Assessment of Penetration of a Topical Glucosamine Formulation through Skin of Healthy Volunteers using a Tape Stripping Method

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Purpose

Tape stripping of human stratum corneum is widely used as a method to assess the kinetics and penetration depth of drugs. In this study, seven topical glucosamine formulations were developed. The aims of this study are: 1. to develop an effective extraction method of glucosamine on tape or in the formulation; and 2. to evaluate the penetration of topical glucosamine formulation through human skin using a tape stripping method.

Methods

A HPLC method for the glucosamine has been developed for the assay of glucosamine extracted from the tape and the formulation. Various extraction media (100% methanol, 100% water, 50:50 Methanol:Water, and 50:50 Acetonitrol:Water) were evaluated for extraction efficiency. Seven glucosamine HCl topical formulations were developed (3 creams, 2 lotion, and 2 gel). Six healthy subjects were recruited and applied 250 mg of the glucosamine formulations on their lower arm at the area of 3x3 cm2. A dressing was then applied to the same area. The dressing was removed at pre-determined time points (4, 8, 24, and 30 hours in order to determine the amount of glucosamine penetrated into the skin. Glucosamine was extracted from the dressing using 10 mL of extraction media. A tape in a size of 3 cm x 5 cm was then applied on the same skin area and a weight of 300 g was applied on the tape. The tape was removed and extracted. This action was repeated 4 times by 4 different tapes to ensure all the surface glucosamine has been removed. Penetration rate of each formulation was estimated and compared.

Results

50:50 Methanol:Water was selected as the extraction medium which provided the highest extraction efficiency of 98.6%. Of the seven formulations evaluated, the Formulation G, one of the cream formulations, provided highest penetration with the penetration rate of 66 mcg/sq. cm/hr (~13% penetrated into the skin).

Conclusion

The topical glucosamine formulations were observed to demonstrate zero-order release profiles through human skin. The highest penetration rate was achieved for the Cream Formulation G and the Formulation G Cream will be further optimized.