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Design and Development of Oral Medicated Jelly of Palonosetron Hydrochloride

Mahendrakumar Dubey Sat Kaival College of pharmacy, Sarsa, Gujarat, India.

Dr.Zankhana Sheth Sat Kaival College of pharmacy, Sarsa, Gujarat, India.

ABSTRACT

The present study is conducted with the aim to formulate and evaluate the unit molded medicated jelly containing Palonosetron hydrochloride for treatment of chemotherapy and radiation therapy induce nausea and vomiting. Jellies are semisolid to thick viscous fluids which is easily taken by patients of advanced age, patients with disability in ingestion of food and drink, in other words, those having difficulty in mastication and swallowing. The jelly dosage form can be swallowed easily without water and are soft and smooth. The prepared medicated jellies were evaluated for their physicochemical parameters like appearance, stickiness, pH, viscosity, drug release and content uniformity. All batches (F1-F12) of medicated jelly showed acceptable and comparable appearance, pH, viscosity range was found to be 536000-636000 cps., The drug content of F1-F12 formulations was found to be in the range of 97.2 to 103.26 %, The formulation F8 shows 100.03 % drug release.

KEYWORDS Oral Medicated jelly, Palonosetron hydrochloride, Chemotherapy induces nausea and vomiting, Radiation therapies induce nausea and vomiting.

1. Introduction

Despite tremendous advancement in drug delivery oral route remains the preferred route for the administration of therapeutic agents, low cost of therapy and ease of administration leads to patient compliance. Jellies are semisolid to thick viscous fluids which is easily taken by patients of advanced age and patients with dysphasia. Moreover jelly formulation with solidity appropriate for swallowing and with good texture which is suitable for improvement of patient compliance. The jelly dosage form can be swallowed easily without water and are soft and smooth. Inconvenience of administration and patient compliance are gaining significant importance in the design of dosage forms. So the present investigation is focused to develop the elegant, acceptable, stable Palonosetron hydrochloride oral medicated jelly [1].

2. Materials and Methods

2.1 Materials

Formulation of medicated jelly were prepare using Palonosetron hydrochloride (API) received from Intas pharmaceutical Ltd, Ahmadabad as gift sample and Tragacanth gum, sodium alginate, gelatin, Carbopol 940, Xanthan gum and Carrageenan (Astron Chemicals (India) pvt ltd as gelling agents. Excipients like propylene glycol (ACS Chemicals Pvt, Ltd) use to enhance softness and slipperiness of jelly. Citric acid (ACS Chemicals Pvt, Ltd) use to maintain the pH. Coloring agent and flavoring agent. Methyl paraben and Propyl paraben use as preservative. Sugar syrup use as bulking agent.

2.2 Formulation of medicated jelly

All the ingredients are weight accurately. In one beaker gelling agent, propylene glycol and citric acid heat to dissolve with constant stirring. In another beaker sugar syrup prepare by adding 67 gm of sugar in beaker and make up the volume up to 100 ml. sugar syrup add into solution and boil for few minutes. Methyl paraben and Propyl paraben, amaranth color dissolves in raspberry water. After boiling the solution is mix thoroughly and uniformly. Palonosetron hydrochloride is weight accurately, dissolve in little amount of water and add before jelly is allow to set, mix thoroughly. These whole solutions transfer in to moulds and then allow it for cooling and settling [5]. Shown in Table 1.

2.4 Evaluation Methods [2, 3, 4]

2.4.1 Physical appearance

The prepared medicated jelly is inspected visually for clarity, color and presence of any particulate materials. The test is important regarding patient compliance and acceptance.

2.4.2 Stickiness

Texture of the medicated jelly in terms of stickiness has been evaluated by visual inspection of the product after mildly rubbing the jelly sample between two fingers.

2.4.3 Viscosity

Viscosity will be measure by using Brookfield viscometer (DV-type II-Pro) by using fresh samples at each time.

2.4.4 Determination of pH

The pH values of 1% aqueous solutions of prepare medicated jellies are check by using a calibrated digital pH meter at constant temperature.

2.4.6 Content uniformity

1 medicated jelly from each formulation takes and dissolves in 50mL of Phosphate buffer pH 6.8 to give 100µg/ml solution. From the above solution 1, 1.5, 2ml taken and made up to 10mL with pH 6.8 Phosphate buffer to give 10, 15, 20 µg/ml solutions respectively. The absorbance of each solution will measure at the 255nm, using UV-Visible Spectrophotometer.

2.4.7 In vitro dissolution study

An in-vitro dissolution study will performed with USP basket apparatus using pH 6.8 Phosphate buffer solution. Dissolution medium was kept at 37° C ± 0.5° C and 50rpm. The samples (5 ml) withdrawn after 10, 20, 30, 40, 50, and 60 minute and replaced with fresh pH 6.8 Phosphate buffer solution. 5mL samples then diluted up to 10 ml in a volumetric flask. The samples were determined for the drug content using U V spectrophotometer at λ max 255nm.

3. Result and Discussion

4. Physical properties of medicated jelly

As per visual inspection appearance of prepared batch from F1 to F12 carried out in that F1 –F2 and F9-F10 was found to be opaque, F3-F4, F7-F8 and F11-F12 were found to be transparent appearance, and F5-F6 was found to be milky white. For-

mulation F3-F4, F7-F8 and F11-F12 showed good appearance.

pH of all prepared batches was carried out by using digital pH meter, all batches from F1-F12 within the range (7.3-8) which fall within standard pH range of oral medicated jelly. The standard pH of oral medicated jelly is 7.5-8.1 [5].

The viscosity of all formulation (F1-F12) was determined by using Brookfield viscometer. The results indicated that the formulations were found uniform in consistency. Result shown in Table 2.

5. Content uniformity

The drug content of prepared Palonosetron hydrochloride medicated jelly of batches F1-F12 was evaluated by using UV spectroscopy method. The drug content of F1-F12 formulations was found to be in the range of 97.2 to 103.26 % which shows all the formulation have uniformity of content. Result shown in Table 3.

6. In-vitro dissolution study

The formulation F1 to F12 was evaluated for the drug release within the 60 min.. The formulation F8 shows 100.03 % drug release.

From the observations of various parameters that the formulation F8 containing 3% gelatin as gelling agent showed acceptable values as compared to the others,. Result shown in Table 4 and fig.No.1.

Conclusion

From all evaluation parameters to be concluded that prepared medicated jelly is more organoleptically accepted particularly by patients with disability in ingestion of food and drink, in other words, those having difficulty in mastication and swallowing. Prepared medicated jelly is cost wise cheap, acceptable and more stable over other Palonosetron hydrochloride formulations available in market.

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Figures:

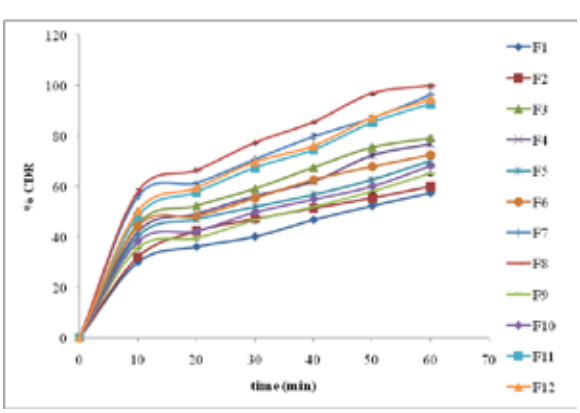

Fig.1. In-vitro dissolution study.

Tables:

Table 1 Formulation batches.

ingredients	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12
Quantity (%)	%	%	%	%	%	%	%	%	%	%	%	%
Palonosetron hydrochloride (mg)	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Sodium alginate	2	3	--	--	--	--	--	--	--	--	--	--
Carbopol 940	--	--	2	3	--	--	--	--	--	--	--	--
Tragacanth gum	--	--	--	--	1	1.5	--	--	--	--	--	--
Gelatin	--	--	--	--	--	--	2	3	--	--	--	--
Xanthan gum	--	--	--	--	--	--	--	--	4	4.5	--	--
Carrageenan	--	--	--	--	--	--	--	--	--	--	2	3
Citric acid	1	1	1	1	1	1	1	1	1	1	1	1
Sugar syrup	60	60	60	60	60	60	60	60	60	60	60	60
Distilled water	30	30	30	30	30	30	30	30	30	30	30	30
Propylene glycol	3	3	3	3	3	3	3	3	3	3	3	3
Raspberry water	2	2	2	2	2	2	2	2	2	2	2	2
Methyl paraben	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Propyl paraben	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02
Amaranth color	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s

7. Table 2 Physical properties of oral medicated jelly

Test	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12
Appearance	Opaque	opaque	transparent	transparent	Milky white	Milky white	transparent	transparent	opaque	opaque	transparent	transparent
pH	7.5	7.6	7.7	7.3	7.6	7.8	7.9	8.0	7.6	7.8	7.7	7.9
Viscosity(cps)	51600	61000	56950	62700	57850	60000	53500	55500	60600	62580	54600	56700
Stickiness	Sticky	Sticky	Non-sticky	Non-sticky	sticky	sticky	Non-sticky	Non-sticky	sticky	sticky	Non-sticky	Non-sticky

Table 3 Content uniformity.

Formulations	*Content uniformity (%) ± S.D
F1	99.31 ± 0.5
F2	100.08 ± 0.8
F3	98.30 ± 0.4
F4	103.26 ± 0.9
F5	100.35 ± 0.7
F6	98.24 ± 0.5
F7	100.11 ± 0.9
F8	102.24 ± 0.4
F9	97.2 ± 0.6
F10	97.46 ± 0.3
F11	99.8 ± 0.6
F12	100.43 ± 0.8

n = 3,*mean ± S.D

Table 4 In-vitro dissolution study.

Time (min)	* % Cumulative Drug release ± S.D					
	F1	F2	F3	F4	F5	F6
0	0	0	0	0	0	0
10	30.11 ± 0.6	32.14 ± 0.7	45.24 ± 0.5	42.20 ± 0.3	40.28 ± 0.5	44.32 ± 0.6
20	36.2 ±0.5	42.32 ± 0.9	52.42 ± 0.7	49.26 ± 0.5	46.9 ± 0.9	48.22 ± 0.5
30	40.22 ± 0.3	47.22 ± 0.6	59.22 ± 0.4	56.34 ± 0.8	51.9 ± 0.7	55.32 ± 0.9
40	46.9 ±0.8	51.44 ± 0.4	67.60 ± 0.9	62.12 ± 0.4	56.7 ± 0.5	62.65± 0.7
50	52.46 ± 0.7	55.54 ± 0.9	75.54 ± 0.3	72.44 ± 0.6	62.64 ± 0.9	67.85± 0.5
60	57.6 ± 0.9	60.15 ± 0.8	79.22 ± 0.6	77.02 ± 0.9	70.13 ± 0.7	72.47 ± 0.8

n = 6, *mean ± S.D

Time (min)	* % Cumulative Drug release ± S.D					
	F7	F8	F9	F10	F11	F12
0	0	0	0	0	0	0
10	56.22 ± 0.6	58.12 ± 0.9	35.6 ± 0.6	38.22 ± 0.8	48.32 ± 0.5	50.33 ± 0.9
20	61.51 ± 0.5	66.44 ± 0.7	39.5 ± 0.8	42.35 ± 0.5	57.78 ± 0.7	59.44 ± 0.5
30	70.9 ± 0.7	77.39 ± 0.5	46.63 ± 0.5	49.8 ± 0.7	67.44 ± 0.9	69.75 ± 0.7
40	79.88 ± 0.9	85.57 ± 0.8	51.9 ± 0.7	54.9 ± 0.9	74.55 ± 0.3	76.12 ± 0.4
50	87.21 ± 0.8	96.9 ± 0.5	58.02 ± 0.9	60.07 ± 0.8	85.33 ± 0.5	87.25 ± 0.8
60	96.40 ± 0.6	100.03 ± 0.9	65.21 ± 0.6	68.22 ± 0.9	92.74 ± 0.8	94.55 ± 0.6

n = 6, *mean ± S.D

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