Evaluation Of Piroxicam Conventional and Hollow Suppositories Formulation

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Abstract

Suppositories are solid dosage forms intended to be inserted into body orifices where they melt at body temperature or dissolve in body fluid to exert local or systemic effects. Their action is determined by the drug's nature, concentration, vehicle, and absorption rate.Many reasons have been advanced for using the rectal route for drug administration, including avoiding gastrointestinal problems in patients, the unpleasant taste or odour of drugs, the first-pass effect, and the ease of use for children and unconscious patients.This study looks at how to make piroxicam suppositories in traditional and hollow forms for rectal administration to produce a higher and faster drug release by combining different bases**.**Piroxicam pure powder (Provizier Pharma, India), disodium hydrogen phosphate dihydrate (Na2HPo4.2H2O), gelatin and liquid paraffin, lactose powder, PEG 200, PEG 4000, and PEG 6000, ethyl oleate, glycerin, and potassium dihydrogen ortho-phosphate (KH2PO4), PEG 400, tween 80, and propylene glycol, the following two varieties of piroxicam suppositories were made:1- Piroxicam suppositories in their traditional form. 2-Suppositories with piroxicam powder or solution in a hollow kind. The difference between various groups was investigated using the variance (ANOVA) test. Using the SPSS18 window, the difference between the two groups was analyzed using the student's t-test. The minimum level of statistical significance was defined as a probability value (p0.05).In comparison to corresponding conventional suppositories (F1, F2, F4, and F5) and hollow suppositories loaded with Piroxicam in powder form (F6–F9) containing the same base, Piroxicam released faster with a higher percentage from hollow suppositories loaded with Piroxicam in solution form (F10–F13) in addition to their best physical properties.

Key Words:Piroxicam,Metabolites, Rectal Administration, Acute Gout

Introduction:

Suppositories are solid dosage forms intended to be inserted into body orifices where they melt at body temperature or dissolve in body fluid to exert local or systemic effects. Their action is determined by the drug's nature, concentration, vehicle, and absorption rate. Many reasons have

been advanced for using the rectal route for drug administration, including avoiding gastrointestinal problems in patients, the unpleasant taste or odour of drugs, the first-pass effect, and the ease of use for children and unconscious patients. Hollow-type suppositories are one approach for suppositories. Suppositories with a hollow cavity to accommodate drugs in powder or solution forms. The type of base material had less of an effect on hollow-type suppositories than on conventional types. They also eliminate the effect of the heating process on the nature of the drug during suppository preparation. They are expected to eliminate interaction between drugs and base materials because they are separated. 4-Hydroxy-2-methyl-N-(pyridin-2-yl)-2H-1,2-benzothiazine-3-carboxamide 1,1-dioxide is the chemical name for piroxicam. It is a nonsteroidal anti-inflammatory medication (NSAID). It is used to treat rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, and acute gout as an anti-inflammatory, analgesic, and antipyretic.Piroxicam is a class II drug with low solubility and high permeability. Piroxicam is quickly absorbed after oral or rectal administration but rapidly metabolizes to inactive metabolites. It is highly bound to plasma proteins (approximately 99 per cent).

Aim and Objective:

This study looks at how to make piroxicam suppositories in traditional and hollow forms for rectal administration to produce a higher and faster drug release by combining different bases**.**

Material and Methods:

Piroxicam pure powder (Provizier Pharma, India), disodium hydrogen phosphate dihydrate (Na2HPo4.2H2O), gelatin and liquid paraffin, lactose powder, PEG 200, PEG 4000, and PEG 6000, ethyl oleate, glycerin, and potassium dihydrogen ortho-phosphate (KH2PO4), PEG 400, tween 80, and propylene glycol, the following two varieties of piroxicam suppositories were made:1- Piroxicam suppositories in their traditional form. 2-Suppositories with piroxicam powder or solution in a hollow kind. By fusing multiple types and ratios of suppository bases, conventional suppositories containing 20 mg of Piroxicam were created. Suppository bases for formula (F1–F5) included Witepsol H35, PEGs 200:6000 (70:30), PEGs 200:6000 (50:50), PEGs 400:4000 (70:30), and glycerinated gelatin, as stated in table 1.

Table 1: composition of Piroxicam conventional suppositories of 2g mould

Formula no	Piroxicam (mg)	Suppository Base
F1	20	Witespol H35
F2	20	PEGs 201: 6100 (70: 30)
F3	20	PEGs 200; 6000 (50;50)
F4	20	PEGs 400; 4000 (70;30)
F5	20	Glycerinated gelatin base (glycerin, gelatin and water)

The fusion procedure entailed gently heating the base in a water bath to melt it, then adding the equivalent weight of 20mg piroxicam to each suppository. The molten substance was agitated

frequently but slowly before being put into 2 g suppository moulds to avoid air entrapment. The moulds were allowed to cool completely in the refrigerator before scraping any remaining congealed substance from the moulds. The moulds were then opened, and the suppositories were taken out. When making suppositories with a mixture of PEGs as a basis, the higher molecular weight PEGs were melted first, then the lower molecular weight PEGs were added and thoroughly combined.

On the other hand, Glycerinated gelatin foundation was made according to B. P. by dissolving gelatin in a mixture of gelatin, glycerin, and distilled water at 70 °C. These suppositories were made by gently melting a variety of suppository bases in a water bath. The melted bases were poured into 2 g suppository moulds with a cylindrical tube in the centre and set aside to harden for 2 hours at room temperature. Piroxicam was inserted in the cavity in one of the following forms once the hollow-cavity was constructed in the solidified bases:(1) Powder mixture (400 mg) made by combining Piroxicam with lactose at a 5 per cent (ww) concentration as described. Piroxicam solution (400 l), made in two ways depending on the type of base utilized, as shown below; Solution for Piroxicam (a): This solution was made by dissolving Piroxicam in ethyl oleate and then mixing it with tween 80 at a ratio of 70:30 w: w to make hydrophilic suppository bases (PEGs or glycerinated gelatin) to make piroxicam solution. The hardness of the tablet was assessed, the melting point was determined, and the softening time was calculated. The difference between various groups was investigated using the variance (ANOVA) test. Using the SPSS18 window, the difference between the two groups was analyzed using the student's t-test. The minimum level of statistical significance was defined as a probability value (p0.05).

Results and Discussion:

The table below shows the physical parameters of the produced suppositories containing 20 mg piroxicam and their equivalent bases. Table 2 shows the effect of changing the kind of suppository on the physical parameters of piroxicam suppositories made using witepsol H35 as the oleaginous suppository base

Table 2: Effect of suppositories on the physical properties of Piroxicam suppositories utilizing H35 base

Formula No	Type of the suppositories	Hardness (kg)	Melting time (min)	Softening time (min)
F1	Conventional	3.25±0.42	14.16±1.62	6.32±0.42
F6	Hollow (Piroxicam Powder)	3.00±0.41	12.12±1.20	4.21±0.55
F10	Hollow (Piroxicam solutions)	2.50±0.40	11.02±1.10	3.21±0.40

For traditional suppositories (F1), the hardness, melting, and softening times were 3.57 kg, 14.17 min, and 6.35 min, respectively. 3.02 kg, 12.07 min, and 4.21 min for hollow type suppositories containing Piroxicam in powder form (F6), 2.52 kg, 11.03 min, and 3.23 min for those containing Piroxicam in solution form (F10), respectively. Hardness, melting time, and softening time for both hollow type suppositories containing Piroxicam in powder (F6) or solution (F10) form were considerably lower (p0.05) than those obtained for conventional suppositories (F1).

This decrease in physical qualities could be attributed to the presence of voids in the hollow type, which could damage the skeleton structure, as opposed to the conventional type's compact backbone, which is more rigid and consolidated than the hollow type. The oleaginous base (Witepsol H35) is melted to release Piroxicam. During the first 5 minutes, the per cent release of Piroxicam for F1, F6, and F10 was determined to be 92%, 52%, and 653%, respectively. After 50 minutes, the per cent release of Piroxicam was increased to 213 per cent, 72.5 percent, and 982.per cent, respectively, for F1, F6, and F10. The melting of the suppository substrate was blamed for drug release**.**

Furthermore, the % release of Piroxicam after 5 minutes was discovered. For F2, F3, and F4, the percentages will be 212.75 per cent, 161.5 percent, and 283.25 percent, respectively. A significant (p0.05) increase in % release ofF4 stands for Piroxicam. F4 had a higher release rate. F2 and F3 have a different profiles than F1. These discrepancies in the % of a substance's releasepiroxicam were either attributable to grade discrepancies (F2 and F4), or they werePEG bases grade and ratio (F3 and F4) PEGs of a lower molecular weight, on the other hand,Suppositories with a more significant release profile have a higher molecular weight(high per cent release) and the other way around. These were the outcomes when these bases were created for ibuprofen; there were many consensussuppositories.

Conclusion:

In comparison to corresponding conventional suppositories (F1, F2, F4, and F5) and hollow suppositories loaded with Piroxicam in powder form (F6–F9) containing the same base, Piroxicam released faster with a higher percentage from hollow suppositories loaded with Piroxicam in solution form (F10–F13) in addition to their best physical properties. Other critical aspects affecting the physical features of suppositories and the release profile of Piroxicam include the kind of base used, the grade and ratio of PEGs bases, and the grade and ratio of PEGs bases.

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