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Formulation and *In-Vitro* Evaluation of Doxylamine Oral Dispersible Tablets using Natural and Synthetic Disintegrating Agents

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Abstract
Histamine H1 opponent with articulated narcotic properties. It is utilized in sensitivities and as an antitussive, antiemetic, and mesmerizing. Doxylamine has additionally been managed in veterinary applications and was once in the past utilized in parkinsonism. In the current investigation Doxylamine oral dispersible tablets were prepared DXMN 7 shown 98.21% which is finalized as best formulation.

Keywords
Doxylamine, oral dispersible tablets

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INTRODUCTION
Doxylamine succinate is an antihistaminic commonly used to prevent morning sickness in pregnant women. It is an extremely bitter drug therefore it is very essential to mask the bitter taste. It's formulation into simple tablet may induce vomiting, but formulation of taste masked doxylamine succinate in orodispersible tablet will give rapid action and will prevent morning sickness.

MATERIALS AND METHODS
Doxylamine, Microcrystalline cellulose, Sodium starch glycollate, Crospovidone, Guar gum, Magnesium stearate, Talc all the chemicals were laboratory grade.

Formulation development of Tablets:
All the formulations were prepared by direct compression. The compositions of different formulations are given in Table 1. The tablets were prepared as per the procedure given below and aim is to prolong the release of Doxylamine. Total weight of the tablet was considered as 120mg.

Procedure:
1) Doxylamine and all other ingredients were individually passed through sieve no ≠ 60.
2) All the ingredients were mixed thoroughly by triturating up to 15 min.
3) The powder mixture was lubricated with talc.
4) The tablets were prepared by using direct compression method.

Table 1: Formulation composition for oral dispersible tablets

Ingredients	DXMN1	DXMN2	DXMN3	DXMN4	DXMN5	DXMN6	DXMN7	DXMN8	DXMN9
Doxylamine(mg)	25	25	25	25	25	25	25	25	25
Crospovidone (mg)	25	50	75	-	-	-	-	-	-
Sodium Starch Glycollate (mg)	-	-	-	25	50	75	-	-	-
Guar gum (mg)	-	-	-	-	-	-	25	50	75
Magnesium Stearate(mg)	3	3	3	3	3	3	3	3	3
Talc(mg)	3	3	3	3	3	3	3	3	3
MCC (mg)	Qs	Qs	Qs	Qs	Qs	Qs	Qs	Qs	Qs
Total wt(mg)	120	120	120	120	120	120	120	120	120

All the quantities were in mg, Total weight is 120 mg.

Evaluation of post compression parameters for prepared Tablets

The designed compression tablets were studied for their physicochemical properties like weight variation, hardness, thickness, friability, and drug content.

RESULTS AND DISCUSSION

Standard Calibration curve of Doxylamine:

Table 2: Concentration and absorbance obtained for calibration curve of Doxylamine In pH 6.8 Phosphate buffer

S. No.	Concentration (µg/ml)	Absorbance* (at 257 nm)
1	0.2	0.163
2	0.4	0.342
3	0.6	0.519
4	0.8	0.674
5	1	0.862

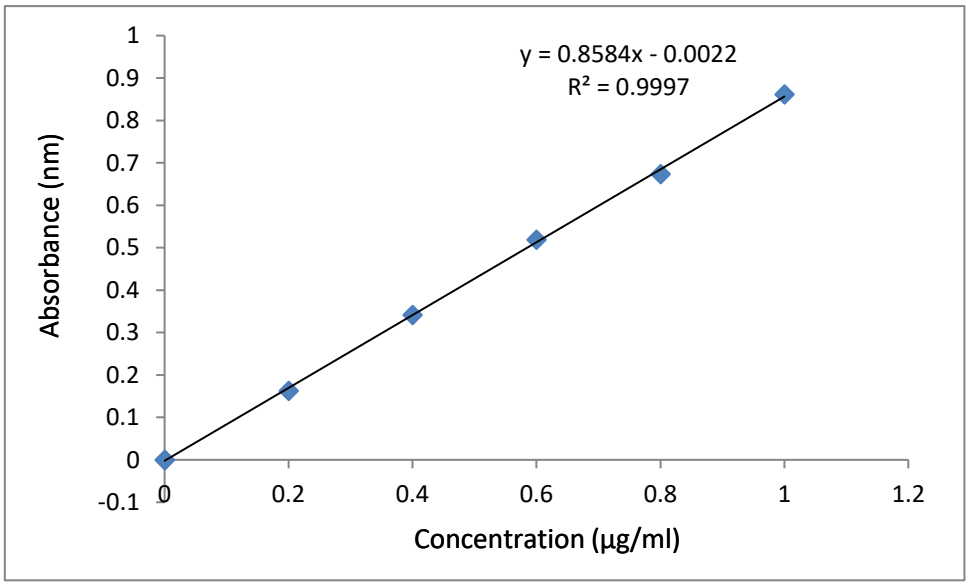

Fig 1: Standard graph of Doxylamine in pH 6.8 Phosphate buffer

Evaluation Parameters for Oral dispersible Tablets of Doxylamine:

Table 3: Pre-compression parameters

Formulations	Bulk Density (gm/cm^2)	Tap Density (gm/cm^2)	Carr's Index (%)	Hausner ratio	Angle Of Repose(Θ)
DXMN1	0.43	0.55	14.26	1.18	25.25
DXMN2	0.45	0.54	16.06	1.17	27.06
DXMN3	0.46	0.57	15.68	1.19	26.17
DXMN4	0.43	0.55	17.25	1.20	28.35
DXMN5	0.47	0.59	15.11	1.17	27.36
DXMN6	0.49	0.56	19.95	1.19	26.05
DXMN7	0.50	0.53	18.04	1.30	26.27
DXMN8	0.51	0.56	20.12	1.27	28.03
DXMN9	0.47	0.57	16.16	1.25	29.36

Table 4: Post-Compression parameters

Formulation code	Weight variation (mg)	Hardness (kg/cm^2)	Thickness (mm)	Disintegration Time (sec)	Friability (%)	Assay (%)
DXMN1	120	2.6	1.47	23.05	0.51	99.10
DXMN2	123	2.4	1.66	20.34	0.53	97.56
DXMN3	118	2.8	1.45	26.36	0.55	99.46
DXMN4	122	2.9	1.52	20.05	0.51	98.05
DXMN5	121	2.8	1.55	22.36	0.55	97.45
DXMN6	121	2.5	1.58	28.45	0.56	97.23
DXMN7	122	2.7	1.54	29.11	0.57	99.06
DXMN8	121	2.7	1.50	27.37	0.54	99.45
DXMN9	120	2.9	1.47	28.44	0.58	98.57

***In-vitro* Dissolution studies:**

Table 5: *In-vitro* dissolution studies of all formulations

TIME (min)	% Drug release of DXMN1	% Drug release of DXMN2	% Drug release of DXMN3	% Drug release of DXMN4	% Drug release of DXMN5	% Drug release of DXMN6	% Drug release of DXMN7	% Drug release of DXMN8	% Drug release of DXMN9
0	0	0	0	0	0	0	0	0	0
2	19.21	17.54	19.77	17.03	23.93	23.97	25.09	14.56	17.11
4	39.33	33.93	35.10	36.75	45.85	45.19	46.34	33.99	43.85
6	58.89	58.95	68.18	63.88	63.72	71.06	71.33	47.74	64.68
8	71.17	68.61	79.92	76.54	79.97	78.91	87.77	64.98	80.97
10	75.53	76.97	85.11	84.27	85.61	85.99	98.21	78.71	86.61

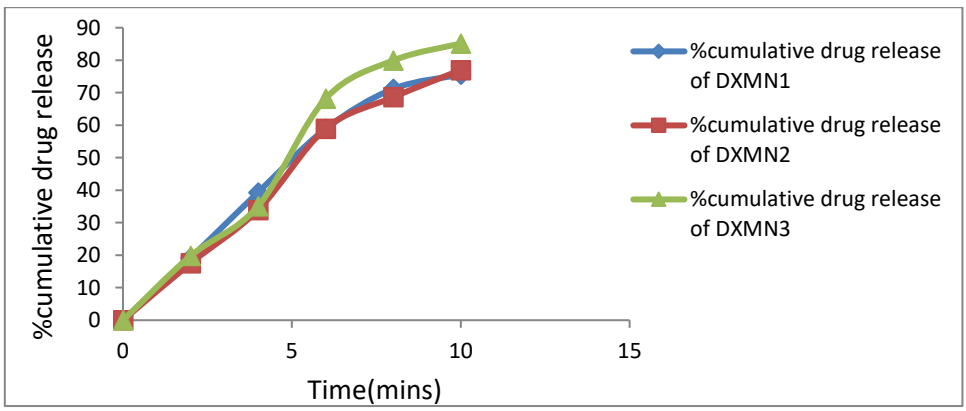

Fig 2:Dissolution profile of formulations prepared with Crospovidone as superdisintegrant

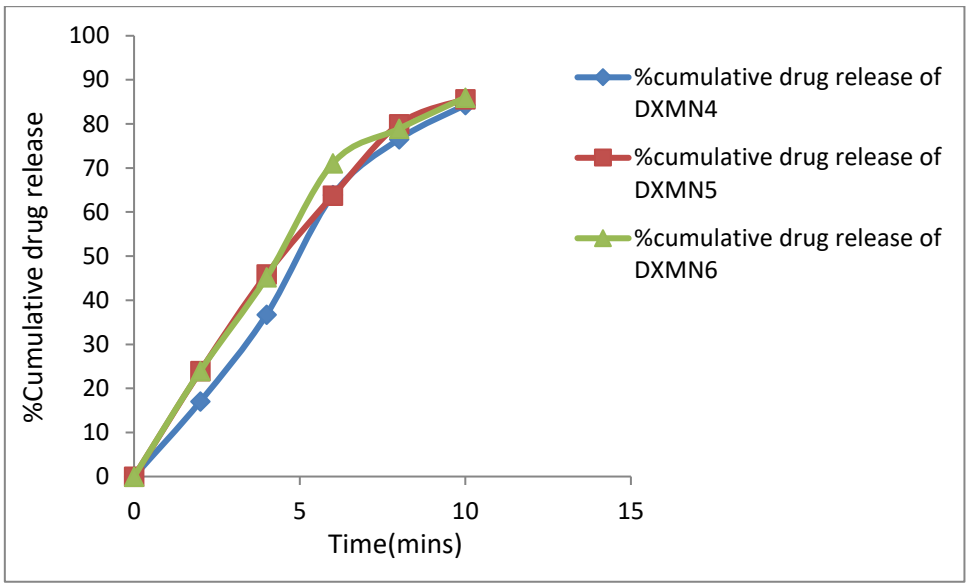

Fig 3: Dissolution profile of formulations prepared with Sodium Starch Glycollate as superdisintegrant

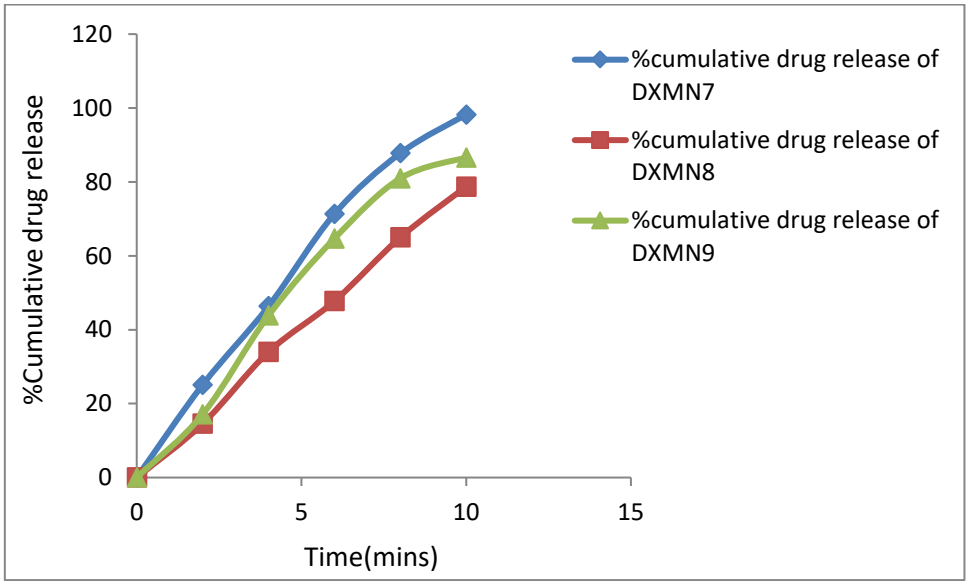

Fig 4: Dissolution profile of formulations prepared with Guar gum as superdisintegrant

CONCLUSION

In the present work, an attempt has been made to develop oral dispersible tablets of Doxylamine. Novel method of co processed super disintegrates technology was employed to formulate the tablets. All the formulations were prepared by direct compression method. The blend of all the formulations showed good flow properties such as angle of repose, bulk density, tapped density. The prepared tablets were shown good post compression parameters and they passed all the quality control evaluation parameters as per I.P limits. Among all the formulations DXMN7 formulation showed maximum drug release i.e., 98.21% in 10 min hence it is considered as optimized formulation.

BIBLIOGRAPHY

1. DebjitBhowmik, S.Duraivel, Rajalakshmi. A.N and K.P.Sampath Kumar Tablet manufacturing processs and defects of tablets Elixir Pharmacy 70 (2014) 24368-24374
2. R.D. Rahane, Dr. Punit R. Rachh A Review On Fast Dissolving Tablet Journal of Drug Delivery & Therapeutics. 2018; 8(5):50-55
3. R. Santosh Kumar, KumariAnnu Oral Disintegrating tablets: waterless patient compliance dosage forms Journal of Drug Delivery & Therapeutics. 2019; 9(1):303-317
4. Nitin K Kapse, Vilas P Bharti, Arunadevi S Birajdar, Anirudha V Munde, Pranita P Panchal Co-Processed Superdisintegrants: Novel Technique for Design Orodispersible Tablets JIPBS, Vol 2 (4), 541-555, 2015
5. P. A. Hannan, J. A. Khan, A. Khan, and S. Safiullah Oral Dispersible System: A New Approach in Drug

Delivery System Indian J Pharm Sci. 2016 Jan-Feb; 78(1): 2–7.

6. Swati L. Khedeka , Subhash V. Deshmane Formulation, Development and Evaluation of Mouth Dissolving Tablet Containing Cyclodextrin as Taste Masker IOSR Journal Of Pharmacy www.iosrphr.org (e)-ISSN: 2250-3013, (p)-ISSN: 2319-4219 Volume 9, Issue 1 Version. I (January 2019), PP. 21-29
7. SamreenFathima Sridhar R Formulation and Evaluation of Clonazepam Oro Dispersible Tablets J Drug Dev Del 2019 Volume 2: 1
8. Greeshma Mohan, Sheri P.S, M.A Kuriachan Formulation and Evaluation of Orodispersible Tablet of Esomeprazole Human Journals Research Article June 2018 Vol.:12, Issue:3
9. SatputeVivek M, K. Shirsat , Rakesh M. Wani, Avinash V. Dhobale , Sagar N. Kharde Formulation And Evaluation Of Rosuvastatin Oral Dispersible Tablet International Journal of Advanced Pharmaceutical Sciences, Volume 1, Issue 08, Page 105-121 ISSN:2456-8147
10. SatputeVivek M., ShirsatMrunal K., Dhobale.Avinash V., WaniRakesh M and KhardeSagar N Formulation and evaluation of atorvastatin calcium oral dispersible tablet International Journal of Current Advanced Research Vol 7, Issue 7(E), pp 14170-14174, July 2018