

Propylene Glycol FREE Minoxidil Formulation

Towards the revolution in pharmaceutical
development in topical drug delivery

Background

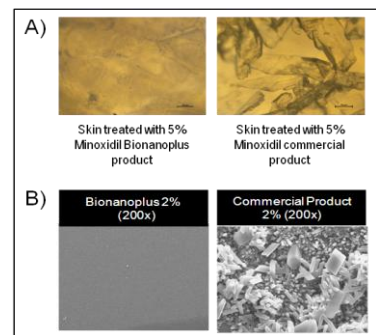
Minoxidil is the only topical medication approved by regulatory agencies for the treatment of hair loss since the early 1990's. The most common side effect of minoxidil hair loss treatment is scalp irritation and redness. All current minoxidil commercial formulations are made with alcohol-based agents as a media to maintain a stable composition, being propylene glycol the basic ingredient of these formulations. However, **propylene glycol is the main cause for scalp irritation and redness**. In addition, other drawbacks also include non acceptable cosmetic properties since propylene glycol makes hair oily/greasy after ethanol evaporation.

Minoxidil needs to be applied twice a day and must be used indefinitely. Thus, for successful long-term use it is important to avoid undesirable side effects and achieve a pleasant use on the cosmetic level. Therefore, propylene glycol elimination is a big challenge.

This product has been licensed for Spain, Italy and Portugal.

Innovation

Thanks to its proprietary technology, Bionanoplus has achieved a stable topical minoxidil formulation free from propylene glycol with more elegant cosmetic properties. This new formulation contains minoxidil, ethanol, water, a non volatile water miscible organic solvent and a butyl ester of PVM/MA copolymer (commercially known as Gantrez® ES-425). The final product is a transparent hydro alcoholic solution able to form nanoparticles once the product is applied onto the scalp and after the evaporation of a small portion of ethanol.



A) Observation of minoxidil 5% formulations by optical microscopy. B) Observation of minoxidil 2% formulations by scanning electron microscopy.

Pharmaceutical development

Bionanoplus' minoxidil formulation is a hydroalcoholic solution for topical application.

According to the different regulatory agencies criteria, there are two possible ways in order to obtain the marketing authorization for this product:

- An human bioequivalence study.
- An *in vitro* bioequivalence permeation test study with human skin supported with expert justification.

Partnership Conditions

Bionanoplus is open to different forms of partnering including:

- ✓ Worldwide exclusive licensing (except Spain, Italy and Portugal).
- ✓ Country based exclusive licensing.
- ✓ Opt-in rights + research fee.

IP: Intellectual property rights until 2032. PCT/EP2012/056900. Nanoparticles comprising esters of poly (methyl vinyl ether-co-maleic anhydride) and uses thereof.

BIONANOPLUS

provides solutions based on different polymeric systems that allow tackling delivery, processing, and efficacy issues of molecules with cheap and easy to scale-up technologies that fit market needs and regulatory requirements.

Bionanoplus is seeking for partner for out-licensing and/or product co-development