

Agomelatine Transdermal System Product Cycle: Development, Material/Process Screening, Optimization, Characterization, Delivery Mechanics and Irritation study ...

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Introduction

Agomelatine (AGT) is used for the treatment of major depressive disorder in adults. Agomelatine is highly susceptible to first-pass metabolism, and it has less than 5% oral bioavailability. Therapy for major depressive disorder extends for a long period and every time, additional caregivers are required to remind and manage the timely dosing of oral medicine to patients. In such cases, once a week, administration of agomelatine *via* transdermal patch dosage form provides major patient benefits and lowers overall therapy costs.

Methods

An agomelatine transdermal patch was prepared using the solvent evaporation method using the LTE-S Werner Mathis AG coater and dryer. A patch was prepared using silicon adhesive after screening different pressure-sensitive adhesives like acrylate, polyisobutylene, and silicon. To make a crystal-free patch, the concentration of povidone k-29/32 was optimized in preliminary trials. To deliver the drug over a 7-day period, propylene glycol monolaurate (PGML) was identified from different penetration enhancers. Three factors optimization was carried out, like the concentration of povidone k-29/32, the concentration of PGML, and the mixing time of the blend using the Box Behnken design. 3D surface response curves and contour plots were derived using Design Expert and Minitab software. From overlay plots, design spaces were identified.

Results

The optimized AGT patch has good adhesion properties along with a desirable flux of $4.63 \mu\text{g}/\text{cm}^2/\text{h}$ on human cadaver skin along with a lower residual drug. There was no impact of heat flux studies on normal conditions, hence justifying the in-use condition of the patient population during hot showers, baths, and saunas. AGT Patch was also non-irritating in skin irritation studies performed on Wistar albino rats.

Conclusion

It was concluded that agomelatine transdermal patches can be manufactured using silicon adhesive, povidone k-29/32, and propylene glycol monolaurate for the treatment of major depressive disorder and will be the most convenient and cost-effective therapy for the patient.