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FORMULATION DEVELOPMENT AND EVALUATION OF MEDICATED CANDY CONTAININGPARACETAMOL FOR NEONATE

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ABSTRACT

There were so many different types of dosage forms were available in the market, but there was a need for new dosage forms which increases the bioavailability also decrease the first passmetabolism. The research work was increased to extend the bioavailability and decrease the first pass metabolism. Oral route of drug administration was the very popular method of administration of drug due to ease to ingestion, avoid the pain and most importantly patient compliance. Candy was a solid dosage form, containing medicament in a sweetened and flavoured base, intended to dissolved slowly in the mouth. Candy was medicated dosage formintended to place in the mouth of the neonate containing the paracetamol so that the candy havemelted easily in the mouth of the neonate. Candy was prepared by heating the sucrose and thewater and then the paracetamol drug was added to it and mix it well after that this candy solution was slowly poured on the rotator of the candy preparation machine so that the threadsof the candy came out from the holes of the rotator of candy preparation machine, then candy was automatically collected and placed inside the plastic packet and sealed it. It was found thatthere is a no inter-reaction in middle of the drug and the sugar

KEYWORDS: Paracetamol, Candy, Neonate.

INTRODUCTION

There were so many routes of drug administration but administration of drug by oral route was most common route of drug administration and it has many advantages compared to other route

of drug administration.[1,2,3] Paracetamol drug was used to get relief from the fever and headache. The neonate wasn't taking the medicines and the neonate spit the liquid dosage form so to overcome this problem the medicated paracetamol candy was prepared. This medicated paracetamol candy was placed in the mouth of the neonate so that the medicated paracetamol candy has melted easily in the mouth of the neonate, so that the paracetamol drug has reached into the systemic circulation of the neonate.[8,10] This medicated paracetamol candy was prepared by using the paracetamol, water and sucrose, first the sugar and the water was added in the beaker and kept it for boiling until the sugar turns into viscous liquid after that the paracetamol drug was added into the viscous solution and mix it well, then the viscous solution was poured on the rotator of the candy preparation machine so that the medicated paracetamol candy have come out from the holes of the rotator of the candy preparation machine, then the medicated paracetamol candy was collected by using the stick and collected in the plastic and sealed the plastic to avoid the environmental moisture went into the plastic. The medicated paracetamol candy formulation was diluted with different concentration and absorbance was taken at 243 nm in the UV-spectrophotometry and the standard calibration curve was plotted and purity of formulation was checked. The changed in the peak of the medicated paracetamol candy formulation and the interaction of the drug and the excipient was observed by using the FTIR.[4,5,9]

MATERIALS AND METHODS

Material

Paracetamol was obtained from Sigma Aldrich, Sucrose was obtained from the local store, Water was taken from Water purifier.

Method

I. Preformulation studies[7]

Preformulation studies gave us the concepts of physicochemical properties of the pure drug substance and when it was mixed with excipients. Pre-formulation studies were the first step in the development of a drug molecule to develop a safe, effective, and stable dosage form Phosphate Buffer (pH 6.8) was prepared as per the procedure available online resource

- **Melting point:** The melting point of the paracetamol was determined by usingthe Thieles tube, The one end of the capillary tube was sealed by using the flame then the small amount of paracetamol was introduced into the capillary tube by another side and then the capillary tube was tied to the thermometer, then heated the bath slowly and observed the

temperature at which the meltingof paracetamol begins

- **Determination of ƛmax:** UV absorption maximum was determined by dilution of standard stock solutions of paracetamol with phosphate buffer (pH 6.8) solution containing 10 go/mL of paracetamol and was scanned separatelybetween 200 and 400 nm using UV-visible spectrophotometer. Then we have got the wavelength of the paracetamol. Paracetamol showed absorption maxima at 243 λmax

II. Calibration

The UV-spectroscopy and IR spectroscopy machine was calibrated before performing the preformulation studies.

Calibration of UV-spectrophotometer =First warmup the spectrophotometer for 45 minutes, then selected the wavelength to calibrate, depending on what type of filter we were using have determined if we needed a dedicated blank for the machine. Either way, if our standard came with a blank insert it at that time, if there is no blank leave the cuvette holder empty and closed the lid, Zero the spectrophotometer so the display showed all zeros, Remove the blank (if we used one), Insert the NIST calibration standard and closed the cover, Recorded the reading and compared it to the data on the certificate of calibration.

Calibration of FTIR: Checked that all the connections of the instrument are proper. Ensured that printer was attached to the instrument. Attached sample compartment. Logged in the software. went to Set up > validation > System suitability. The instrument might ask for gathering the configuration, then clicked OK. System suitability set up have appeared.

Went to checks & selected only Abscissa, screen report. went to archive and set archive prefixas required clicked OK.

III. Method to prepare paracetamol candy

Took the sucrose and the water in a beaker and kept for heating until the sugar turned into viscous liquid and lastly added the 5mg of paracetamol drug into the above viscous solution and mixed it well, then automatically the viscous solution was slowly poured on the rotator of the candy preparation machine so that the threads were came out from the small holes of the rotator of the candy preparation machine, then automatically the threads were collected from the stick and packed in the plastic packets and sealed the plastic packet prope.

Evaluation parameters of the medicated paracetamol candy[6]

- **Stability testing:** Medicated paracetamol candy were subjected to different conditions; these included a variation of temperature. Stability studies werecarried out at 20°C (room temperature) for 1 day.
- **Compatibility testing:** The compatibility of the medicated paracetamol candy wastested by using the FTIR, the medicated paracetamol candy was mixed with the potassium bromate and the test was carried out then we have got a different peak after that we have matched the peaks with the standard paracetamol drug.
- **Determination of drug content:** The drug content was tested by taking the medicated paracetamol candy that was equivalent to 100 mg of paracetamol was weighed and taken into 100 mL volumetric flask and dissolved in 100ml of phosphate buffer that has a pH of 6.8 and left on a shaker overnight, then it was filtered. From that 1 mL of solution was withdrawn and taken in 100 mL volumetric flask and the volume was adjusted with phosphate buffer (pH 6.8) up to 100 milk The absorbance was measured using a UV spectrophotometer at a wavelength of 264 nm; using phosphate buffer (pH 6.8) as a blank

RESULT AND DISCUSSION

The medicated paracetamol candy is kept in the room temperature so that it has easily absorbed the moisture from the environment. The medicated paracetamol candy formulation was diluted with different concentration and absorbance was taken at 243 nm in the UV-spectrophotometry and the graph was plotted and R^2 value was determined the R^2 value was found to be 0.996 by this we have confirmed that the formulation was pure and stable.

The peaks of the pure paracetamol API were observed by taking the graph in the FTIR and the peaks of the medicated paracetamol candy formulation was also observed by taking the graph in the FTIR then both the graphs were observed and the peaks in the medicated paracetamol candy formulation was not changed it has same peaks as there in the pure API of the paracetamol.

The drug content was found to be uniform among all formulation and ranged from 93.79 ± 0.38 to 96.34 ± 1.17%, Stability studies were carried out at 20°C (room temperature) for 1 day, the medicated paracetamol candy have melted after 5 hours.

The melting point of the pure paracetamol was found to be 172 degrees delicious, the wavelength of the paracetamol was found to be 264 nm FTIR spectra of paracetamol has

shown the characteristic peaks at 3323.35-2931.80cm-1(-OH), 3062.96-3001.24cm-1(-NH), 1658.78cm-1(C=0), 1556.55cm-(C=C). The medicated paracetamol showspeak at 3520. 09-3061.03cm-1(OH), 3194.12-3174.83cm-1 (NH),1658.78cm-1 (C=O), 1500cm-1(C=C)

Table 1: Formulation of medicated paracetamol candy.

Ingredient	F1	F2	F3	F4	F5	F6
Sucrose (gm)	30	35	40	45	50	55
Water (ml)	5	7	9	11	13	15
Paracetamol (mg)	5	5.5	6	6.5	7	7.5

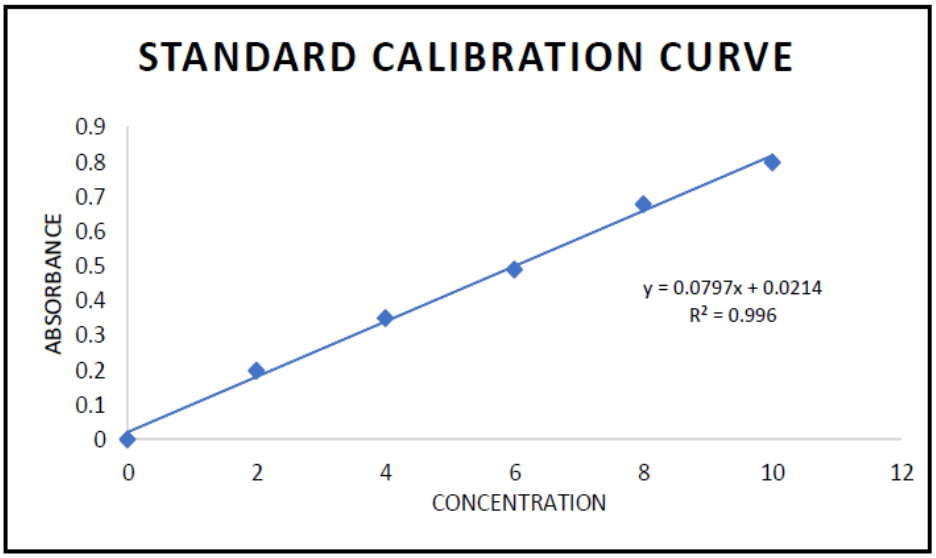

Fig. 1: Standard calibration curve of medicated paracetamol candy.

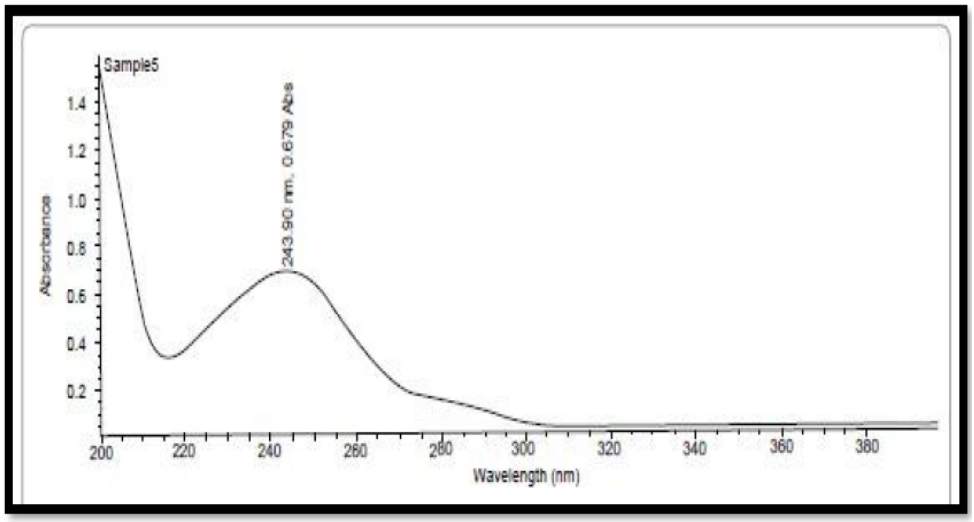

Fig. 2: UV spectrum of paracetamol.

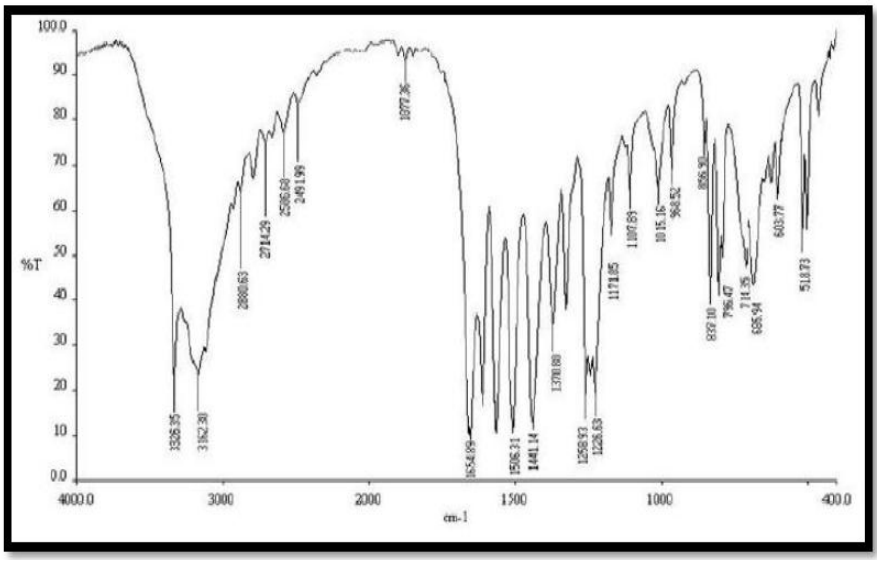

Fig. 3: IR spectra of paracetamol API.

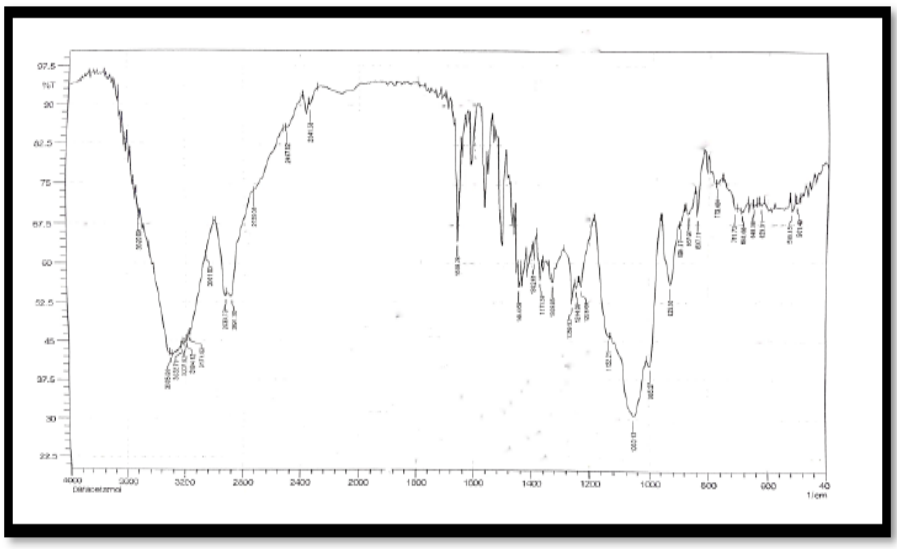

Fig. 4: IR- Spectra of the medicated paracetamol candy.

CONCLUSION

From the above data it is concluded that the medicated paracetamol candy is compatible with the excipients present in it. This medicated paracetamol candy is not having any side effect. This is the best alternative formulation for the neonate as compared to the tablets and the syrup. This medicated paracetamol candy formulation is easily administered to the neonate, this formulation can be administered by placing the formulation on the tongue of the neonate so that the paracetamol drug will enter into the systemic circulation.

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