International Journal of Research in Pharmacy and Pharmaceutical Sciences
ISSN: 2455-698X
Impact Factor: RJIF 5.22
www.pharmacyjournal.in
Volume 3; Issue 4; July 2018; Page No. 48-49

Kollidon SR new extended release matrix excipient: A review

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Abstract
Kollidon SR is a blend of is a blend of polyvinyl acetate and for use as a matrix-forming agent in directly compressible sustained – release tablets. It consists of 80 % polyvinyl acetate and 19 % povidone along with small quantities of sodium sulfate and silica as stabilizers. Polyvinyl acetate is a very plastic material that produces a coherent matrix under low compression forces. When the tablets formulated using Kollidon SR are introduced into gastric or intestinal fluid, the water soluble povidone is leached out to form pores through which the active ingredient slowly diffuses out through these pores to give sustained action. Kollidon SR contains no ionic groups and is therefore inert to drug substances. The sustained – release properties are unaffected by ions or salts.

Keywords: sodium sulfate, silica, Kollidon SR

Introduction
Polyvinyl acetate/Povidone based polymer (Kollidon® SR) is a relatively new extended release matrix excipient. It consists of 80% polyvinyl acetate and 19% Povidone in a physical mixture, stabilized with 0.8% sodium lauryl sulfate and 0.2% colloidal silica.

Polyvinyl acetate: Homopolymer of vinyl acetate. It is obtained by emulsion polymerization. Description: water white, clear solid resin, soluble in benzene and acetone, insoluble in water or emulsion readily diluted with water Polyvinylacetate is a very plastic material that produces a coherent matrix even under low compression forces. Regulatory status: diluents in color additive mixtures for food use exempt from certification, food additive (21CFR73).

Povidone: White amorphous hygroscopic powder, soluble in water it has good binding properties both under dry or wet conditions. Due to its hygroscopicity, Povidone promotes water uptake and facilitates diffusion and drug release.

Manufacture
The manufacture procedure for the polyvinyl acetate/ povidone redispersible polymer powders and their application as binder at 0.5-20% (of the tablet weight), when the active ingredients are released within a time of 0.1 to 1.0 hour. The redispersible polymer powders are manufactured by emulsion polymerization of vinyl acetate followed by addition of polyvinylpyrrolidone (as 10-50w/w solution) and spray- or freeze-drying. The polymerization takes place at temperature of 60-80°C and results in shear-stable fine-particle dispersion. The k value of the polymers should be in the range from 10-350, preferably 50-90. To prevent particles caking together, silica (spraying aid) is added to the dispersion before spraying. Spray drying is done in spray towers (with disks or nozzles) or in fluid beds.

Physicochemical properties
Description: white or slightly yellowish, free flowing powder;
Particle size distribution: average particle size of about 100µm; Molecular weight of polyvinyl acetate 450 000;
Bulk density: within the range of 0.30-0.45g/ml; 0.37g/ml.
Tap density: 0.44g/ml
Flow ability: good flow properties with a response angle below 30,
Solubility: Polyvinyl acetate is insoluble in water. Povidone gradually dissolves in water; in tablets it acts as a pore-former. The manufacturer generally claims for Kollidon® SR good compressibility and drug release independent of the dissolution medium (pH and salt/ion content) and rotation speed. Compressibility results were published for propranolol 160mg tablets (drug: polymer 1:1). The compression force did not affect the drug release profile. The pH-independent release was also tested for caffeine. The evaluated Kollidon® SR as matrix excipient for Theophylline tablets. Tablets containing 20-70% theophylline showed Higuchian release kinetics; the release rates increased exponentially with the drug loading. The increase in compressional force from 20kN to 60kN caused a slight linear decrease in the release rate. Annealing of the tablets for 24 hours at temperatures of 45 and 55°C showed a slight decrease in the release rate compared to the room temperature. Reported the effect of accelerated stability conditions on diphenhydramine HCl tablets prepared with Kollidon® SR. A decrease in dissolution rate along with an increase in tablet hardness was noticed for tablets with high level of Kollidon® SR (>37%) prepared without diluents or with 15% diluents (lactose, Emcompress®). At 25% Emcompress®, no changes occurred. Such changes were not observed for tablets stored at 25°C/ 60%RH or cured at 60°C for at least one hour.
The evaluated different additives: diacetyl-tartaric acid diglyceride ester, pectin, stearic acid and methyl hydroxyethyl

cellulose for optimization of caffeine release from Kollidon® SR -based matrix tablets. Stearic acid retarded the initial drug release in acidic medium due to its hydrophobic character, but failed to accelerate it in neutral medium. Diacetyl-tartaric acid diglyceride ester, methyl hydroxyethyl cellulose and pectin reduced the initial drug release and intensified the dissolution after the pH change. The applicability of Kollidon® SR in hot melt technology using acetaminophen.

Conclusion

The characteristics of a new polyvinlacetate/povidone based excipient, Kollidon SR were evaluated for application in extended release matrix tablets. The effects of the Kollidon SR based formulation and process variables on tablet properties and drug release were studies Kollidon SR concentration in the table. Addition of external binder for wet granulation, presence of an enteric polymer in the matrix, method of manufacturing and compression force. A pilot bioequivalence study was performed in human volunteers to confirm in vivo the extended release characteristics of the tablets manufactured with Kollidon SR. It was found that Kollidon SR suitable for extended release matrix excipient.

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