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Validating Compounded Suppositories for Three Analgesic Product

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Editorial

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In this research editorial, the validation of compounded suppositories using commercially available analgesic products will be presented. Compounding pharmaceuticals by pharmacists remain an integral function in their practice of comprehensive clinical pharmacy. Suppositories containing analgesic medications may be used by the elderly and the very young for pain relief as well as in hospice care. In making compounded suppositories, most often the pharmacist has to utilize molds for shaping the suppositories. However, this requires melting the suppository base, mixing the drug with the melted base, and then filling a number of cavities of the suppository mold. When cocoa butter (theobroma oil) is used as a suppository base, caution must be exercised during the melting process for cocoa butter is sensitive to heat. The stable crystal of the base is converted to unstable forms when a high temperature is used during the melting process. Another issue concerning suppository making is related to the amount of the base displaced by the addition of drugs during the preparation. Since the suppositories molds are filled by volume, the amount of the base that is displaced by the drug is estimated by a parameter known as the density factor. The density factor is defined as the weight in grams of a substance that displaces 1 gram of cocoa butter. The density factor values for a number of commercially available non-prescription analgesics were previously reported [1]. The aim of the this study was to *validate* the density factor values reported by preparing cocoa butter-base suppositories using aluminum molds containing ibuprofen (IBP), aspirin (ASA), or acetaminophen (APAP). Blank suppositories (36) were made of cocoa butter base each weighing 1.736 g on average. These suppositories served as blank controls for the analytical methods. Also, 36 suppositories were prepared by adding an IBP powder (200 mg) per suppository. Another batch of suppositories (36 suppositories) was made from Motrin® IB (McNeil PPC Inc.; 200 mg IBP) powder (a tablet triturate) by using the density factor value of 1.06. The amount of IBP per suppository was determined using acid/base titration (0.1 N NaOH solution). Three batches of 12 suppositories each containing 371 mg of ASA per suppository (ASA powder was added individually to each of the suppository) were prepared. In addition, three batches of 12 ASA suppositories (made from BC® Powder, GlaxoSmithKline) calculated to contain 371 mg of ASA per suppository were formulated using the density factor of 1.21. The experiment was repeated with APAP powder and Tylenol Extra Strength-EZTabs (McNeil-PPC, Inc.) [500 mg of APAP/suppository (the density factor for Tylenol Extra Strength-EZTabs was 1.32)]. The amount of ASA in each suppository was analyzed by an acid/base titration (0.1 N NaOH solution) method and APAP was determined by HPLC (Phenomenex Luna C18 column; mobile phase: 5% acetonitrile/95% water with 0.05% trifluoroacetic acid; isocratic method; flow rate: 1 mL/min; injection volume: 20 µL; UV detector set at 244 nm). The average amount of IBP found in suppositories made with Motrin® IB tablets (i.e., suppositories prepared by the density factor method) was 192.06 mg (96.03%) and that with IBP powder was 195.15 mg (97.58%). The difference was statistically insignificant ($p > 0.05$). ASA suppositories prepared by adding 371 mg of ASA powder produced units containing on average 355.1 mg of ASA (95.7% of the labeled amount). Suppositories made by the density factor method (made with BC® Powder) produced units with an average of 386.0 mg of the drug (104% of the labeled amount; this was within the accepted limits for compounded preparations, which is commonly stated as ±5%). The difference between the two methods was statistically insignificant ($p > 0.05$). Similarly, for APAP suppositories the values were 93.6% and 95.2% for the units prepared by adding APAP to each suppository and those prepared by the density factor method, respectively. The difference between the two methods in preparing APAP suppositories was not statistically significant ($p > 0.05$). For all the preparations, drugs were extracted from the units by first melting the suppository at low heat (35°C) (using a water bath) and then using methanol as extractant. To assure complete extraction, each suppository was extracted five times using a 10-mL of

fresh portion of methanol per extraction. In conclusion, suppositories prepared by the density factor method were similar to those made with the drug added to suppository individually. This validates the previously reported method for employing commercially available products using their density factor values in compounding suppositories.

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REFERENCES

1. Antoine Al-Achi, et al. Density Factor Determination for Some Over-the-Counter Analgesic Products. J Pharm Technol. 2009; 25:303-308.