**MKPPL - CLARITHROMYCIN
CLARITHROMYCIN TASTE MASKED PELLETS/GRANULES**

Clarithromycin is a semi-synthetic macrolide antibiotic. Chemically, it is 6-0-methylerythromycin. The molecular formula is C38H69NO13, and the molecular weight is 747.96.

Clarithromycin is a white to off-white crystalline powder. It is soluble in acetone, slightly soluble in methanol, ethanol, and acetonitrile, and practically insoluble in water.

Clarithromycin is a member of macrolide antibiotic. It binds to the 50S sub unit of bacterial ribosome and inhibits translocation i.e. they interfere with the transfer of the newly formed peptide chain from the A site to the P site and fails to expose the A site .So that A site is unable to bind with the next aminoacyl tRNA complex. This leads to premature termination of amino acid chain and there by inhibits protein synthesis.

The innovator is **BIAXIN** which is available as

* Immediate-release tablets.
* Extended-release tablets.
* Granules for oral suspension.

After constitution, each 5 mL of BIAXIN suspension contains 125 mg or 250 mg of clarithromycin. Each bottle of BIAXIN granules contains 1250 mg (50 mL size), 2500 mg (50 and 100 mL sizes) or 5000 mg (100 mL size) of clarithromycin and the following inactive ingredients: carbomer, castor oil, citric acid, hypromellose phthalate, maltodextrin, potassium sorbate, povidone, silicon dioxide, sucrose, xanthan gum, titanium dioxide and fruit punch flavor.

**NON-INFRINGING PROCESS**

The process of Manufacturing Clarithromycin Taste Masked Pellets of MKPPL is completely aqueous based. No single solvents is been used in any stage of manufacturing Process. The manufacturing process includes Drug coating on sugar micro pellets followed by taste masker coating and Methacrylic acid copolymer coating. The object of the present invention is to provide a taste masked composition, which effectively masks the taste of the drug without compromising the dissolution rate.

**EXCIPIENTS**

Carbopol and Methacrylic acid copolymer.

**APPLICATIONS** Clarithromycin TM pellets are used in MUPS form with particle size from 180 micron to 600 micron hence has multiple uses as for Tablet Compression, Dry syrup for suspension and Sachet.

The oral taste masked granules are capable of being administered as coated granules dry syrups, sachets and powders that can be reconstituted before usage as a liquid suspension. The reconstitutable compositions prepared from granules are stable during storage and the suspensions, once reconstituted present a masked taste during the entire course of treatment.

The sachet formulations are solid powders containing three essential components:

(i) Coated spherical micro particles.

(ii) Partially recrystallized shear form floss particles produced from compositions containing

 Saccharide based carrier.

(iii) Additives selected from the group consisting of lubricants, flavors, glidants, fillers and

 Colorants.

When ingested, the combinations become somewhat syrupy in the mouth giving a pleasing mouth feel and enhanced organoleptic acceptability.

Sachets of 250 mg are indicated in adults and children 12 years and older.