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Review Article

## Formulation and evaluation of levamisole oral dispersible tablets

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### ABSTRACT

Levamisole is an anthelmintic drug that expel parasitic worms and other internal parasites from the body. The present investigation was to formulate and evaluate Levamisole oral dispersible tablets are prepared by direct compression technique using different super disintegrants such as Crosscarmellose sodium, Cross povidone, Sodium starch glycolate. Evaluation was performed according to the pharmacopoeial standards including drug excipient compatibility determined by FTIR study to identify the interaction between the drug and excipient, all the prepared formulations were evaluated for various pre-compressional parameters such as angle of repose, bulk and tapped density, hausners ratio and the prepared tablets are evaluated for various physico chemical parameters weight variation, thickness, hardness, friability, disintegration, wetting time, *in-vitro* drug dissolution study. The best results were shown in F3 formulation containing the Levamisole 8% and Crosscarmellose sodium 2%. In comparison of *in-vitro* drug dissolution studies for all developed formulations, F3 formulation releases 95-100% of drug at the end of 5min and was considered as best formulation.

**Keywords:** Crosscarmellose sodium; direct compression; levamisole; sodium starch glycolate.

### INTRODUCTION

Among the all routes of administrations oral route of administration have most convenient and preferred route due to various advantages compared with other route of administration ease of administration, avoided pain, versatility and mostly patient compliance. There are different types of dosage forms those are tablets, capsules, pellets etc. The tablets have so many advantages those are convenience to self-administration this tablets are manufactured easily. Some oral dosage forms having some disadvantages that are difficulty swallow the drug in pediatric and geriatric patients. Now a days the recent advances in NDDS to increase the safety and efficacy of the drug that's why the manufacturing of formulati ng dosage form is administration is easy.

This ODTs have other advantages such as improved solubility and stability of drug properties. This solid dosage forms having medicinal substances which can dispersible fastly a few seconds after placed on the tongue. Those ODTs have more advantageous compared with other formulations because of both liquid and conventional tablet formulations, traditional dosage forms. This ODTs provide the convenience of tablet

formulation, easy of swallowing provide by liquid formulations.

The development of oral dispersible tablets formulations have some of the disintegrants like crosscarmellose sodium, cross povidone, sodium starch glycolate. Where the disintegration of ODT tablets on the tongue after administration release the drug in saliva. ODTs are desire to provide patient with more conventional means of taking their medication like taste masking and to enhance the bioavailability of the drug.

### MATERIALS AND METHODS

Here using Levamisole drug received as a gift sample from Drug India Pvt, Ltd., Hyderabad. Crosspovidone, crosscarmellose sodium, sodium starch glycolate, lactose, magnesium stearate, sodium saccharin and talc etc. All the above chemicals and organic solvents used in analytical grade.

### Formulation of ODTs tablets

The drug and excipients weighed accurately and passed through sieve no #40 and mixed thoroughly. The lubricant magnesium stearate are added to the above blended mixture. This Levamisole ODTs formulation was initially developed with different super disintegrants, sodium starch glycolate, cross carmellose sodium, and cross povidone concentration range of 4.5%, 2%, 4%. Tablets are prepared by direct compression technique using rotary punching machine. The tablet weight was 500mg.

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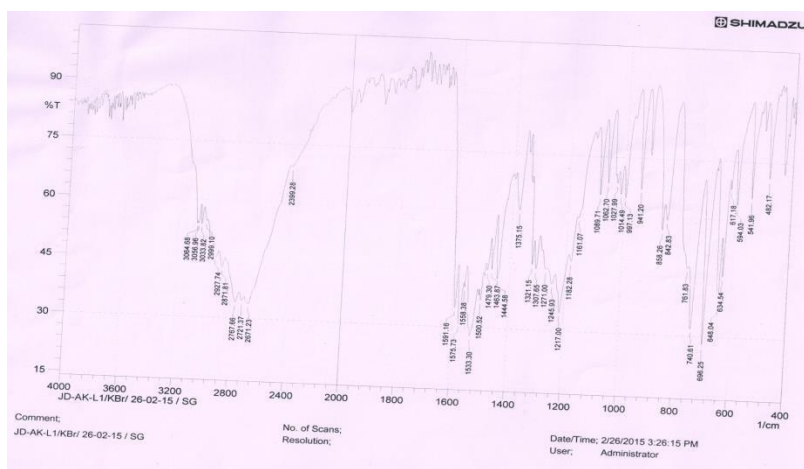
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**Table 1: Physicochemical Parameters of Levamisol**

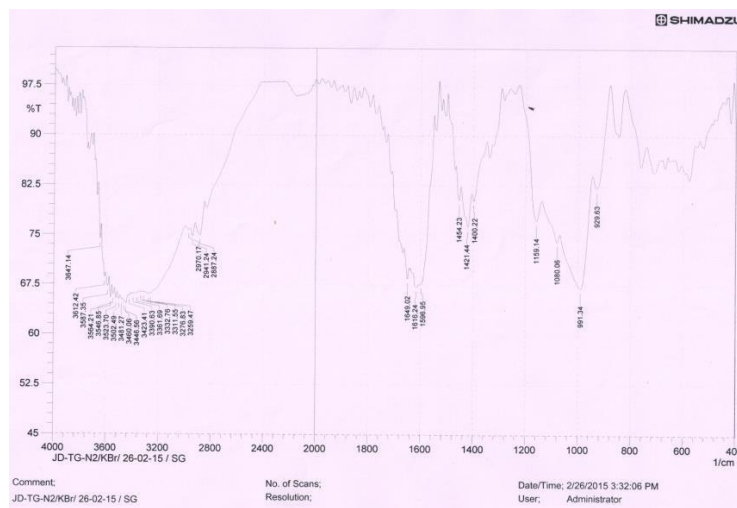
Parameter	F1	F2	F3	F4	F5	F6	F7	F8	F9
Weight variation	502	501	501	503	504	501	500	501	500
Friability (%)	0.49	0.54	0.83	0.52	0.65	0.56	0.71	0.74	0.91
hardness(Kg/Cm2)	3.4	2.9	3.5	3.4	3.3	3.0	3.2	3.0	3.1
thickness(mm)	2.99	2.46	2.90	2.80	2.80	2.77	2.9	2.5	2.4
Disintegration time(Sec)	38.6	38.99	39.99	26.4	27.8	18.11	8.9	12.51	8.96
Wetting time(sec)	53	55	56	42	45	40	41	44	41
Drug content (%)	97	96	99	98	97	96	99	99	99



**Figure 1: FTIR Spectra of Levamisol**

**Table 2: In-vitro dissolution data of Levamisol**

Time (sec)	F1	F2	F3	F4	F5	F6	F7	F8	F9
30	66.70	64.90	65.15	75.26	69.35	65.33	63.66	69.56	68.35
60	76.23	78.65	88.65	83.21	76.45	72.54	78.98	75.95	75.66
90	90.21	88.68	94.65	90.12	89.65	83.22	89.78	85.65	82.32
120	93.15	95.65	98.88	93.45	94.78	93.14	90.31	92.66	94.58



**Figure 2: FTIR Spectra of Levamisol+Soium starch glycolate**

**Evaluation studies**

Were the tablets are evaluated by different parameters.

**Weight variation**

From the all formulations collet 10 tablets were collected and calculate the weight variation.

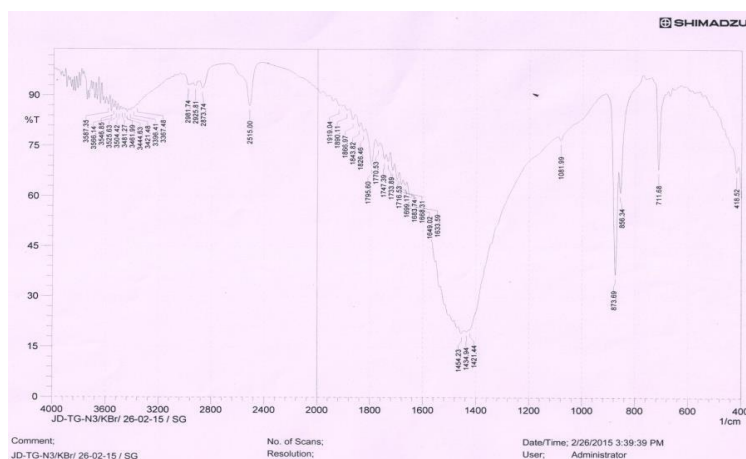


Figure 3: FTIR Spectra of Levamisol+cross carmellose sodium

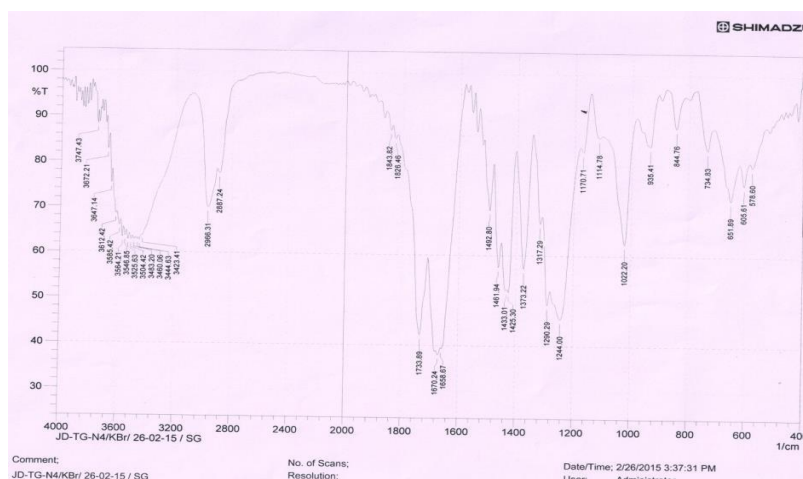


Figure 4: FTIR Spectra of Levamisol+cross povidone

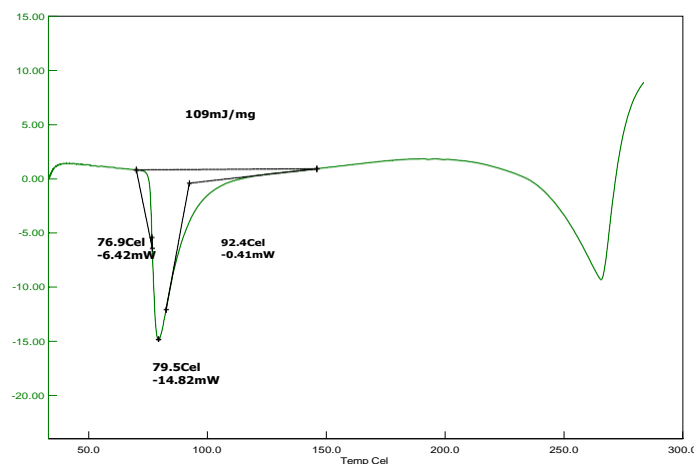


Figure 5: DSC Study of Levamisol

**Thickness**

It is an important characteristic evaluation study of thickness and reproducing appearance using vernier caliper.

**Friability**

The friability is mainly for determine the loss of drug and during transport and handling. Which is deter-

mined by using roche friabilator by using following procedure. It is a plastic chamber revolves at 25 rpm were the preweighed tablets are placed in the friabilator, dropping at a distance of 6 inches. The tablets are rotated for at least 4 min. at the end the test tablets are dusted and reweighed and then calculate the loss in the weight.

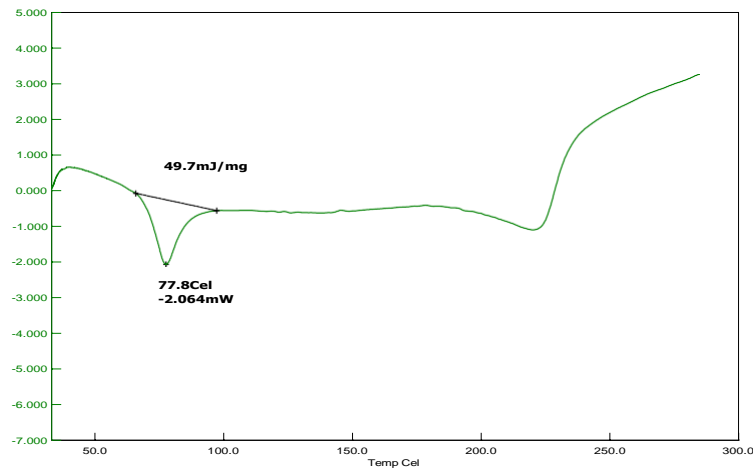


Figure 6: DSC Study of Levamisol+ Cross carmellose

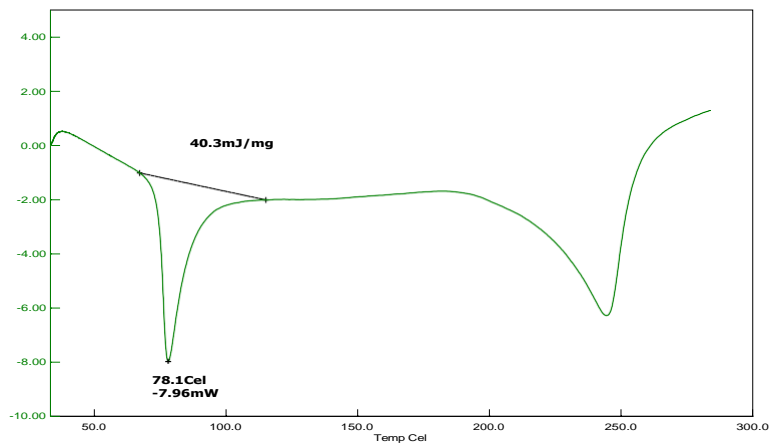


Figure 7: DSC Study of Levamisol+Sodium starch glycolate

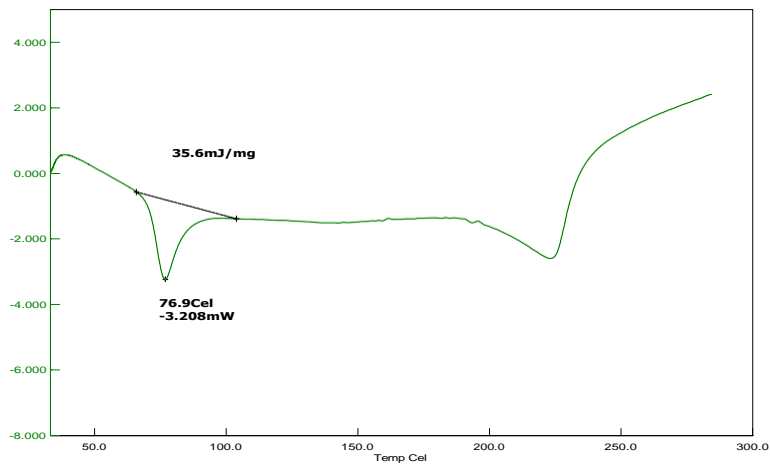


Figure 8: DSC Study of Levamisol+ Cross povidone

**Drug content**

The drug content is determined by collect 10 tablets from each batch equivalent to 40mg of levamisole was dissolve in solvents like methanol or water dilute with pH 7.2 phosphate buffer solution. The absorbance measured by UV spectrophotometry against the blank at wavelength of 213 nm.

**Wetting time**

Which was calculated by using tissue papers (have the diameter of 10cm in diameter) in pertri dish, 10ml of water contain 0.1% of methylene blue was added. The wetting time is noted by tablet placed on tissue paper within time to reach the surface of the tissue paper.

### Disintegration time

The disintegration of tablets determined by disintegration apparatus contains six tubes. The tablets are placed on the inside the tubes for determine the disintegration time.

### In-vitro drug release

*In-vitro* drug release study is determined by using dissolution apparatus at 50rpm speed. Prepare 1000ml of pH 7.2 buffer medium used for dissolution study temperature is  $37 \pm 0.050^{\circ}\text{C}$ . Tracking the dissolution medium at the time intervals and to determine the percentage purity of sample by UV spectroscopy at 213nm.

### Drug-excipient compatibility study

Drug and excipient compatibility studied by FTIR and DSC studies.

### FTIR Spectroscopy

This FTIR spectrums of pure drug Levamisole and drug combined with polymers like SSG, CCS and CP. This FTIR analysis frequency range between 4000 and 400 $\text{cm}^{-1}$  were using little amount of drug.

### DSC Study

DSC study is used to determine the drug and polymer compatibility study performed at a rate 50 $\text{c min}^{-1}$  from 500 $\text{c}$  to 2000 $\text{c}$ .

## DISCUSSION

### Weight variation & thickness

The weight variation is determined by average weight of the tablets 501 and the thickness is determined by 2.45mm to 2.90mm.

### Hardness & friability

The hardness was determined 3 kg/ 2cm during compression and friability for all the formulations have less than 1% is the good mechanical strength.

### Drug content & wetting time

The drug content of levamisole from all the formulations was found to be 97% to 98.9%. Wetting time was found to be between 48-58%.

### Disintegration time

Disintegration time was determined by 1% CCS (F1), 2% CP (F4), 2.5% SSG (F6), taken in 37-38 seconds. Disintegration time is 1.5%CCS (F2), 3%CP (F5), 3.5% SSG (F8), taken in the range of 19-29 seconds. And disintegration time of formulations containing 2% CCS (F3), 4% CP (F6), 4.5% SSG (F9) observed in 9-13sec. by all the formulations observed improved disintegration time.

### In-vitro dissolution

The formulation F3 and F2 shows maximum percentage of drug release and increase the bioavailability of the drug. The odt tablets are contain disintegration within 2min.

## CONCLUSION

It is concluded that the ODT tablets have shown that higher disintegration time and improved dissolution and bioavailability of the drug.

- Here the flow properties of both drug and polymers is good.
- Here the FT-IR studies is to determine the no chemical interaction between Levamisole and polymers used in the study are compatible to each other.
- Here the tablets preparation was good and without any chipping capping and sticking.
- All the formulations shows good results of physico-chemical evaluations.

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