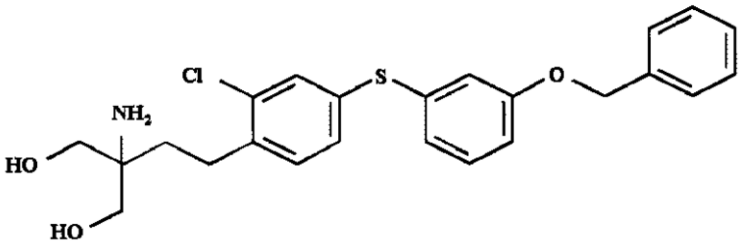
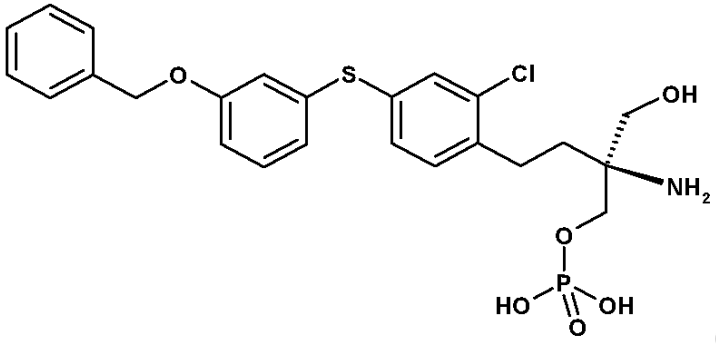
CLAIMS

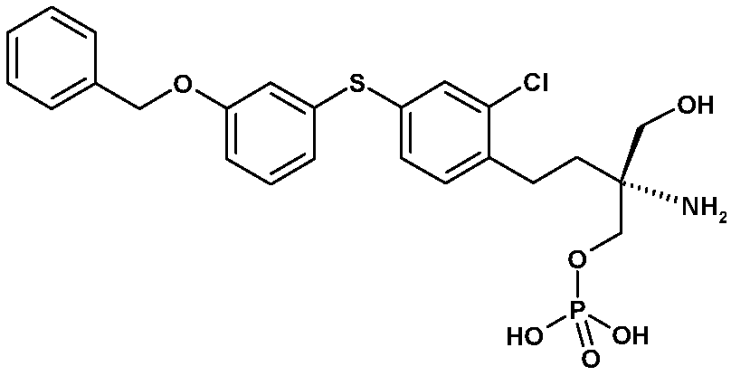
1. A pharmaceutical composition comprising an S1P receptor modulator of formula (II) or formula (IIa) or formula (IIb):



(II),



(IIa),



(IIb),

or pharmaceutically acceptable salts thereof,

characterized in that the dosage strength of the S1P receptor modulator, preferably the hydrochloride salt of formula (II), in the solid dosage form unit is about 1 mg/unit, and comprising

- mannitol at a content from 48 to 88 mg/unit, preferably from 58 to 78mg/unit, more preferably at a content about 68 mg/unit;
- microcrystalline cellulose at a content from 5 to 45 mg/unit, preferably from 15 to 35 mg/unit, more preferably at a content about 25 mg/unit;
- sodium starch glycolate at a content from 1 to 8 mg/unit, preferably from 2 to 6 mg/unit, more preferably at a content about 4 mg/unit;

- magnesium stearate at a content from 0.025 to 4 mg/unit, preferably from 0.5 to 2 mg/unit, more preferably at a content about 1 mg/unit; and
- colloidal silicon dioxide at a content from 0.125 to 2 mg/unit, preferably from 0.25 to 1 mg/unit, more preferably at a content about 0.5 mg/unit.

2. The pharmaceutical composition of claim 1, characterized in that the S1P receptor modulator is the hydrochloride salt of formula (II).

3. The pharmaceutical composition of claim 1 or 2, characterized in that the composition is a solid dosage form suitable for oral administration selected from capsules, tablets, pills, powders, and granules, preferably capsules or tablets.

4. The pharmaceutical composition of claims 1 to 3, characterized in that the solid dosage form is immediate or modified such as delayed, targeted or extended, preferably an immediate release dosage form.

5. The pharmaceutical composition of claims 1 to 4, characterized in that the S1P receptor modulator has an average particle size of less than or equal to 8µm, preferably 6µm, more preferably 5µm and/or a D90 of less than or equal to 25µm, preferably 22µm, more preferably 18µm.

6. The pharmaceutical composition of claims 1 to 5, characterized in that said pharmaceutical composition is stable for at least 24 months at 25°C.

7. A process of preparing the pharmaceutical composition according to claims 1 to 6, characterized in that said process comprises the step of:
    a. Blending the S1P receptor modulator with microcrystalline cellulose, colloidal silicon dioxide,
    b. adding mannitol and blending the resulting mixture,
    c. adding sodium starch glycolate and blending the resulting mixture,
    d. adding magnesium stearate, blending the resulting pharmaceutical composition,
    e. recovering the pharmaceutical composition.

8. The process of claim 7, characterized in that it further comprises the step of:
    f. filling the resulting pharmaceutical composition into capsules,
    g. recovering the resulting capsules filled with the pharmaceutical composition.