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(54) Title: TADALAFIL ORAL SUSPENSION

(57) Abstract: The present invention relates to a tadalafil oral suspension comprising 0.01-5 % w/v of tadalafil, a cyclodextrin, co-processed microcrystalline cellulose and sodium carboxymethyl cellulose, xanthan gum and water as vehicle. The suspensions are chemically and physically stable and show a dissolution profile equivalent to that of commercial tadalafil film-coated tablets. The tadalafil suspensions are suitable for treating male erectile dysfunction and benign prostatic hyperplasia. The invention also relates to a fixed-dose combination dosage forms comprising said tadalafil suspension and either tamsulosin, in particular, in the form of modified-release pellets, or dutasteride. Said combined forms are useful for treating lower urinary tract symptoms associated with benign prostatic hyperplasia. The invention also relates to a process for the preparation of said tadalafil composition.



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