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FORMULATION AND EVALUATION OF PARACETAMOL SUPPOSITORIES CONTAINING MENTHOL AS A COOLING AGENT

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ABSTRACT

The purpose of this research is to formulate and evaluate Paracetamol suppositories that contain menthol as a cooling agent. Since oral administration is difficult or impossible with certain groups of people, such as children, elderly patients, comatose patients, and those suffering from nausea/vomiting, suppositories can be used as an alternate route of administration. Paracetamol was chosen because it has long been recognized as an analgesic and antipyretic. Menthol was added to the suppositories to produce a localized cooling sensation. The suppositories were produced by a fusion molding technique using two different grades of polyethylene glycol (PEG 4000 and PEG 1500) as bases. In addition to evaluating their effectiveness based upon their physicochemical properties (physical appearance, weight variation, drug content homogeneity, hardness, melting point and disintegration times), all suppository formulations passed. However, among these formulations, F5 was found to have the greatest percentage of drug released during the test period and therefore the shortest disintegration time and thus was identified as the most optimal formulation.

KEYWORDS: Paracetamol, Suppositories, Menthol, Cooling Agent, Fusion Molding Method.

1. INTRODUCTION

Suppositories are medicated solid dosage forms of different sizes and shapes intended for insertion into body cavities. The drug is incorporated into a base such as cocoa butter, which melts at body temperature, or glycerinated gelatin and PEG, which dissolve slowly in mucosal secretions. They are mainly used for local effects but can also produce systemic effects or aid bowel evacuation.[1]

An ideal suppository base should be inert, non-toxic, non-irritating, compatible with drugs, and easy to mold or compress. It should melt, dissolve, or disintegrate in body fluids to release the medication effectively. Like ointment bases, the composition of the base influences drug release.[2]

A suppository is a dosage form inserted into a body orifice where it melts or dissolves to produce local or systemic effects. The three main types are rectal, vaginal, and urethral suppositories.[3]

Suppositories are stable medicated dosage forms inserted into body orifices to deliver drugs locally or systemically. The term is derived from the Latin word *supponere*, meaning "to place under." They are particularly useful for rectal and vaginal drug administration.[4]

Their effectiveness depends on drug concentration, vehicle, and absorption rate. The rectal route is preferred in certain cases because it avoids gastrointestinal irritation, unpleasant taste, and partially bypasses first-pass metabolism. It is also useful for children and unconscious patients. Suppositories are solid medicated preparations designed for insertion into body cavities.[5] They are valuable for local action, systemic absorption, and facilitating bowel emptying. The ideal base should be safe, non-irritating, compatible with drugs, and easy to mold. It should also melt or dissolve at body temperature to release the drug.[6] The composition of the base significantly affects drug release. Suppositories may contain one or more active ingredients along with excipients such as lubricants, absorbents, diluents, preservatives, and coloring agents. They are generally intended for single-dose administration for local or systemic effects.[7]

Ideal Properties of Suppository Bases[8]

- Non-toxic and non-irritant to mucous membranes
- Compatible with incorporated drugs
- Stable during storage
- Retain proper shape and size
- Shrink sufficiently for easy mold removal
- Non-reactive and non-irritating
- Melt at body temperature

Advantages of Suppositories[9]

- Suitable for patients unable to take oral medications
- Can improve drug bioavailability
- Effective for local treatment
- Avoid first-pass metabolism
- Provide rapid action
- Useful in rectal and vaginal fungal infections

Disadvantages of Suppositories[9]

- May cause irritation in some patients
- Can be uncomfortable or embarrassing
- More complex to prepare than tablets or liquids
- Often require cool storage conditions
- Limited number of drugs can be formulated as suppositories

Size and Shape of Suppositories

Fig. 1: Different Types of Suppositories.

Suppositories are available in different sizes and shapes depending on patient age, condition, route of administration, active ingredient, and desired drug release pattern. They may be molded or compressed and are commonly wrapped in plastic, foil, or gelatin coverings.[10] Common suppository sizes include:

- **1 g:** Usually bullet- or cone-shaped with a rounded tip.
- **2 g:** Typically torpedo-shaped, widening gradually toward the base. This shape helps the anal sphincter muscles draw the suppository into the rectum after insertion. It is the most common commercial size.
- **Glycerol suppositories:** Generally weigh about **4 g** for adults.
- Some suppositories may weigh **4–8 g** and are often cone-shaped with a rounded tip.[11]

Fig. 2: Prepared Paracetamol Menthol Suppositories.

2. MATERIALS AND METHODOLOGY

1. Material and Excipients

- Active Pharmaceutical Ingredients (API): Paracetamol. The primary antipyretic drug.

Excipients

Base (Suppository Formulation Base): Common bases include:

- Polyethylene glycol (PEG): Widely used in both vaginal and rectal suppositories.
- Cooling Agent: Menthol

- Lubricants: e.g., Liquid paraffin (to aid in mold release).
- Surfactants (optional): e.g., Tween 80/ Polysorbate 80 to enhance solubility of poorly soluble drugs
- Antioxidants (optional): e.g., Vitamin E to prevent oxidation of the active ingredients.

2. Methodology

All the chemicals used in this research were of standard pharmaceutical grade.

Paracetamol, Menthol, and excipients Polyethylene glycol (PEG 4000 & PEG 1500), Tween 80 and Vitamin E are obtained from laboratories of SDBIT College Dehradun.

3. Experimental work

Ingredient: Table 1: Details of ingredient used in Paracetamol suppositories.

S.No.	Ingredients	Quantity For 1 Supp.	Quantity For 20 Supp.	Role in formulation
1	Paracetamol	250mg	5g	Analgesic and Antipyretic
2	Menthol	10mg	200mg	Cooling And Soothing agent
3	PEG Base PEG 4000	1.05g	21g	Provide Hardness
4	PEG 1500	0.65g	13g	Improve Melting & Softness
5	Tween 80	20mg	400mg	Surfactant
6	Vitamin E	5mg	100mg	Antioxidant
7	Liquid Paraffin	Few drops	q.s.	Lubricant and Mould release

Formulation: Table 2: composition of Paracetamol suppositories.

Ingredients (mg/supp.)	F1	F2	F3	F4	F5
Paracetamol	250mg	250mg	250mg	250mg	250mg
Menthol	0mg	5mg	10mg	15mg	20mg
Tween 80	10mg	15mg	20mg	25mg	30mg
Vitamin E	5mg	5mg	5mg	5mg	5mg
PEG 4000	1200mg	1150mg	1100mg	1050mg	1000mg
PEG 1500	500mg	550mg	600mg	650mg	700mg
Liquid Paraffin	q.s.	q.s.	q.s.	q.s.	q.s.

4. Equipment

1. **Precision balance:** To measure the weight of ingredients accurately.
2. **Beakers and Glass Stirring Rods:** For melting and mixing the base.
3. **Suppository Molds:** For shaping the suppositories, typically made of metal or plastic.
4. **Heating Plate or Water Bath:** To heat the suppository base without direct heat (to avoid degradation of the active ingredients).
5. **Thermometers:** To monitor the temperature during melting.
6. **Pipette or Syringe:** For accurately dispensing the melted mixture into molds.

PROCEDURE

Preparation of Paracetamol suppository by fusion molding method

Preparation of Excipients:

- Weighing: Accurately weigh the amount of Paracetamol and the excipients (e.g., base, surfactant, antioxidant) using the precision balance.
- Preparation of the Suppository Base: Select the appropriate base (e.g. PEG or cocoa butter).

- For fatty bases (e.g., cocoa butter): Melt the base at approximately 40–45°C using a water bath.
- For water-soluble bases (e.g., PEG 4000 & PEG 1500): Melt at around 60°C.

Dissolution of Active Ingredient

- Paracetamol is slightly soluble in water and is uniformly dispersed and suspended in PEG based suppository formulation.
- If using PEG, paracetamol can be added directly to the melted PEG.
- If using a fatty base, ensure the Paracetamol is finely ground and mix it well in the molten base, ensuring uniform dispersion.
- Ensure that both the active ingredients are dissolved or uniformly suspended in the molten base.
  Mixing and harmonization:
- Mixing: Stir the molten mixture of the active ingredients and the base thoroughly to ensure uniform distribution. A glass stirring rod can be used to avoid contamination
- Optionally, add surfactants (e.g. Tween 80, Polysorbate 80) to aid in solubilizing the active ingredients if needed, particularly for Paracetamol, which has low water solubility.

Incorporation of Drug with Menthol

- To provide even dispersion, the melted base is gradually mixed with finely powdered paracetamol while being constantly stirred.
- To create a homogenous molten mixture, menthol is next added in a tiny, controlled amount and well stirred.
  Lubrication of Mould
- Clean the suppository moulds and lightly lubricate them using liquid paraffin or glycerin.

Pouring into Moulds

- Molding: Once the mixture is homogeneously mixed, use a pipette or syringe to fill the suppository molds. Ensure that the molds are clean and dry to avoid contamination.
- The amount of mixture should correspond to the desired weight of each suppository. Typically, a standard suppository weighs between 2–3 grams.

Cooling and Solidification

- Allow the molds to cool at room temperature or in a refrigerated environment (if using PEG-based bases).
- This will enable the suppositories to solidify and take shape. The cooling time varies, but it typically takes about 30 minutes to 1 hour.

Removal From Moulds

- Once solidified, carefully remove the suppositories from the molds.
- This step can be done by gently pressing on the mold's edges or using a lubricant like magnesium stearate to ensure easy release.

Packaging

- Pack the suppositories in suitable packaging to protect them from environmental conditions (heat and moisture).
- Ensure the packaging is airtight and suitable for the intended use (e.g., blister packs or individual packaging for vaginal/rectal use).

Fig. 3: Preparation of Paracetamol Menthol Suppositories by Fusion Molding.

3. EVALUATION PARAMETER OF SUPPOSITORY

- **Physical Appearance of Suppositories:** With the naked eye, the prepared suppositories color and shape were observed. The findings were noted on an observation sheet.[12]
- **Drug content uniformity test of suppository:** Suppository was taken in a volumetric flask (100 mL) and, after a little heating, was dissolved in methanol (10 mL). Acetate buffer pH 4.8 was then used to adjust the final volume to the desired level. A UV visible spectrophotometer was used to measure the presence of the drug after the final solution was filtered through a membrane filter following the proper dilutions with acetate buffer at a wavelength of 294 nm. Ten suppositories were chosen from each batch for this study.[13]
- **Uniformity of Weight Test:** Every suppository should weigh the same. The weight variation can happen if some cavities are overfilled and others are underfilled. For this test, twenty suppositories are weighed, and the average weight is calculated. Each suppository is weighed independently, and the weight is noted. No suppository should be lighter than the norm by more than 5%.[14]
- **Melting Point Test:** The suppository was placed in a glass tube with a 2.5cm diameter and a 2 mL phosphate buffer solution (pH 7.8). The tube was immersed in water that had been heated to 37°C. It was determined how long it would take each suppository to dissolve completely.[15]
- **Disintegration Test:** The disintegration test of the suppositories in appropriate dissolution media to ensure proper release of the active ingredients. The disintegration time of suppositories was determined using the pharmacopoeial method. Paracetamol suppositories have been reported to show disintegration times in the range of 27–29 minutes, depending on the type of suppository base used.[16]
- **Hardness Test:** A hardness test was used to gauge the brittleness and fragility of the suppositories. Each batch's suppositories were tested for hardness at room temperature using a Erweka Suppository hard tester (TYPE SBT, Germany). The hardness of ten suppositories from each batch was successfully measured.[17]

4. RESULT

Table 3: Evaluation Results of Paracetamol Suppositories (F1-F5).

Parameters	F1	F2	F3	F4	F5
Appearance	Smooth	Smooth	Smooth	Smooth	Smooth
Colour	White	White	White	White	White
Average Weight (g)	1.98±0.02	1.98±0.01	1.99±0.02	1.98± 0.01	1.99± 0.02
Drug Content (%)	98.2 ±0.8	98.9±0.7	99.5 ± 0.6	99.1±0.5	98.7 ± 0.8
Hardness (kg/cm²)	3.8 ± 0.1	3.7±0.1	3.6 ± 0.1	3.5 ± 0.1	3.4 ± 0.1
Melting/Liquefaction Time(min)	36 ± 1	35 ± 1	34± 1	35 ± 1	33 ± 1
Disintegration Time (min)	28 ± 1	27 ± 1	25 ± 1	24 ± 1	23 ± 1
Drug Release at 30 min (%)	32.4	35.8	39.6	42.1	45.3
Drug Release at 60 min (%)	58.7	62.5	67.8	71.2	74.6
Drug Release at 90 min (%)	79.3	83.1	87.5	90.2	92.4
Drug Release at 120 min (%)	91.2	94.6	97.8	98.5	99.1

5. DISCUSSION

Although the formulations prepared using the fusion molding technique presented good physical characteristics, which indicated that PEG 1500 and PEG 4000 can serve as appropriate bases for suppositories; the consistency of their appearance, minimal weight variations, and sufficient mechanical strength suggest satisfactory manufacture and uniformity of contents among the different preparations.

Menthol affected the dissolution properties of the suppositories (i.e., drug release behavior and disintegration time), and there was an inverse relationship between these two variables. The inclusion of increasing amounts of menthol resulted in decreasing values of disintegration times. Menthol increases the ability of the dissolving medium to penetrate the PEG matrix, thereby accelerating the breakdown of the suppository.

Formulations containing higher concentrations of menthol exhibited greater rates of drug release than those without menthol. Specifically, F5 had both the smallest disintegration time (23 min.) and greatest total amount of drug released (99.1%) at 120 min. Improved drug release due to enhanced paracetamol diffusion through the porous structure of the suppository base when menthol is present would explain the improved drug release profile of these preparations.

Overall, these data provide evidence that menthol can improve drug release and disintegration properties of paracetamol suppositories. Among all of the tested preparations, F5 is considered to be the most desirable due to its superior pharmaceutical performance.

6. CONCLUSION

A novel formulation and evaluation of paracetamol suppository in combination with menthol as an active cooling agent was created utilizing the fusion molding process.

All manufactured formulations had adequate physical properties (formulation), were within acceptable limits for weight variation, had suitable hardness values, contained the same amount of drug, and demonstrated similar melting profiles.

The presence of menthol in the formulation resulted in improved disintegration times and drug release rates compared to control formulations.

Therefore, we conclude that paracetamol suppositories containing menthol could serve as an appropriate and advantageous alternative to oral medication for patients who cannot or will not use them. In addition, the optimized

formulation F5 is pharmacologically effective because it has a fast release of active substance (99.1 % within 2 hours), fast disintegration time (23 minutes).

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