

Title (en)

THIN FILM FORMULATIONS OF 4-DIPHENYLMETHYL-1-PIPERAZINE DERIVATIVES AND THEIR SALTS

Title (de)

DÜNNSCHICHTFORMULIERUNGEN VON 4-DIPHENYLMETHYL-1-PIPERAZINDERIVATEN UND DEREN SALZEN

Title (fr)

FORMULATIONS DE FILM MINCE DE DÉRIVÉS DE 4-DIPHÉNYLMÉTHYL-1-PIPÉRAZINE ET DE LEURS SELS

Publication

**EP 3562475 A4 20200701 (EN)**

Application

**EP 17889328 A 20171222**

Priority

- IN 201621044488 A 20161227
- IN 2017050613 W 20171222

Abstract (en)

[origin: WO2018122867A1] This invention comprises a stable oral dispersible thin film and a process of making the same, the film comprising a 4-Diphenylmethyl-1-piperazinyl derivative or its pharmaceutically acceptable salts; characterized by, during storage of the film, level of the individual impurities arising out of degradation of the 4-Diphenylmethyl-1-piperazinyl derivative or its pharmaceutically acceptable salts not exceeding 1% of the added drug, and total impurities not exceeding 2% and the taste is not less than "acceptable" when scored by a taste panel on a scale of Excellent (5), Pleasant (4), Acceptable (3), Bitter (2) and Extremely bitter (1). The film is also thin, translucent, non-curving, non-tacky and flexible with folding endurance of 25 or more, dissolution not less than 75% in 45 minute. The process comprises a step of adding sodium hydroxide before the film casting is done, selecting temperature range for drying step of the film appropriate for getting a stable film, and adding plasticizer/s.

IPC 8 full level

**A61K 9/70** (2006.01); **A61K 31/495** (2006.01); **A61K 47/22** (2006.01); **A61K 47/32** (2006.01); **A61K 47/38** (2006.01); **A61P 37/08** (2006.01); **C07D 295/03** (2006.01)

CPC (source: EP)

**A61K 9/0056** (2013.01); **A61K 9/7007** (2013.01); **A61K 31/495** (2013.01); **A61K 47/22** (2013.01); **A61K 47/32** (2013.01); **A61K 47/38** (2013.01); **A61P 37/08** (2017.12)

Citation (search report)

- [XY] US 2010112050 A1 20100506 - RYOO JE PHIL [US], et al
- [XY] DE 102010049708 A1 20120503 - HEXAL AG [DE]
- [YA] WO 2006061700 A2 20060615 - THEMIS LAB PRIVATE LTD [IN], et al
- See references of WO 2018122867A1

Designated contracting state (EPC)

AL AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HR HU IE IS IT LI LT LU LV MC MK MT NL NO PL PT RO RS SE SI SK SM TR

DOCDB simple family (publication)

**WO 2018122867 A1 20180705**; EP 3562475 A1 20191106; EP 3562475 A4 20200701

DOCDB simple family (application)

**IN 2017050613 W 20171222**; EP 17889328 A 20171222