

Claims

We claim:

1. A pharmaceutical composition of conventional single-layered dosage form of entacapone, levodopa and carbidopa comprising
 - (i) one or more diluents one of which is essentially microcrystalline cellulose,
 - (ii) croscarmellose sodium in an amount not more than 4% by weight of the composition,
 - (iii) atleast one adsorbant,
 - (iv) atleast one lubricant,and optionally other excipients like binders, glidants, additional disintegrants, alkalizing agents, lubricants and coating agents.
2. A pharmaceutical composition of conventional single-layered dosage form of entacapone, levodopa and carbidopa according to claim 1 the preparation of which involves
 - (i) dissolving entacapone in methylene chloride and methanol,
 - (ii) adsorbing the aforementioned entacapone solution on to one or more pharmaceutically acceptable excipients or an adsorbant premix prepared therefrom,
 - (iii) drying off the solvents till a slightly wet mass is obtained,
 - (iv) followed by serially adding and mixing an adsorbant in an amount not more than 10% w/w of the total weight of formulation, a lubricant in an amount not more than 10% w/w of the total weight of formulation, levodopa and carbidopa to the above wet mass containing entacapone, while drying off the solvents, mixing while drying till the

- required drying end-point as ascertained from the loss on drying of the granules is attained followed by sifting the dried granules through a sieve of required aperture size, adding disintegrant and lubricating the resultant blend with a lubricant and
- (v) optionally compressing the lubricated blend into tablets and film coating them or filling the lubricated blend into capsules.
3. A pharmaceutical composition of conventional single-layered dosage form of entacapone, levodopa and carbidopa according to claim 1 the preparation of which involves
- (i) mixing entacapone and one or more pharmaceutically acceptable excipients with methylene chloride and methanol,
 - (ii) drying off the solvents till a slightly wet mass is obtained,
 - (iii) followed by serially adding and mixing an adsorbant in an amount not more than 10% w/w of the total weight of formulation, a lubricant in an amount not more than 10% w/w of the total weight of formulation, levodopa and carbidopa to the above wet mass containing entacapone, while drying off the solvents, mixing while drying till the required drying end-point as ascertained from the loss on drying of the granules is attained followed by sifting the dried granules through a sieve of required aperture size, adding disintegrant and lubricating the resultant blend with a lubricant and
 - (iv) optionally compressing the lubricated blend into tablets and film coating them or filling the lubricated blend into capsules.
4. A method of preparing a solution of entacapone according to claim 2 wherein entacapone is first dispersed uniformly in methylene chloride followed by the addition of methanol to this dispersion to dissolve entacapone.
5. The solvent mixture or combination used according to claims 2 and 3 wherein the ratio of methylene chloride : methanol ranges from 1:9 to 9:1.
6. The solvent mixture or combination used according to claims 2 and 3

wherein the ratio of methylene chloride : methanol is 9:5.

7. Pharmaceutically acceptable excipients or an adsorbant premix prepared therefrom according to claims 2 and 3 which include one or more diluents one of which is essentially microcrystalline cellulose and optionally containing other excipients like adsorbants, glidants, disintegrants, alkalizing agents and lubricants.
8. A method according to claim 2 wherein the adsorption of entacapone solution is effected by spraying the entacapone solution under atomizing air pressure on to one or more pharmaceutically acceptable excipients or an adsorbant premix prepared therefrom in a high or medium shear mixer like a steam jacketed rapid mixer granulator or a steam jacketed planetary mixer respectively or in a low shear mixer like a fluid bed processor while drying off the solvents till a slightly wet mass is obtained while mixing or continued fluidization.
9. A method according to claim 3 wherein the preparation of the dried granules of entacapone, levodopa and carbidopa is effected in a high or medium shear mixer like a steam jacketed rapid mixer granulator or a steam jacketed planetary mixer respectively.

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