# Improving the Stability of a Moisture-Sensitive Drug - Ranitidine HCl

## CHALLENGE

Multi-compartment compliance aids (MCA) or pill organizers are frequently used by patients to manage their treatment regimes. However, there are not many studies showing how the stability of drugs when stored in these aids is impacted. The purpose of this study was to evaluate how the selection of excipients, such as Starch 1500®, partially pregelatinized starch, can impact the formulation of moisture sensitive drugs when used in a MCA. Ranitidine HCl was used as the model drug.

**Multi-compartment compliance aid (MCA)**

## METHODS

- Two formulations of ranitidine HCl, with and without Starch 1500, were film coated, then together with a film coated marketed product all were dispensed into a MCA for stability studies at 40°C/75% RH.

**Composition of Ranitidine HCl 150 mg tablets**

| Ingredients | Formula A % | Formula B % |
|---|---|---|
| **Ranitidine HCl** | 54.00 | 54.00 |
| **Starch 1500** | 15.08 | --- |
| **Microcrystalline cellulose** | 30.17 | 45.25 |
| **Colloidal silicone dioxide** | 0.50 | 0.50 |
| **Magnesium stearate** | 0.25 | 0.25 |
| **Total** | 100.00 | 100.00 |

## RESULTS

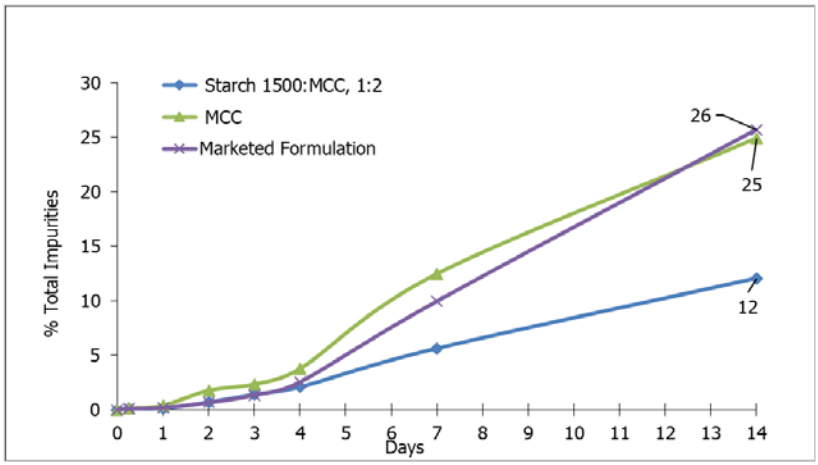
### Visual observation following stability in MCA

| | Formulation A with Starch 1500 | Formulation B with MCC | Reference Marketed Product |
|---|---|---|---|
| Day 1 |  |  |  |
| Day 7 |  |  |  |
| Day 14 |  |  |  |

Formulation A, containing Starch 1500, performed better than Formulation B with MCC alone and the reference marketed product formulation.

### Assay and Impurity Analysis

The level of total impurities in the formulation with Starch 1500 was significantly lower (12% w/w) compared to other formulations.




## CONCLUSION

- Inclusion of Starch 1500 in the core formulation significantly reduced the rate of ranitidine degradation
- The stability improvement of the drug is due to moisture scavenging property of Starch 1500 in the formulation, which reduces drug hydrolysis and degradation

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