Materials and Methods

USP chapters <701> (disintegration equipment standards and setup) and <2040> (disintegration test methods for dietary supplements) were followed.

1. Each test sample included six (6) tablets from a randomly selected lot of an MVM product. Samples were shipped to a certified laboratory with 10% of the products sent as blinded duplicates to verify method reproducibility.

2. The appropriate immersion fluid and allotted disintegration time (see Table 1) were based on the coating of the tablet (coated or uncoated) or tablet matrix (soft gel). Each tablet was placed in a separate transparent receptacle, immersed, and agitated in the appropriate fluid for the allotted time. The temperature of the fluid was monitored and recorded for each tablet in accordance with USP standards (see Table 1).

According to chapter <701> of the USP, complete disintegration is defined as “that state in which any residue of the unit, except fragments of insoluble coating or capsule shell, remaining on the screen of the test apparatus or adhering to the lower surface of the dish, if used, is a soft mass having no palpably firm core.” (3)

Results

For the Adult MVM study 103 products were tested for disintegration. The pass rate was 92.2% or 95 of 103 products. Tablet types soft gel, sublingual, and capsules all passed. The tablet type-coating of failed samples included enteric-coated, coated, and uncoated. Each failed sample had all six tablets fail. To double-check these results, a second sample set of the same products was sent for testing. In all cases, all six tablets in the second sample set failed as well. This method consistency was also observed among the duplicate samples. The one duplicate sample that failed was sent again as a duplicate sample and all 12 tablets of the retested duplicate sample failed.

For the 81 over-the-counter prenatal MVM supplements tested, initial results showed a pass rate of only 52%. Additional investigation revealed that for these samples, the disk was not added to the test receptacles, as required. None of the products were enteric-coated. The 42 products that had initially failed were retested with a disk and 10 of these failed disintegration again. Of the 10 retest samples that failed, 5 samples were from a second lot and 5 were a repeat of the original lot. The three duplicates that initially failed, passed the retesting with disks. The final pass rate was calculated at 86.4%. Table 1 gives an overview of the different types of dosage forms and the usage of disks.

Conclusions

1. Approximately 92% of samples tested (95/103) passed disintegration testing in the adult MVM study and 86.4% of the samples tested (70/81) passed disintegration testing for over the counter prenatal MVMs. This shows that a large percentage of the MVM tablets have good content uniformity and quality.

2. It can be clearly seen that the usage of disks increased the probability of disintegration for Over-the-Counter prenatal MVM products.

3. DSID study will continue to use disintegration to assess the quality and content uniformity of supplement tablets and capsules for the next pilot studies, including botanicals (green tea study and flavonoids study) and a prescription prenatal MVM study.

References


3. May Almukainzi, Mahmor Sayed, Naad Aracei (Beu-Chacra), and Raimart Lőbenberg. Investigation of the Performance of the Disintegration Test for Dietary Supplements. The AAPS Journal, Vol. 12, No. 4, December 2010