

# A Case Study of a Novel Nutraceutical with a Proprietary Delivery System

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## Abstract

This case study examines the efficacy of a proprietary Directline™ delivery method via a lozenge compared to a gummy supplement. The Directline™ delivery enabled three times more ingredients to be delivered and extended the benefits in the body by 33% compared to the gummy, resulting in higher bioavailability through the lozenge.

## Introduction

Many supplements and therapies utilize numerous delivery systems, such as injections, creams, pills and capsules [1]. The most common alternative is a pill or capsule supplementation. Common practice does not mean best practice; especially as superior delivery methods are developed [2]. The nature of the digestive system is not compatible with a pill or capsule supplementation unless the doses are extraordinarily high and the delivery mechanism has numerous protective additives to help the ingredients attempt survival in the gut [3,4]. A more substantial and viable alternative is to deliver the necessary ingredients in a medium that allows for maximum absorption while not being destroyed in the gut [5]. The proprietary Directline™ delivery method utilized in the Rebalance Health formulations produces a significantly higher bioavailable outcome via lozenge. The delivery method plays an integral part in regulating constant fluctuations of serum cortisol levels and realigning beneficial ratios to reset the balance [6]. An area where significant data shows the effects of elevated cortisol is sleep [7,8]. Sleep disruption may lead to hormonal imbalance and if you can affect sleep quality and support hormonal repair with natural ingredients working with the body's internal rhythm, sleep becomes restorative at a cellular and hormonal level [9].

## Materials and Methods

In a controlled case study, a female participant, age 55, was administered a Rebalance Health product (RHP) containing 5mg of melatonin combined with Astragin®, Ashwagandha and EDTA through the Directline™ delivery method in a lozenge form. The participant discontinued the use of all supplements and nutraceuticals two weeks prior to the administration of RHP. Fifteen separate blood draws were taken at specified intervals before and after the dose at 10, 20, 30, 40, 50, 60, 75, 90, 105, 120, 150, 180, 210 and 240 minutes. The same female participant discontinued the use of RHP for one week and was

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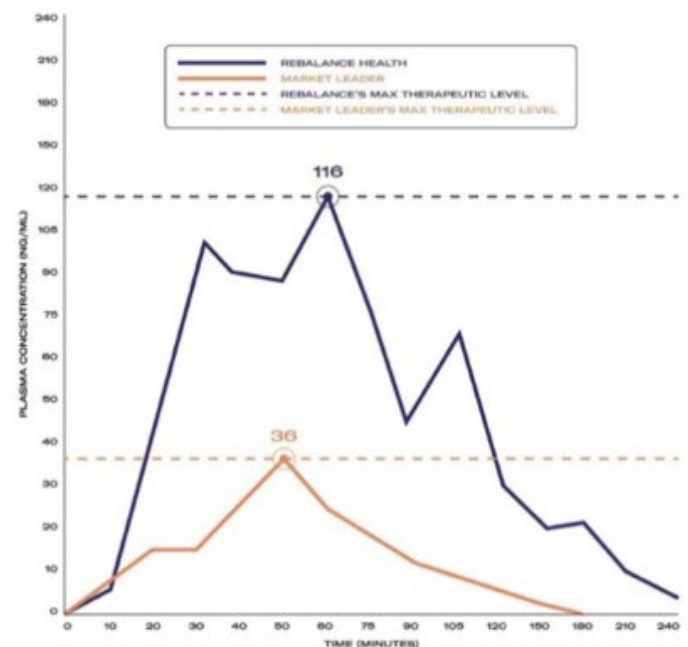


Figure 1. The blood results of Directline™ delivery method.

administered a leading melatonin gummy product at a comparable dosage with blood draws at the same time points.

## Results

The lozenge led to a higher peak and longer-lasting serum melatonin levels compared to the melatonin gummy product. The blood results showed that the Directline™ delivery method resulted in serum melatonin levels 3-5X higher than the melatonin gummy. Additionally, RHP showed significant levels for greater than 100 minutes, exceeding the comparator's maximum and total serum concentrations (Figure 1).

## Conclusion

This data suggests the delivery method is significantly more efficient and effective in delivering and maintaining serum concentrations of ingredients in the bloodstream. The Directline™ technology may provide better absorption and naturally assist hormone balance for longer, resulting in clinical benefits.

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