



Nalbuphine-Containing Dry Powder Formulation and Uses Thereof

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Experience:

<https://rx.mc.ntu.edu.tw/myDOP/SCENE/FACULTY/facultyview.php?malangue=&rub=faculty//1//c4ca4238a0b923820dcc509a6f75849b21427208faYplvUNw6hbY>

Market Needs:

The existing nalbuphine market has demonstrated substantial clinical demand, particularly in China, where the injectable formulation market exceeds RMB 1 billion. Publicly available estimates place the global market value at approximately USD 150 million to USD 1 billion. Due to the high degree of oral metabolism, existing products remain primarily in injectable dosage forms. As a result, such products are associated with issues including invasive administration, limitations to in-hospital use, insufficient convenience of administration, and the potential need for repeated dosing. Accordingly, a novel aerosol/inhalation dosage form having high bioavailability, dose uniformity, reduced side effects, and long-acting activity may create a new market for non-invasive treatment of acute pain and other indications.

Our Technology:

Utilizing a specialized micronization process to prepare a mixture of nalbuphine free base and nalbuphine salt at a predetermined ratio, and employs excipients commonly used in spray dosage forms, thereby developing a nalbuphine aerosol spray formulation having high bioavailability, long-acting efficacy, reduced side effects, and consistent delivered dosage.

Strength:

Nalbuphine is a typical drug having a high extraction ratio and low oral bioavailability. Therefore, hepatic first-pass metabolism is the major cause of its low oral absorption. In contrast to oral administration, the examples disclosed herein demonstrate that the finished product designed according to the present application can significantly increase the bioavailability of nalbuphine in animals.

Competing Products:

A61K 31/485(2006.01); A61P 11/14(2006.01); A61P 17/04(2006.01)
A61K 31/485(2006.01); A61K 9/20(2006.01); A61P 25/36(2006.01); C07D 489/08(2006.01)
A61K 31/485(2006.01); A61K 9/20(2006.01); A61K 45/06(2006.01); A61P 11/14(2006.01)

Intellectual Properties:

Prior art and literature searched:

1. Paper: Waiting Tai, HJ Wang, Pancy TH Kwong, Patricia Tang, CC Shih, HK Chan. Development of inhalable spray dried nalbuphine hydrochloride powders. Int J Pharm. 2025. 682:125952.
2. Patent: WO2022038403A1/US20230372327 Pharmaceutical composition based on nalbuphine and/or its salts for nasal administration.

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