

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

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Application

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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-piperazinyll 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-piperazinyll 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

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