PHARMACEUTICAL FORMULATIONS COMPRISING A GLUCOCORTICOSTEROID

ABSTRACT:

Sterile formulation comprising glucocorticosteroids, process for the preparation of the sterile formulation and method of using the same are provided. The present invention also relates to sterile formulation comprising budesonide, process for the preparation of the sterile formulation and method of using the same.

We claim:

1. A process for the preparation of a sterile formulation wherein the process comprises of the following steps:
    (i) dispersing budesonide in a solution comprising water and optionally one or more pharmaceutically acceptable excipients to form a slurry,
    (ii) optionally sterilizing and/or homogenizing the slurry of step (i), and
    (iii) mixing the slurry of step (ii) with sterile excipient liquid comprising water and optionally one or more pharmaceutically acceptable excipients to obtain the sterile formulation.
2. The process according to claim 1, wherein the process comprises of the following steps:
    (i) dispersing budesonide in a solution comprising water and optionally one or more pharmaceutically acceptable excipients to form a slurry,
    (ii) sterilizing the slurry of step (i),
    (iii) homogenizing the slurry of step (ii) aseptically, and
    (iv) mixing the slurry of step (iii) with sterile excipient liquid comprising water and optionally one or more pharmaceutically acceptable excipients to obtain the sterile formulation.
3. The process according to claim 1, wherein the process comprises of the following steps:
    (i) dispersing budesonide in a solution comprising water and optionally one or more pharmaceutically acceptable excipients to form a slurry,
    (ii) homogenizing the slurry of step (i),
    (iii) sterilizing the slurry of step (ii), and
    (iv) mixing the slurry of step (iii) with sterile excipient liquid comprising water and optionally one or more pharmaceutically acceptable excipients to obtain the sterile formulation.
4. The process according to claim 1, wherein the budesonide is micronised and non-sterile.
5. The process according to claim 1, wherein the budesonide is unmicronised and sterile.
6. The process according to claim 1, wherein the budesonide is unmicronised and non-sterile.

7. The process according to claims 1-3, wherein the pharmaceutically acceptable excipient is selected from a group comprising surfactants, pH regulating agents, chelating agents and agents rendering the suspension isotonic, and mixtures thereof.
8. The process according to claim 7, wherein the surfactant is selected from a group comprising tyloxapol, polyoxyethylene sorbitan esters, polyoxyethylene ethers, poloxamers, polyoxyethylene castor oil derivatives, polyvinylalcohol and block copolymers of polyethyleneoxides, polypropyleneoxides, polybutyleneoxides, polyethyleneglycols (PEGs), polyethylene glycol derivatives, and mixtures thereof.
9. The process according to claims 1-3, wherein the budesonide is dispersed in a solution comprising surfactant, water and one or more pharmaceutically acceptable excipients to form the slurry.
10. The process according to claims 2 and 3, wherein the slurry is sterilized by heat treatment.

Dated this 07 day of April 2015.

For Aurobindo Pharma Limited

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