Patent claims

1. A drug formulation of vardenafil which disintegrates rapidly in the mouth, comprising vardenafil hydrochloride trihydrate and sugar alcohol, wherein at least 80% of the vardenafil hydrochloride trihydrate in the drug formulation dissolves at 25°C in 10 ml of physiological saline and the rate of release of the vardenafil hydrochloride trihydrate from the drug formulation in 900 ml of physiological saline within the first 5 minutes in the USP pedal stirrer apparatus at 50 rotations per minute at 37° C is at least 70%.

2. Drug formulation according to Claim 1, comprising vardenafil hydrochloride trihydrate in ground or amorphous form.

3. Drug formulation according to Claim 1 or 2, wherein the vardenafil hydrochloride trihydrate is in micronized form with a mean particle size of less than 20 μm.

4. Drug formulation according to any one of claims 1 to 3, comprising from 40% to 99% sugar alcohol.

5. Drug formulation according to any of claims 1 to 4, comprising mannitol as sugar alcohol.

6. Drug formulation according to any of claims 1 to 5, comprising sorbitol as sugar alcohol.

7. Drug formulation according to any of claims 1 to 6, comprising a mixture of sorbitol and mannitol as sugar alcohol.

8. Drug formulation according to any of claims 1 to 7, comprising from 0.8% and 25% vardenafil, calculated as vardenafil base

Patent claims

1. Drug formulation which disintegrates rapidly in the mouth and comprises vardenafil hydrochloride trihydrate from 0.8% to 25% by weight calculated as vardenafil base and sugar alcohol from 40% to 99% by weight,

2. Drug formulation according to Claim 1, comprising vardenafil hydrochloride trihydrate in ground or amorphous form.

3. Drug formulation according to Claim 1 or 2, wherein the vardenafil hydrochloride trihydrate is in micronized form with a mean particle size of less than 20 μm.

4. Drug formulation according to any of claims 1 to 4, comprising mannitol as sugar alcohol.

5. Drug formulation according to any of claims 1 to 4, comprising sorbitol as sugar alcohol.

6. Drug formulation according to any of claims 1 to 4, comprising a mixture of sorbitol and mannitol as sugar alcohol.