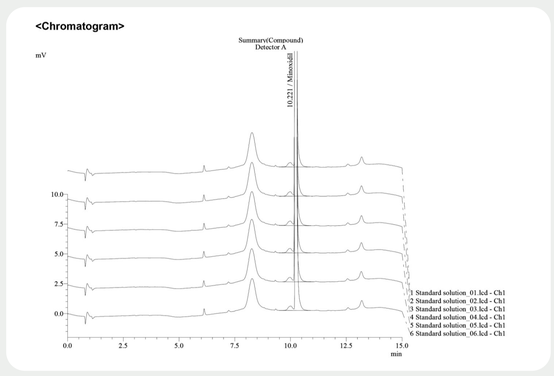


Table 2 Results Interpretation

No. injections of Standard	Retention time	Area
Standard solution_01	10.2	742116
Standard solution_02	10.2	747521
Standard solution_03	10.2	745873
Standard solution_04	10.2	748202
Standard solution_05	10.2	744846
Standard solution_06	10.2	757123
Average	10.2	747614
%RSD		0.686

2% Minoxidil Topical Solution.

Figure 5 Chromatogram of 2% Minoxidil Topical Solution before stability testing

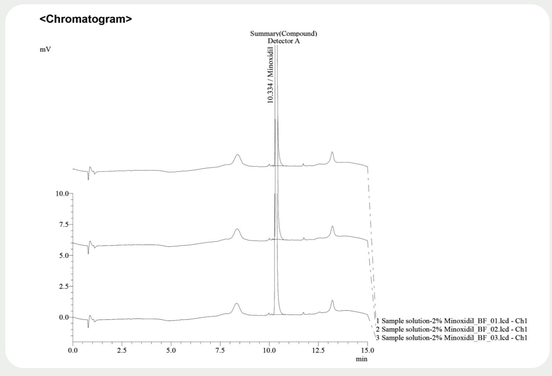


Table 3 Results Interpretation and assay of 2% Minoxidil Topical Solution before stability testing

No. injections of 2% Minoxidil BF	Retention time	Area	Assay (w/w%)
Sample solution-2% Minoxidil_BF_01	10.3	824970	109.8564
Sample solution-2% Minoxidil_BF_02	10.3	823108	109.6084
Sample solution-2% Minoxidil_BF_03	10.3	824300	109.7672
Average	10.3	824126	109.74
%RSD		0.114	

Figure 6 Chromatogram of 2% Minoxidil Topical Solution after stability testing

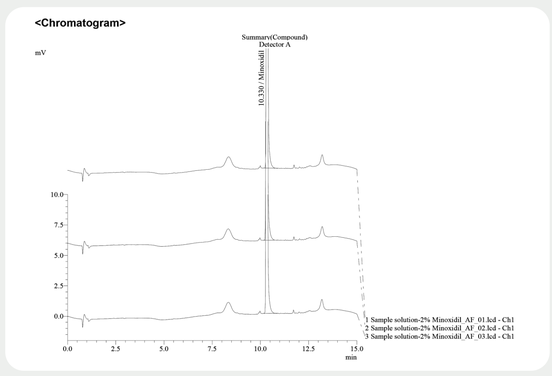


Table 4 Results Interpretation and assay of 2% Minoxidil Topical Solution after stability testing

No. injections of 2% Minoxidil AF	Retention time	Area	Assay (w/w%)
Sample solution-2% Minoxidil_AF_01	10.3	829928	108.5301
Sample solution-2% Minoxidil_AF_02	10.3	826375	108.0654
Sample solution-2% Minoxidil_AF_03	10.3	824948	108.8788
Average	10.3	827084	108.16
%RSD		0.531	

5 CONCLUSION

The study concluded that formulation F5D was the optimal formulation. It consists of minoxidil 2 g, solvent 40 g, co-solvent-1 15 g, co-solvent-2 20 g, polymer-5 0.30 g, pH adjuster-2 2.25 g, preservative-2 0.85 g, and deionized water 19.60 g. High-Performance Liquid Chromatography (HPLC) analysis confirmed excellent chemical stability, with the active pharmaceutical ingredient (API) content measuring 109.74% w/w before and 108.16% w/w after the freeze-thaw stability testing. These results indicate that the API levels remained within the standard acceptance criteria of 90.0% to 110.0%, indicating that the developed formulation is highly stable and viable for future industrial-scale production.

6 ACKNOWLEDGEMENTS

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