MSN SCIENTIFIC SPARKLES

MSN
Research for Better Medicines

MSN TAPINAROF

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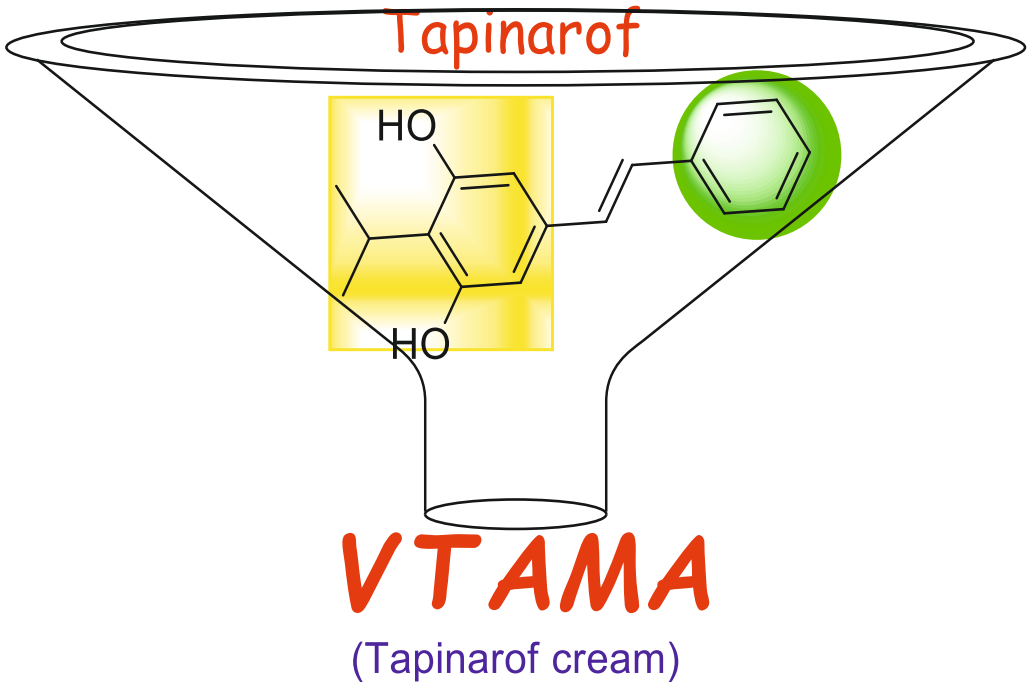
HIGHLY PURE AND STABLE CRYSTALLINE TAPINAROF WITH UNIQUE PHYSICAL PROPERTIES



Psoriasis is a chronic, immune-mediated skin disease that affects nearly 2% of humans in globe. Tapinarof is a nonsteroidal, first-in-class small molecule, topical aryl hydrocarbon receptor agonist for the treatment of psoriasis and atopic dermatitis. Tapinarof reduces skin inflammation, normalizes the skin barrier, reduces oxidative stress, and regulates immune cell gene expression. It was approved by USFDA on 23 May 2022 and marketed under the brand name VTAMA. MSN scientific team developed atom economic and eco-friendly manufacturing process for Tapinarof and can cater Tapinarof with broad spectrum of PSD.

MANUFACTURING TECHNOLOGY OF HIGHLY PURE AND STABLE TAPINAROF WITH UNIQUE PHYSICAL PROPERTIES

Tapinarof is manufactured in a USFDA approved facility of MSN. The complexity of Tapinarof lies in achieving pharmaceutically acceptable quality and stability. The manufacturing protocol of Tapinarof was designed and developed with advanced statistical tools. Process optimization was carried out with critical quality attributes, which lead to supreme quality of Tapinarof. A highly precise analytical method was developed and validated, which could identify all possible degradation impurities of Tapinarof.

MSN Tapinarof meets the pharmaceutically acceptable limits of nitrosamine and GTI impurities. The route of synthesis of Tapinarof was designed with insightful research and scrutinization to avoid the formation of nitrosamine and mutagenic impurities. All the process related/degradation and elemental impurities are well controlled.

MSN developed a technology that can provide broad spectrum of particle size distribution of Tapinarof API to meet requirements of different customers. MSN is offering a crystalline polymorph of Tapinarof that is stable at ambient conditions with unique morphological properties. The polymorph is stable under different stress conditions and also during stability study. Importantly, polymorph is not disturbed during micronization as well.

Tapinarof is duly characterized using orthogonal analytical techniques such as 1D/2D NMR, IR, UV, PXRD, DSC, TGA, Solubility, pH, Residual solvents by GC, DVS etc.

HIGHLIGHTS OF THE PROJECT

- Stable polymorph with unique morphological properties.
- MSN is capable to provide broad spectrum of PSD as per customer requirements.
- The degradation impurities are identified, synthesized and well controlled in the API to accomplish highly pure Tapinarof.
- Very precise validated methods to evaluate the quality of the drug substance.
- Suitable manufacturing process to produce multi kilos of Tapinarof.
- Controlled all possible mutagenic impurities well within the limits.
- Controlled all possible nitrosamine impurities well within the limits.
- Eco-friendly manufacturing process with high atom economy.
- Our manufacturing process is completely backward integrated to the basic starting materials.