CLAIMS

Claim 1: A process of manufacturing a pharmaceutically acceptable product comprising an aqueous based isotonic solution of acetaminophen, said solution (i) comprising about 2 mM to about 500 mM of a buffering agent, (ii) having a pH of about 5 to about 6, (iii) having dissolved oxygen levels of ≥ 3 ppm, and (iv) being contained in a moist heat sterilizable container which is a flexible infusion bag made of a plastic material, and said process comprising sterilizing said flexible infusion bag filled with the acetaminophen solution by moist heat sterilization performed at a minimum temperature of about 121 °C, for a time of about 10 minutes to about 30 minutes and an air overpressure between about 0.2 bar to about 1.2 bar, wherein the water is not deoxygenated and a nitrogen blanket is not used during formulation, or the formulation is stored in ambient conditions in the polymer bag before autoclaving.

Claim 2: The process of claim 1 wherein said flexible infusion bag is made of a plastic material which is one of a cycloolefinic polymer, a polypropylene polymer, a polyvinyl chloride polymer, and any combination thereof.

Claim 3: The process of claim 1, wherein the fill volume of said moist heat sterilizable container is about 20 ml to about 1000 ml.

Claim 4: The process of claim 1, wherein said buffering agent is selected from an acetate buffer, a citrate buffer, a borate buffer, a phosphate buffer, a maleic buffer, a succinic buffer, a tartaric buffer, a phthalate buffer, a formate buffer, a tris buffer, and any combination thereof.

Claim 5: The process of claim 1 wherein said aqueous based isotonic solution of acetaminophen comprises the following ingredients:

- 10.00 mg/ml of acetaminophen;
- 1.93 mg/ml of citric acid;
- 6.40 mg/ml of sodium chloride;
- sodium hydroxide and hydrochloric acid to adjust pH to 5.5; and
- water for injection.

Claim 6: The process of claim 1, wherein said moist heat sterilizable container is enclosed within one or more overwraps.

Claim 7: The process of claim 6, wherein said one or more overwraps comprise one or more of oxygen scavengers and moisture scavengers.

Claim 8: The process of claim 6, wherein said one or more overwraps is configured to provide a barrier to ingress of one or more of oxygen, moisture, and light to said acetaminophen solution within said moist heat sterilizable container.

Claim 9: The process of claim 1, wherein said moist heat sterilization of said moist heat sterilizable container with said acetaminophen solution is performed by one of water cascade sterilization and steam sterilization.