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FORMULATION & EVALUATION OF MOUTH DISSOLVING TABLETS OF DIMENHYDRINATE USING COPROCESSED SUPERDISINTEGRANTS

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ABSTRACT

This research involves preparation of mouth dissolving tablets of Dimenhydrinate by direct compression method using various concentrations of co-processed superdisintegrants i.e. Sodium starch glycolate and crospovidone prepared by different methods viz. Microwave and Lyophilization. SSG and crospovidone used in different ratio (1:1, 1:2, 1:3, 2:1, 2:2, 2:3, 3:1, 3:2 and 3:3). The tablets were evaluated for parameters like thickness, hardness, friability, *In vitro* & *In vivo* disintegration time, wetting time, water absorption ratio, % drug content and *In vitro* drug release studies. Based on the results, formulation containing 6% superdisintegrants in combination (CP:SSG = 3:3) (DL-9) was identified as ideal and better formulation among all formulations developed for Dimenhydrinate tablets. *In vitro* release of optimized formulation of Dimenhydrinate Mouth dissolving tablets (DL-9) prepared by lyophilized technology was found to be 99.98% drug release within 15minutes and *in-vitro* disintegration time being ranges between 33-35sec. Though formulation DM-9 also showed good release (96.83%) prepared by microwave technology but since the release rate & disintegration profile is comparatively poor hence it is not selected. Optimized formulation DL-9 showed very good stability profile. From this observation it was concluded that the formulated tablets of Dimenhydrinate (DL-9) were superior, economic and effective in achieving patient compliance.

KEYWORDS: Dimenhydrinate superdisintegrants crospovidone Lyophilization.

1. INTRODUCTION

Drugs are rarely administered in their original pure state due to various issues like stability, proper dose strength, etc. They are administered in various dosage forms after converting it into a suitable stable formulation.[1] The aim of dosage form is to administer a drug at a therapeutic concentration to a particular site of action for a specified period of time.[2] Oral routes of drug administration are widely used up to 50-60% of total dosage forms.[3]

MDT is not only indicated for people who have swallowing difficulties, but also are ideal for active people.[4] Mouth dissolving tablets are also called as fast-dissolving tablets, melt-in mouth tablets, orodispersible tablets, rapimelts, porous tablets, quick dissolving etc. Fast dissolving tablets are those when put on tongue disintegrate instantaneously releasing the drug which dissolve or disperses in the saliva.[5]

In the present investigation, the preparation and evaluation of fast dissolving tablets by using coprocessed superdisintegrants containing crospovidone and sodium starch glycolate was studied. The reasons for selection of crospovidone are high capillary activity, pronounced hydration capacity and little tendency to form gels.[6] Sodium starch glycolate was chosen because of its high swelling capacity.[7] The concept of formulating fast dissolving tablets (FDT) of metoclopramide hydrochloride (anti-emetic)[8] using co-processed superdisintegrants helps to increase the water uptake with shortest wetting time and thereby decrease the disintegration time of the tablets by simple and cost effective direct compression technique. Various coprocessing techniques used are Solvent Evaporation, Microwave and Lyophilization.

Nausea and vomiting are the most commonly occurring symptoms in majority of pathophysiological conditions such as motion, cancer, pregnancy, and postoperative conditions. Nausea refers to feeling of impending vomiting. Vomiting refers to forceful expulsion of contents of the stomach and the proximal small intestine.[9]

Antiemetic drugs are used to prevent or suppress vomiting. They act by blocking several receptors located in vomiting centres such as H1 histaminic, dopamine D2, 5-HT3 receptor, muscarinic, and neurokinin1(NK1) receptor. Drugs such as Anticholinergics, H1-antihistamines, Neuroleptics, 5-HT3 antagonists act by penetrating blood brain barrier which leads to sedation.[10]

Dimenhydrinate is the diphenhydramine salt of 8-chlorotheophylline.[11] It has the general properties of the antihistamines and is used mainly as an antiemetic in the prevention and treatment of motion sickness. Similar to diphenhydramine, dimenhydrinate has CNS depressant, anticholinergic, antiemetic, antihistaminic and local anesthetic effects. It is well absorbed after oral or parenteral administration. The duration of action is 3–6 h. For motion sickness, 50–100 mg dimenhydrinate is given by mouth at least 30 min before the journey. This dose may be repeated every 4 h if required, but a total daily dose of 300 mg should not be exceeded.[12]

Dimenhydrinate was earlier made as controlled release and buccal release tablets but there were no reported works regarding gastro-retentive floating tablets, hence we have chosen mouth dissolving tablet formulation of dimenhydrinate. In this study, mouth dissolving tablet formulations of dimenhydrinate will be prepared using coprocessed superdisintegrants by direct compression method.

2. MATERIALS AND METHODS

2.1. Materials. Dimenhydrinate (API) was obtained as a gift sample from M/s. Wallace Pharmaceuticals Pvt. Ltd and other excipients Sodium Starch Glycolate, Crospovidone, Mannitol, Microcrystalline Cellulose, Talc, Magnesium Stearate, and Lactose were procured from R.S. Enterprises, Jaipur, India manufactured by Central Drug House (P) Ltd – CDH, New Delhi, India. All chemicals used were of analytical grade.

2.2 Methods

2.2.1 Preparation of physical mixture and co-processed superdisintegrants: The physical mixture of sodium starch glycolate and crospovidone was prepared by mixing them together in glass pestle motor. The coprocessed superdisintegrant was prepared by **Microwave & Lyophilized Technology**. Blends of SSG and crospovidone in different ratio (1:1, 1:2, 1:3, 2:1, 2:2, 2:3, 3:1, 3:2 and 3:3) were prepared.

2.2.2 Preparation of fast dissolving tablets The tablets were prepared by using single punch tablet machine (Cadmach, Ahmedabad) to produce flat faced tablets weighing 200 mg each with a diameter of 5 mm. A minimum of 50 tablets were prepared for each batch. Before compression tablet blends were evaluated for mass-volume relationship (Bulk density, Tapped density, Hausner's ratio, Compressibility index) and flow properties (Angle of repose).

The superdisintegrants (Sodium Starch Glycolate and Crospovidone) coprocessed by various techniques were used to develop the tablets. All the ingredients were shown in Table 1 were passed through sieve no. 60 and were co-grounded in a glass pestle motor.[13-15]

Table 1: Composition of MDT with Coprocessed* Superdisintegrants.

Ingredients	DM1	DM2	DM3	DM4	DM5	DM6	DM7	DM8	DM9
	DL1	DL2	DL3	DL4	DL5	DL6	DL7	DL8	DL9
Drug	50	50	50	50	50	50	50	50	50
SSG	2	2	2	4	4	4	6	6	6
Crospovidone	2	4	6	2	4	6	2	4	6
Avicel PH 102	40	40	40	40	40	40	40	40	40
Mannitol	30	30	30	30	30	30	30	30	30
Talc	5	5	5	5	5	5	5	5	5
Mg. stearate	5	5	5	5	5	5	5	5	5
Lactose (qs)	200	200	200	200	200	200	200	200	200
Ratio(SSG:CP)	1:1	1:2	1:3	2:1	2:2	2:3	3:1	3:2	3:3
% superdisintegrant	2	3	4	3	4	5	4	5	6

*M indicates microwave technique, L indicates lyophilized technique

Nine MDT formulations each weighing 200 mg, were prepared by using constant amount(50mg) of Dimenhydrinate, along with a mixture of Crospovidone, Sodium starch Glycolate at different concentrations viz. 2,3,4,5 & 6% as these superdisintegrants work best in between range of 2% to 8%. Powdered blends, each weighing 200 mg, were then directly compressed using a single punch tablet machine equipped with convex shaped punches with a die diameter of 10 mm. Machine settings were adjusted to get the desired hardness value, which gives an intact tablet.

3. Evaluation Parameters

3.1 Evaluation of Powder Blends: All formulation powder bland batches were evaluated for precompression studies viz. angle of repose, bulk density, tapped density, Carr's consolidation index, and Hausner's ratio as per the official methods. Flow property of all formulation batches for preparing tablets by direct compression technique was accessed through the parameters like Tapped density, Bulk density, Angle of repose, Carr's index, Hausner's ratio. Results were shown in table 2 & 3.

Table 2: Pre-compression characterization of different batches blend of Dimenhydrinate MDT (Microwave Technology).

Batch No.	Bulk Density	Tapped Density	Angle of Repose	Hausner's ratio	Carr's index
DM1	0.447	0.49	25.39	1.09	8.77
DM2	0.458	0.507	23.11	1.10	9.66
DM3	0.46	0.519	24.06	1.12	11.36
DM4	0.463	0.508	25.47	1.09	8.85
DM5	0.481	0.533	23.31	1.10	9.75
DM6	0.465	0.514	26.85	1.10	9.53
DM7	0.463	0.513	25.47	1.10	9.74
DM8	0.473	0.515	25.99	1.08	8.15
DM9	0.469	0.519	24.06	1.10	9.63

Table 3: Pre-compression characterization of different batches blend of Dimenhydrinate for preparing tablets by direct compression technique (Lyophilized Technology).

Batch No.	Bulk Density	Tapped Density	Angle of Repose	Hausner's ratio	Carr's index
DL1	0.443	0.493	25.43	1.11	10.14
DL2	0.454	0.51	23.15	1.12	10.98
DL3	0.456	0.522	24.1	1.14	12.64
DL4	0.459	0.511	25.51	1.11	10.17
DL5	0.477	0.536	23.35	1.12	11.01
DL6	0.461	0.517	26.89	1.12	10.83
DL7	0.459	0.516	25.51	1.12	11.04
DL8	0.469	0.518	26.03	1.10	9.45
DL9	0.465	0.522	24.1	1.12	10.91

Table 2 & 3 reported results of flow properties of powder blends for preparing tablets by direct compression technique. It was found that all the batches exhibited acceptable flow property with respect to angle of repose, Carr's index, Hausner's ratio.

3.2 Evaluation 0f Compressed Tablets

After compression of powder blends, all the prepared batches of MDT's were evaluated for organoleptic characteristics like color, odor, taste and physical characteristics like diameter, thickness, hardness, friability, weight variation, disintegration time, and dissolution studies.

3.2.1 Shape and Colour of Tablets

Randomly picked tablets from each formulation batch examined under lens for shape and in presence of light for colour. Tablets showed flat, circular shape & in white colour.

3.2.2 Thickness Test

Average tablet thickness (Table No. 4 & 5) was found to be consistent throughout the batch. Tablet thickness ranges between 2.07mm to 2.16mm.

3.2.3 Hardness Test

The results of hardness are given in Table No. 4 & 5. Hardness test was performed by Monsanto tester. Hardness was maintained to be within 2.00 kg/cm^2 to 4.20 kg/cm^2, as these tablets are rapidly disintegrating. The lower standard deviation values indicated that the hardness of all the formulations were almost uniform in specific method and possess good mechanical strength with sufficient hardness.

3.2.4 Friability Test

The study results are tabulated in Table No. 4 & 5, was found well within the approved range (<1%) in all the formulation.[16]

3.2.5 Weight Variation Test: 83

20 tablets from each formulation were randomly selected to calculate average weight and standard deviation. All the formulations exhibited uniform weight (as per IP-2010) with low standard deviation values (Table No. 4 & 5). It was found between 200mg to 204mg, indicating the uniformity of the tablets prepared by direct compression method.[17]

3.2.6 Drug Content Uniformity: 88

The drug content of randomly selected tablets was determined. Three trials from each formulation were analyzed spectrophotometrically. The mean value and standard deviation of all the formulations were calculated. The percent drug content of the tablets was found between 97.06% - 100.79% of Dimenhydrinate. Drug content of all the formulations was found to be within the limits (Table 4 & 5) specified in IP 2010, indicating the uniformity of the tablets prepared by direct compression method & melt granulation method.[18]

3.2.7 Wetting Time: 85, 86

Wetting is closely related to inner structure of tablets. The record of the wetting time was shown in Table No. 4 & 5. The wetting time in all the formulation was very fast. This may be due to ability of swelling and also capacity of absorption of water of Superdisintegrants.[19,20]

Table 4: Weight, Thickness, Hardness, Friability & Drug Content of tablets (Microwave Technology).

Form. Code	Uniformity of Thickness (n = 3) (mm)	Diameter (n = 3) (mm)	Hardness (n = 3) (kg/cm2)	Friability %	Weight Variation (n = 20) (mg)	Drug Content Uniformity (n = 10) (%)
DM1	2.15	10.02	2.69	0.51	202	100.79
DM2	2.13	10.05	2.25	0.55	201	98.35
DM3	2.14	10.00	2.47	0.57	203	99.26
DM4	2.12	10.04	2.53	0.59	202	97.06
DM5	2.12	10.02	2.29	0.57	204	98.87
DM6	2.11	10.03	2.45	0.54	201	99.64
DM7	2.13	10.03	2.23	0.51	200	96.69
DM8	2.14	10.04	2.62	0.52	202	97.58
DM9	2.16	10.01	2.51	0.51	201	100.73

Table 5: Weight, Thickness, Hardness, Friability & Drug Content of tablets (Lyophilized Technology)

Form. Code	Uniformity of Thickness (n = 3) (mm)	Diameter (n = 3) (mm)	Hardness (n = 3) (kg/cm2)	Friability %	Weight Variation (n = 20) (mg)	Drug Content Uniformity (n = 10) (%)
DL1	2.11	10.09	2.57	0.54	201	99.23
DL2	2.09	10.12	2.13	0.58	200	98.79
DL3	2.1	10.07	2.35	0.6	202	99.7
DL4	2.08	10.11	2.41	0.62	201	97.5
DL5	2.08	10.09	2.17	0.6	202	100.31
DL6	2.07	10.05	2.33	0.57	201	99.17
DL7	2.09	10.06	2.11	0.54	203	97.13
DL8	2.1	10.11	2.5	0.55	202	98.02
DL9	2.12	10.08	2.39	0.54	204	100.08

3.2.8 Mouth Feel and *In vivo* Disintegration Time

The internal structure of tablets, which is pore size distribution, water penetration into tablets and swelling of disintegration substance are suggested to be the mechanism of disintegration. The results are shown in Table No. 6 & 7. This was determined as per U.S.P 30 NF 25 & Japanese Pharmacopoeia[21] for all the formulations. All formulations showed disintegration time less than 50 seconds. Formulation **DM9 & DL9** showed fast disintegration compared to other formulation due to high concentration of disintegrants.

The results of both parameters are shown in Table No. 6 & 7. The prepared formulations were subjected for mouth feel. The volunteers felt good taste in all the formulations. As the drug is not bitter presence of Mannitol showed good, palatable taste.

Table 6: Results of *in vitro, in vivo* disintegration test with Mouth Feel (Microwave Technology)

Formulation Code	*In vitro* Disintegration Time (Sec)	*In-vivo* Disintegration Time (Sec)	Mouth Feel
DM1	46-49	30-33	Good
DM2	44-48	27-30	Good
DM3	42-44	25-27	Good
DM4	45-47	27-29	Good
DM5	43-45	26-29	Good
DM6	41-44	24-28	Good
DM7	43-45	26-28	Good
DM8	40-43	24-27	Good
DM9	38-40	20-23	Good

Table 7: Results of *in vitro, in vivo* disintegration test with Mouth Feel (Lyophilized Technology)

Formulation Code	*In vitro* Disintegration Time (Sec)	*In-vivo* Disintegration Time (Sec)	Mouth Feel
DL1	44-47	30-33	Good
DL2	42-45	27-30	Good
DL3	40-42	25-27	Good
DL4	41-44	27-29	Good
DL5	38-40	26-29	Good
DL6	36-39	24-28	Good
DL7	37-40	26-28	Good
DL8	35-37	24-27	Good
DL9	33-35	20-23	Good

3.2.9 *In-vitro* Dissolution or Drug release studies[22, 23]

Studies were carried out using USP-II dissolution apparatus. Drug release studies were performed in 0.1 N HCl (1, 2, 4, 6, 8, 10 & 15min). Samples of 1 ml were taken from the medium at the definite time intervals and diluted to ten times by same dissolution media. The samples were assayed by using double beam UV spectrophotometer. Table 8 & fig. 1 showed percentage release of Dimenhydrinate in 0.1 N HCl buffer from tablets prepared by direct compression technique (**Microwave Technology)** and Table 9 & fig. 2 showed percentage release of Dimenhydrinate in 0.1 N HCl buffer from tablets prepared by direct compression

technique (**Lyophilized Technology)**. It was observed that formulation **DM9** show **96.83%** drug release in 15 minutes and formulation **DL9** show **99.98%** drug release in 15 minutes.

Table 8: Percentage release of Dimenhydrinate in 0.1 N HCl buffer from tablets prepared by direct compression technique (Microwave Technology)

Time(min)	DM1	DM2	DM3	DM4	DM5	DM6	DM7	DM8	DM9
1	21.4	24.3	28.03	25.39	29.21	32.12	30.44	33.44	36.67
2	41.3	44.02	47.55	45.2	48.27	51.48	49.68	52.42	54.88
4	55.17	58.08	62.69	59.16	63.62	66.69	64.45	67.52	70.04
6	66.19	69.69	71.85	70.29	73.34	76.23	74.5	77.21	80.39
8	75.28	77.11	80.08	78.45	81.53	84.49	82.56	85.19	88.49
10	80.35	83.25	86.81	84.49	87.25	90.76	87.99	91.19	94.28
15	82.7	85.26	88.14	86.28	89.84	92.7	90.15	93.54	96.83

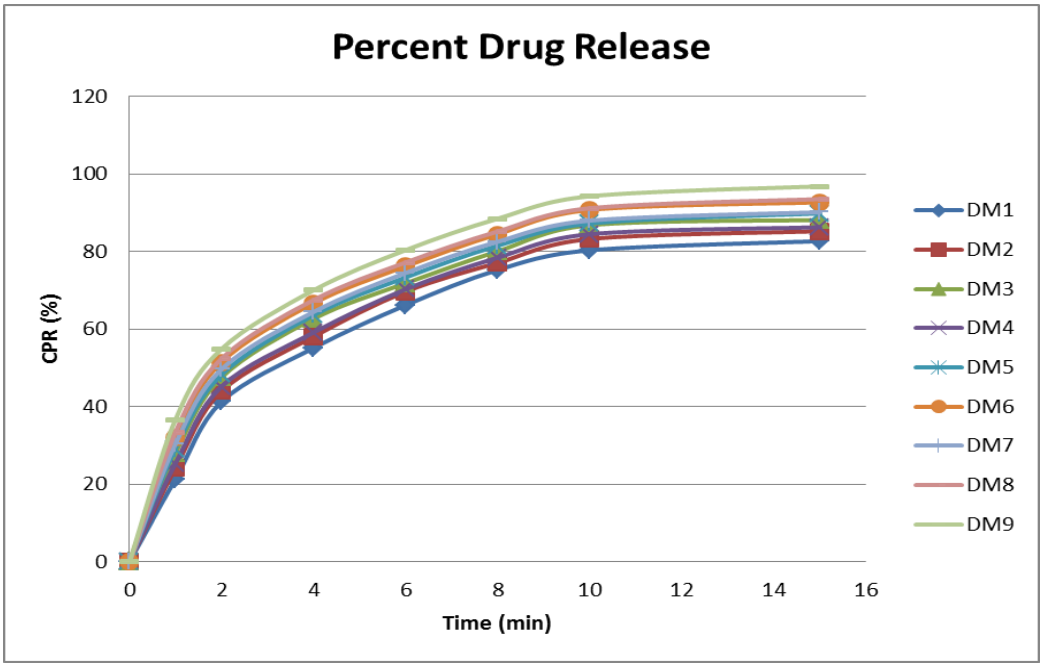

Fig. 1: Percent release of Dimenhydrinate MDTs prepared by direct compression technique (Microwave Technology)

Table 9: Percentage release of Dimenhydrinate in 0.1 N HCl buffer from tablets prepared by direct compression technique (Lyophilized Technology)

Time(min)	DL1	DL2	DL3	DL4	DL5	DL6	DL7	DL8	DL9
1	24.55	27.45	31.18	28.54	32.36	35.27	33.59	36.59	39.82
2	44.45	47.17	50.70	48.35	51.42	54.63	52.83	55.57	58.03
4	58.32	61.23	65.84	62.31	66.77	69.84	67.60	70.67	73.19
6	69.34	72.84	75.00	73.44	76.49	79.38	77.65	80.36	83.54
8	78.43	80.26	83.23	81.6	84.68	87.64	85.71	88.34	91.64
10	83.50	86.40	89.96	87.64	90.40	93.91	91.14	94.34	97.43
15	85.85	88.41	91.29	89.43	92.99	95.85	93.30	96.69	99.98

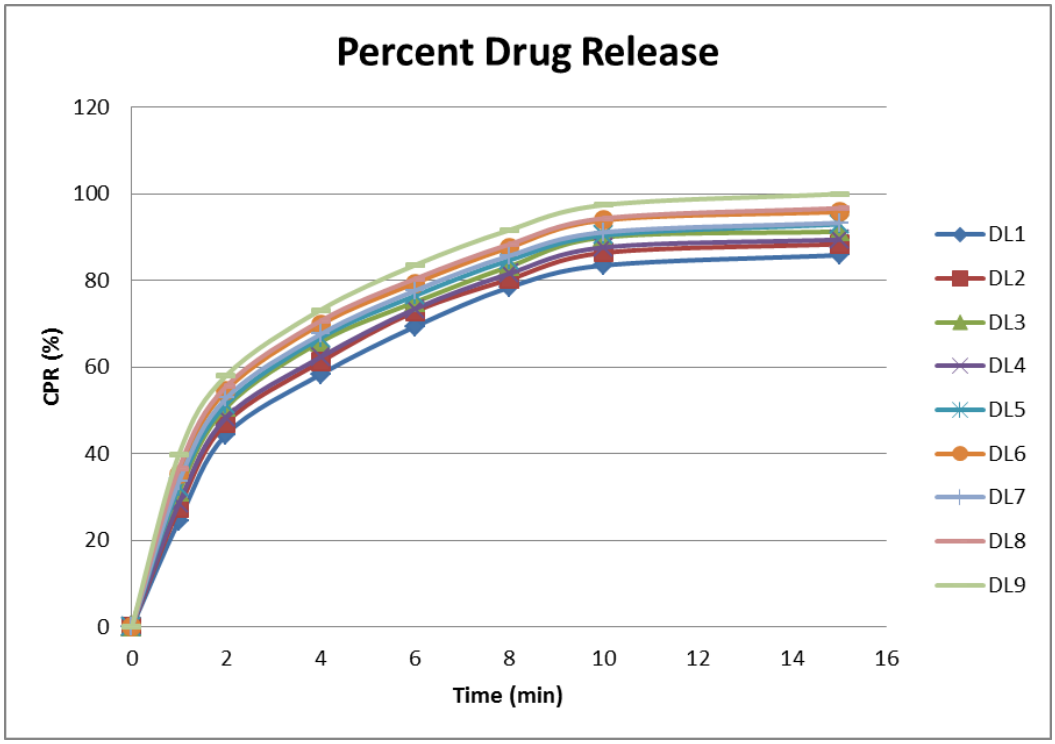

Fig. 2: Percent release of Dimenhydrinate MDTs prepared by direct compression technique (Lyophilized Technology)

4. Study of Release Kinetics of optimized batches[24-26]

The data obtained from *in vitro* dissolution studies were fitted in different models to determine the mechanism of drug release.

Study of Release Kinetics of batch DL9

The correlation coefficient values obtained for all five models, Zero order, first order, Hixon Crowell & Higuchi models were fitted on the optimized formulations. Statistical kinetics values of batch **DL9** is shown in table 10.

Table 10: *In vitro* drug release parameters for Batch DL9.

Time (minutes)	Sqaure root of time	Log time	% CDR	Log %CDR	cumulative drug remaining	Log % cumulative drug remaining
1	1	0.00	39.82	1.600101	60.18	1.78
2	1.414214	0.30103	58.03	1.763653	41.97	1.62
4	2	0.60206	73.19	1.864452	26.81	1.43
6	2.44949	0.778151	83.54	1.921894	16.46	1.22
8	2.828427	0.90309	91.64	1.962085	8.36	0.92
10	3.162278	1	97.43	1.988693	2.57	0.41
15	3.872983	1.176091	99.98	1.999913	0.02	-1.70

Among the entire kinetic model studied for the batch (DL9), it was found that the batch followed **first Order** kinetics because of having maximum R^2 value of **0.974** (closest to 1.0).

5. Stability Study

The stability studies carried out on optimized formulation DL9 at 40±2˚C temperature and 75±5% RH for 90 days. The formulation DL9 was showing good stability with no remarkable changes in Appearance, Drug content, Hardness and *in vitro* drug release profile.

6. CONCLUSION

Mouth dissolving tablets of Dimenhydrinate were formulated using coprocessed super disintegrating Sodium starch glycolate & Crospovidone. Dimenhydrinate was selected for the research work, due to less central nervous system (CNS) side-effects and better pharmacokinetic properties that are well suited for its formulation as MDT. Eighteen batches of Mouth dissolving tablets of Dimenhydrinate were successfully prepared using sodium starch glycolate and crospovidone by direct compression method **(DM1 – DM9 by microwave technology & DL1 – DL9 by lyophilized technology)**.

The tablets were evaluated for parameters like thickness, hardness, friability, *In vitro* & *In vivo* disintegration time, wetting time, water absorption ratio, % drug content and *In vitro* drug release studies. Based on the results, formulation containing 6% superdisintegrants in combination (CP:SSG = 3:3) (DL-9) was identified as ideal and better formulation among all formulations developed for Dimenhydrinate tablets.

In vitro release of optimized formulation of Dimenhydrinate Mouth dissolving tablets of DL-9 was found to be 99.98% drug release within 15minutes and *in-vitro* disintegration time being ranges between 33 and 35sec. Though formulation DM-9 also showed good release (96.83%) prepared by microwave technology but since the release rate & disintegration profile is comparatively poor hence it is not selected.

Optimized formulation DL-9 showed very good stability profile. From this observation it was concluded that the formulated tablets of Dimenhydrinate (DL-9) were superior, economic and effective in achieving patient compliance.

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