finalized in the range of 10-30 rpm and was optimized based on weigh variation and content uniformity. Hardness range of the compressed process was finalized in the range of 3-11 kP and was optimized based on hardness variation and its influence on thickness, % friability, disintegration time and dissolution of tablets. The prepared tablets were seal coated upto 3% w/w build up with Opadry Clear YS-1-7006. The seal coated tablets were then controlled-release coated upto 21% w/w build up with ethyl cellulose as polymer and Hypromellose 3 cps as pore former in ratio of 8:2. After controlled-release coating, the tablets were cured at 40°C for 2 hours. The cured tablets were subjected to disintegration and dissolution testing and the results were comparable to RAYOS®. The prepared tablets were subjected to accelerated stability testing for 3 months and were found to be stable. In vivo studies were performed for both the test and reference product in 10 healthy human volunteers under fed condition. The results were promising with respect to AUC (0-t) and AUC (0-∞) except the C_{max} which needs to be improved and can be achieved by extending the lag time through increasing the controlled-release coating build up to about 25% with ethyl cellulose as polymer and hypromellose 3 cps as pore former in the ratio of 8:2.

6.3 CONCLUSION – CONTROLLED RELEASE TABLETS OF CLARITHROMYCIN
Controlled release tablets of Clarithromycin were designed with an aqueous granulation process utilizing fluid bed processor equipped with top spray assembly. Unlike conventional granulation process utilizing high shear mixer granulator, the selected manufacturing process does both granulation and drying simultaneously. The selected manufacturing process has few unit operations. Hence reduced time. The product was manufactured with few excipients and the excipients selected were not similar to the one’s present in the marketed product. The manufactured product showed comparable in-vitro and in-vivo drug release to the marketed product BIAxin® XL FILMTAB®. Also the prepared product was cost effective as compared to the marketed product. The manufactured product was stable at accelerated stability condition for 3 months.

6.4 CONCLUSION – CONTROLLED RELEASE TABLETS OF PREDNISONE
Controlled release tablets of Prednisone were designed with a simple immediate release core tablet using common excipients coated with aqueous controlled release coating with ethyl cellulose as polymer and hypromellose as pore former utilizing conventional perforated coating pan. The formulated drug product showed comparable In vitro and promising In vivo drug release to the marketed product, which employs patented Geoclock™ technology
utilizing complex and costly tablet in tablet design. The manufactured product was stable at accelerated stability condition for 3 months. Compared to the marketed product, the manufactured product was cost effective and will benefit the chronic Rheumatoid arthritis patient population at large.

6.5 SUGGESTIONS FOR FUTURE RESEARCH - CONTROLLED RELEASE TABLETS OF CLARITHROMYCIN
Before initiating the commercial manufacturing of the drug product, the manufacturing process parameters needs to be validated, since the batch size of the drug product is scaled up from 110,000 Tablets to 1,100,000 Tablets.

6.6 SUGGESTIONS FOR FUTURE RESEARCH - CONTROLLED RELEASE TABLETS OF PREDNISONE
Controlled release tablets of Prednisone to be made with about 25% controlled-release coating with ethyl cellulose as polymer and hypromellose 3 cps as pore former in the ratio of 8:2. Needs to be characterized with respect to In-vitro disintegration time and dissolution profile and if found suitable then In-vivo study shall be taken up.
REFERENCES
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REFERENCES


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