

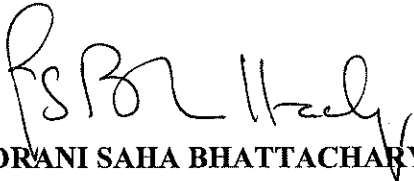
**WE CLAIM:**

1. An oral pharmaceutical fixed dose composition for use in the treatment of tuberculosis, said oral pharmaceutical composition comprising:
  - a) granules comprising isoniazid and at least one intragranular excipient which is selected from the group comprising microcrystalline cellulose, povidone, and mixtures thereof ,
  - b) granules comprising rifapentine and at least one intragranular excipient which is selected from the group comprising microcrystalline cellulose, sodium starch glycolate, pregelatinized starch, and mixtures thereof, and
  - c) at least one 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 according to claim 1, wherein said oral pharmaceutical composition is in the form of a coated tablet.
3. An oral pharmaceutical composition according to any one of the claims 1 to 2, wherein said oral pharmaceutical composition is in the form of a coated bilayer tablet comprising:
  - a layer comprising isoniazid granules (a) and at least one extragranular excipient,
  - a layer comprising rifapentine granules (b) and at least one 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, and
  - a film coating.

4. An oral pharmaceutical composition according to any one of the claims 1 to 3, wherein the ratio of rifapentine to isoniazid is comprised from 5:1 to 1:0.5.
5. An oral pharmaceutical composition according to any one of the claims 1 to 3, wherein the ratio of rifapentine to isoniazid is 1:1.
6. A process for the preparation of an oral pharmaceutical composition according to any one of the claims 1 to 5, characterized in that it comprises distinct steps of granulating isoniazid and granulating rifapentine.
7. A process according to claim 6, characterized in that the preparation of the granules is made by wet granulation.
8. A process according to claim 6 or 7, 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,
  - d) compressing the mixture of step c) to obtain tablets, and
  - e) film coating the tablets.
9. A process according to claims 6 to 8, characterized in that it comprises the steps of:
  - a) preparing the isoniazid granules,
  - b) mixing the granules obtained from step a) with at least 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,
- e) compressing the mixture of steps b) and d) to obtain bi-layer tablets, and
- f) film coating the tablets.

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