

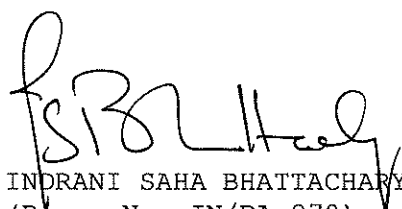
**We Claim :**

- 1) An oral pharmaceutical fixed dose composition in a form of a dispersible tablet for use in the treatment of tuberculosis, said oral pharmaceutical composition comprising:
  - a) granules comprising isoniazid and an intragranular excipient which is selected from the group comprising microcrystalline cellulose, povidone, sodium starch glycollate and mixtures thereof ,
  - b) granules comprising rifapentine and an intragranular excipient which is selected from the group comprising microcrystalline cellulose, sodium starch glycollate, pre-gelatinized starch, sodium ascorbate, hydroxypropyl cellulose and mixtures thereof, and
  - c) an extragranular excipient comprising a stabilizer selected from the group comprising sodium ascorbate, sodium metabisulfite, butyl hydroxylated toluene, citric acid, tocopherol, butyl hydroxyanisole, ascorbic acid, tartaric acid and mixtures thereof.
- 2) An oral pharmaceutical composition as claimed in claim 1, wherein said oral pharmaceutical composition is in the form of a dispersible bilayer tablet comprising:
  - a layer comprising isoniazid granules (a) and an extragranular excipient, and
  - a layer comprising rifapentine granules (b) and an extragranular excipient comprising a stabilizer which is selected from sodium ascorbate, sodium metabisulphite, butyl hydroxylated toluene, citric acid, tocopherol, butyl hydroxy anisole, ascorbic acid, tartaric acid and mixtures thereof.

- 3) An oral pharmaceutical composition as claimed in any one of the claims 1 to 2, wherein the ratio of rifapentine to isoniazid is comprised from 3:1 to 1:0.5.
- 4) An oral pharmaceutical composition as claimed in any one of the claims 1 to 2, wherein the ratio of rifapentine to isoniazid is 1:1.
- 5) A process for the preparation of an oral pharmaceutical composition as claimed in any one of the claims 1 to 4, characterized in that it comprises distinct steps of granulating isoniazid and granulating rifapentine.
- 6) A process as claimed in claim 5, characterized in that the preparation of the granules is made by wet granulation.
- 7) A process as claimed in claim 5 or 6, characterized in that it comprises the steps of:
  - a) preparing the isoniazid granules,
  - b) preparing the rifapentine granules,
  - c) mixing the granules obtained from steps a) and b) with the extragranular excipients comprising a stabilizer which is selected from sodium ascorbate, sodium metabisulphite, butyl hydroxylated toluene, citric acid, tocopherol, butyl hydroxy anisole, ascorbic acid, tartaric acid and mixtures thereof, and
  - d) compressing the mixture of step c) to obtain tablets.
- 8) A process as claimed in claims 5 to 7, characterized in that it comprises the steps of:
  - a) preparing the isoniazid granules,
  - b) mixing the granules obtained from step a) with a part of the extragranular excipients,
  - c) preparing the rifapentine granules,

- d) mixing the granules obtained from step c) with the remaining part of the extragranular excipients comprising a stabilizer which is selected from sodium ascorbate, sodium metabisulphite, butyl hydroxylated toluene, citric acid, tocopherol, butyl hydroxy anisole, ascorbic acid, tartaric acid and mixtures thereof, and
- e) compressing the mixture of steps b) and d) to obtain bi-layer tablets.

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