CLAIMS

1.- Pharmaceutical composition for oral administration in the form of aqueous suspension which comprises:

a) tadalafil in an amount comprised between 0.01 % w/v and 5 % w/v;
b) cyclodextrin;
c) coprocessed microcrystalline cellulose and sodium carboxymethyl cellulose (MCC-NaCMC);
d) xanthan gum; and
e) water.

2.- Composition according to claim 1, characterized in that the amount of tadalafil is comprised 0.02% w/v and 2.0% w/v, preferably comprised between 0.05% w/v and 1.5% w/v, more preferably comprised between 0.08% w/v and 1.2% w/v, still more preferably comprised between 0.09% w/v and 1.1% w/v and still more preferably comprised between 0.1% w/v and 1.0% w/v.

3.- Composition according to claims 1 to 2, characterized in that the amount of cyclodextrin is comprised between 0.01% w/v and 0.25% w/v, preferably comprised between 0.02% w/v and 0.20% w/v, and more preferably comprised between 0.03% w/v and 0.10% w/v.

4.- Composition according to claim 3, characterized in that the cyclodextrin is selected from a α-cyclodextrin, β-cyclodextrin, γ-cyclodextrin, highly-branched cyclodextrin (HBCD), and mixtures thereof, preferably is selected from a α-cyclodextrin and a β-cyclodextrin.

5.- Composition according to any one of claims 1 to 4, characterized in that the amount of coprocessed CMC-NaCMC is comprised between 0.5% w/v and 2.0% w/v, preferably comprised between 0.6% w/v and 1.4% w/v, more preferably comprised between 0.7% w/v and 1.3% w/v, still more preferably comprised between 0.8% w/v and 1.2% w/v, still more preferably comprised between 0.9% w/v and 1.1% w/v, and still more preferably is about 1.0% w/v.

6.- Composition according to any one of claims 1 to 5, characterized in that the amount of xanthan gum is comprised between 0.10% w/v and 1.50% w/v, preferably comprised between 0.20% w/v and 1.00% w/v, more preferably comprised between 0.25% w/v and 0.90% w/v, still more preferably comprised between 0.30% w/v and 0.85% w/v, still more preferably comprised between 0.35% w/v and 0.75% w/v, still more preferably comprised between 0.40% w/v and 0.65% w/v, and still more preferably comprised between 0.45% w/v and 0.60% w/v.

7.- Composition according to any one of claims 1 to 6, characterized in that it comprises a surfactant, preferably sodium lauryl sulfate in an amount comprised between 0.010% w/v and 0.100% w/v, more preferably comprised between 0.020% w/v and 0.085% w/v, and still more preferably comprised between 0.030% w/v and 0.090% w/v.

8.- Composition according to any one of claims 1 to 7, characterized in that the composition comprises a preservative, preferably in a concentration comprised between 0.001% w/v and 5% w/v.

9.- Composition according to any one of claims 1 to 8, characterized in that it comprises a pH adjusting agent to adjust the pH of the composition to a value comprised between 2.5 and 7, preferably comprised between 4.0 and 6.5, more preferably comprised between 5.5 and 6.

10.- Composition according to claim 9, characterized in that the pH adjusting agent is a buffering agent, which is citrate buffer, acetate buffer, citrate-phosphate buffer, Tris buffer, and phosphate buffer.

11.- Fixed-dose combination dosage form comprising tadalafil aqueous suspension according to any one of claims 1 to 10 and a second drug selected from tamsulosin, or a pharmaceutically acceptable salt thereof, and dutasteride, or a pharmaceutically acceptable salt thereof.

12.- Fixed-dose combination dosage form according to claim 11, characterized in that it comprises tamsulosin, preferably as tamsulosin hydrochloride, which is preferably in the form of modified-release pellets.

13.- Process for preparing the composition according to any one of claims 1 to 10, characterized in that it comprises the following steps:

(i) mixing cyclodextrin, coprocessed MCC-NaCMC, and xanthan gum with one part of total water to obtain a homogeneous mixture;

(ii) separately mixing tadalafil with another part of total water, to obtain a homogeneous mixture;

(iii) adding the mixture of step (ii) to the mixture of step (i);

(iv) adding the rest of water.

14.- Composition according to any one of claims 1 to 10 or fixed-dose combination dosage form according to any one of claims 11 to 12 for use in therapy.

15.- Use of a composition according to any one of claims 1 to 10 in the preparation of a therapeutic for the treatment of masculine erectile dysfunction or for the treatment of benign prostatic hyperplasia; or use of a fixed-dose combination dosage form according to any one of claims 11 to 12 in the preparation of a therapeutic for the treatment of benign prostatic hyperplasia.