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[54] **PURE, STERILE, PYROGEN-FREE
HYALURONIC ACID FORMULATIONS
THEIR METHODS OF PREPARATION AND
METHODS OF USE**

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[58] **Field of Search** 514/54; 536/55.1

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[57] **ABSTRACT**

A heat stable, purified, pyrogen-free, heat sterilized fraction of hyaluronic acid suitable for use in formulations for intra-articular treatment of animals which includes minor amounts of sulphated mucopolysaccharides, sulphated ash, chlorides, solvents and less than 0.6% protein, having a molecular weight of less than 750,000 and exhibiting a specific absorbance of a 1% solution at A_{257nm} of less than 3. A formulation for intra-articular treatment of animals including an aqueous solution of the heat stable fraction of hyaluronic acid and preservatives, such as sodium benzoate, methylparaben and propylparaben, having a pH of 6.8-8.0 at 25° C. A method of preparing a formulation for intra-articular treatment of animals involving adding and dissolving methyl parahydroxybenzoate, propyl parahydroxybenzoate and sodium benzoate in hot water, mixing the preservative solution to dissolve the parabens, adding sodium hyaluronate in the solution, adjusting the pH of the resultant solution to 6.8-8.0 and diluting with water to a final volume prior to filling suitable dosages for intra-articular treatment of animals into vials which are autoclaved to sterilize the aqueous formulation. An intra-articular treatment involving injecting a suitable dosage of an aqueous solution containing a heat stable, purified, pyrogen-free, heat-sterilized fraction of hyaluronic acid into a joint of an animal suffering from a degenerative joint disease.

4 Claims, No Drawings