SINGLE-USE MIXING VESSELS FOR POWDER AND/OR LIQUID APPLICATIONS

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Introduction:

This poster focuses on the development of 2 specific new single-use flexible mixing vessels. The drumshaped C-mix vessel, with a non-invasive design that eliminates contact of the impeller or stir rod with the ingredients and the hourglass shaped X-mix vessel that allows single-use mixing of powders with powders.

These unique mixing systems mimic mixing in a stainless steel vessel and combine all the advantages of single-use processes with a controlled, robust,

reproducible and efficient mixing system. Moreover, it is a closed system thereby eliminating the risk of cross-contamination and operator exposure to the product.

Study 1 Objectives:

To demonstrate blend uniformity of a powder-powder mix using the single-use X-mix vessel.

Equipment Used : Table top X-Mix Vessel (0.1 – 1.0 Liters)

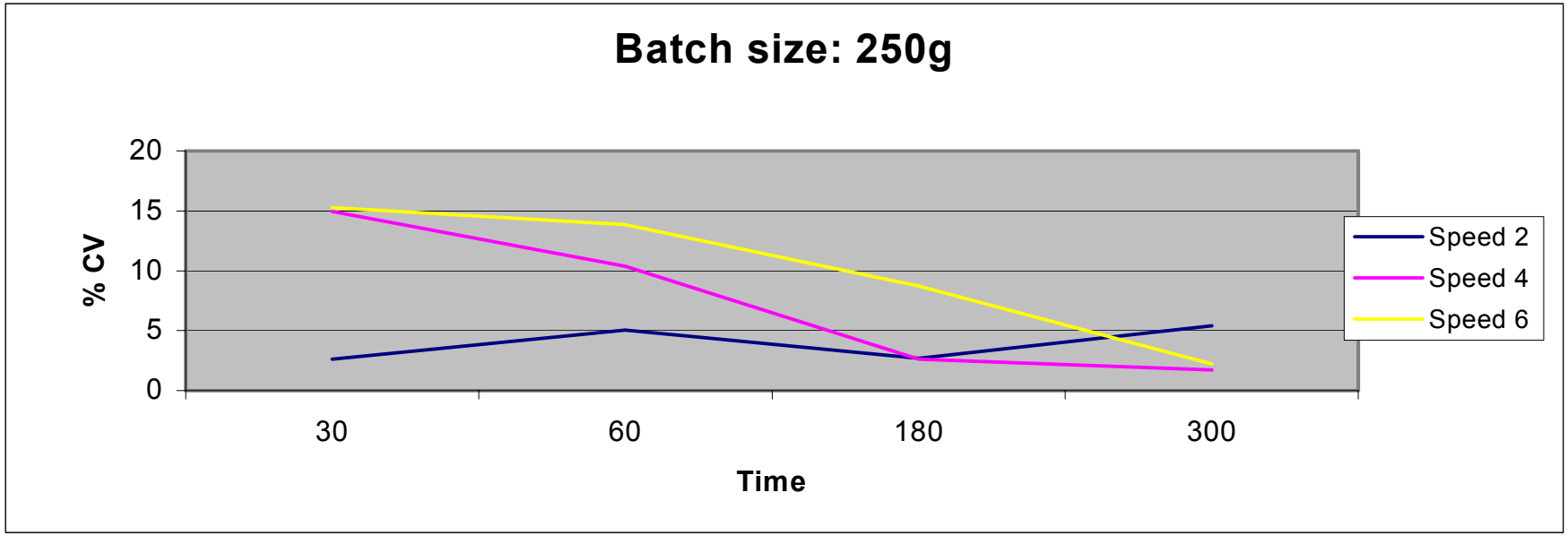
Materials Used :

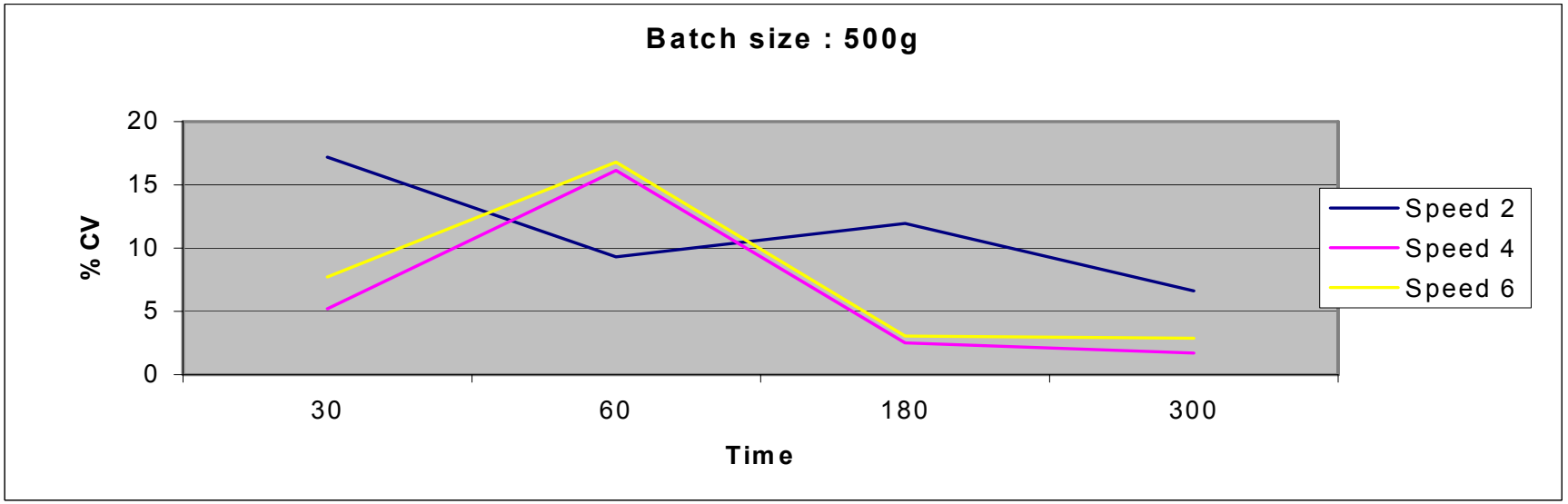
- Aminophyllin	**2%**
- Lactose	**40%**
- Microcrystalline Cellulose	**57.5%**
- Magnesium stearate	**0.5%**

The adjustable parameters were as follows :

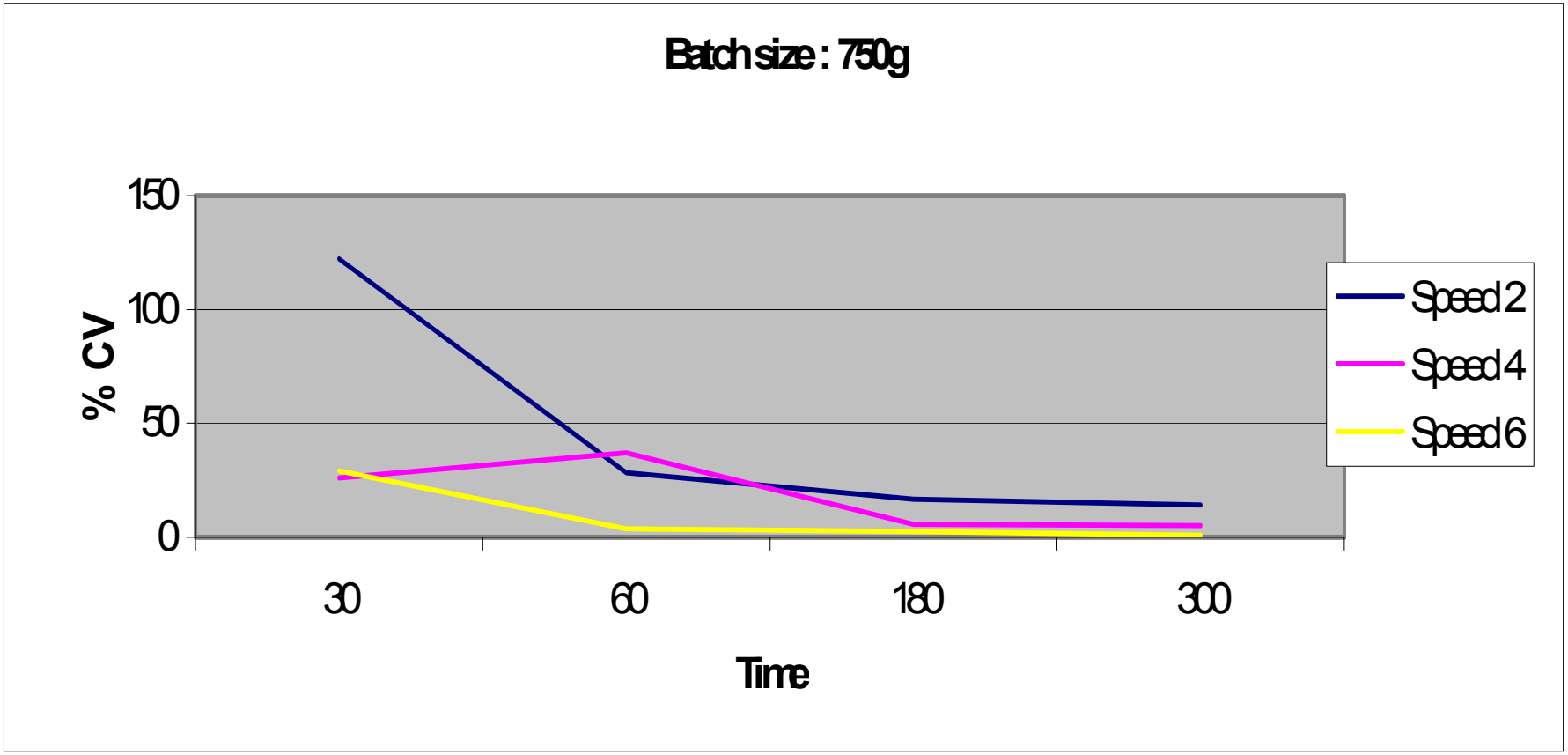
- **Speed of rotation**
- **Time of rotation**
- **Batch size**

Results :


Batch size: 250g
20
15
10
5
0
% CV
30
60
180
300
Time
Speed 2
Speed 4
Speed 6


Batch size : 500g
20
15
10
5
0
% CV
30
60
180
300
Time
Speed 2
Speed 4
Speed 6

Results (Continued) :



Summary

To achieve blend uniformity using a 1L X-mixing vessel, the **CV (Coefficient of Variation) needs to be less than 5%**.

The optimum mix was achieved after 180 seconds for the different batch sizes at the optimal speed of rotation

Conclusion:

The powder/powder mixing trials have demonstrated the efficiency of achieving powder/powder blend uniformity using a single-use mixing vessel.

The advantages of such a system are as follows:

- Efficient mixing
- No cleaning
- Pre-sterilized, Ready-to-use
- Ideal for pilot plant and clinical trials
- System can also be used for powder/liquid and liquid/liquid mixing

C-Mix Vessel (50-200 Liters)

Applications

For volumes up to 200 Liters

- Liquid / Liquid
- Powder / Liquid

Examples :

* Development scale for liquid and powder forms
* Buffer preparation
* Suspension preparation with continuous mixing
* Media preparation
* Mixing steps before and after process purification
* Preparation of sterile product
* Tablet coating

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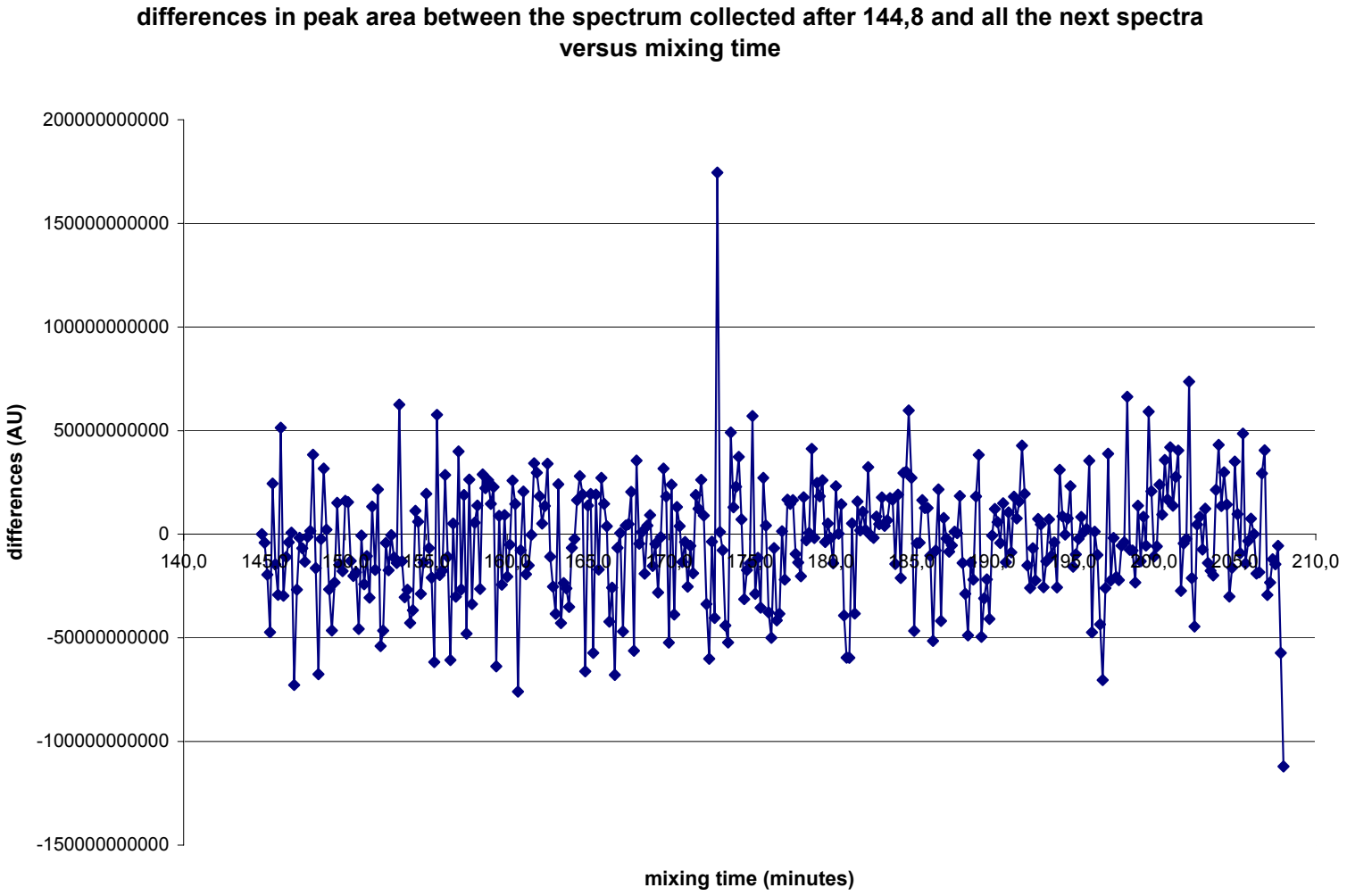
Study 2 Objectives:

The aim of this study was to evaluate if the ATMI mixing vessel was able to homogenize 20% (w/v) of Opadry II®powder [1]suspended in water (160 L). The homogeneous distribution of the Opadry II® components in water was monitored in-line by using Raman spectroscopy in combination with a fibre optic immersion probe.

[1] Supplied by Colorcon

Results


differences in peak area between the spectrum collected after 144,8 and all the next spectra versus mixing time
200000000000
150000000000
100000000000
50000000000
0
-50000000000
-100000000000
-150000000000
differences (AU)
140,0
210,0
mixing time (minutes)

Conclusion

It can be clearly seen that the differences between the peak area from the spectrum collected after 144.8 minutes and the next spectra are distributed around 0. This indicates a homogeneous distribution after 144.8 minutes.

Further, the averages from the peak areas of the Raman signals collected at the different heights in the mixing system were compared to each other. Using a multiple sample comparison t-test, it could be concluded that these averages were not significantly different from each other ($p<0.05$).