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Design And Development Of Taste Masked Oral Disintegrating Tablets For Anti-Vertigo Drug

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Abstract: Mouth dissolving tablets are those that dissolve or disintegrate quickly in the oral cavity, resulting in solution or suspension. In the present study Mouth dissolving tablet of Meclizine was prepared by direct compression method using crosspovidone, Crosscarmellose and Indion 414, as superdisintegrants. FT-IR study shows that there is no significant interactions occur between drug and excipient. The tablets prepared were evaluated for various parameters like various density parameters, thickness, hardness, friability, disintegration time, wetting time and In-vitro dissolution time. All the parameters were found to be within limits. The developed formulation of Meclizine batch F8 (9 % Indion 414) showed good palatability and dispersed within 30 seconds as compared to crosscarmellose.

Index Terms-Mouth dissolving tablets**,** crosspovidone**,** superdisintegrants**,** Indion414 andFT-IR

I. INTRODUCTION

Drug Delivery Systems (DDS) area strategic tool for expanding markets/indications, extending product life cycles and generating opportunities. DDS make a significant contribution to global pharmaceutical sales through market segmentation, and are moving rapidly. Drug delivery systems are becoming increasingly sophisticated as pharmaceutical scientists acquire a better understanding of the physicochemical and biochemical parameters pertinent to their performance1.

Despite of tremendous advancements in drug delivery, the oral route remains the perfect route for the administration of therapeutic agents because of low cost of therapy, ease of administration, accurate dosage, self‐medication, pain avoidance, versatility, leading to high levels of patient compliance. Tablets and capsules are the most popular dosage forms. But one important drawback of such dosage forms is 'Dysphagia' or difficulty in swallowing. This is seen to afflict nearly 35% of the general population. This disorder is also associated with a number of conditions like:

1. Parkinsonism
2. Motion sickness
3. Unconsciousness
4. Elderly patients
5. Children
6. Mentally disabled persons
7. Unavailability of water

Improved patient compliance has achieved enormous demand. Consequently demand for their technologies is also increasing many folds. To develop a chemical entity, a lot of money, hard work and time are required. So focus is rather being laid on the development of new drug delivery systems for already existing drugs, with enhanced efficacy and bioavailability, thus reducing the dose and dosing frequency to minimize the side effects. It is always the aim of a scientist or a dosage form designer to

enhance the safety of a drug molecule while maintaining its therapeutic efficacy. Recent advances in Novel Drug Delivery Systems (NDDS) aim for the same by formulating a dosage form, convenient to be administered so as to achieve better patient compliance. Pharmaceutical technologists have put in their best efforts to develop a Fast Dissolving Drug Delivery System, i.e DispersibleTablet1.

Orally Disintegrated Tablet (OODT)

It is a tablet that disintegrates and dissolves rapidly in the saliva, within a few seconds without the need of drinking water or chewing. A Dispersible tablet usually dissolves in the oral cavity within 15 s to 3 min. Most of the ODTs include certain super disintegrants and taste masking agents.

IdealpropertiesofODT

1. AOrallyDisintigratedTabletshould
    a. Notrequirewaterorotherliquidtoswallow.
    b. Easilydissolveordisintegrateinsalivawithinafewseconds.
    c. Haveapleasingtaste.
    d. Leavenegligibleornoresidueinthemouthwhenadministered.
2. Beportableandeasyto transport.
3. Beabletobemanufacturedinasimpleconventionalmannerwithinlowcost.
4. Belesssensitivetoenvironmentalconditionsliketemperature,humidityetc1.

Advantagesof ODT

1. Noneedofwatertoswallowthetablet.
2. Canbeeasilyadministeredtopediatric,elderlyandmentallydisabledpatients.
3. Accuratedosingascomparedtoliquids.
4. Dissolutionandabsorptionofdrugisfast,offeringrapidonsetofaction.
5. Bioavailabilityofdrugsisincreasedassomedrugsareabsorbedfrommouth,pharynxand esophagusthroughsalivapassing down into the stomach.
6. Advantageousoverliquidmedicationintermsofadministrationaswellastransportation.
7. Firstpassmetabolismisreduced,thusofferingimprovedbioavailabilityandthusreduceddoseandsideeffects.
8. Freeofriskofsuffocationduetophysicalobstructionwhenswallowed,thusofferingimprovedsafety.
9. Suitableforsustained/controlledreleaseactives1.

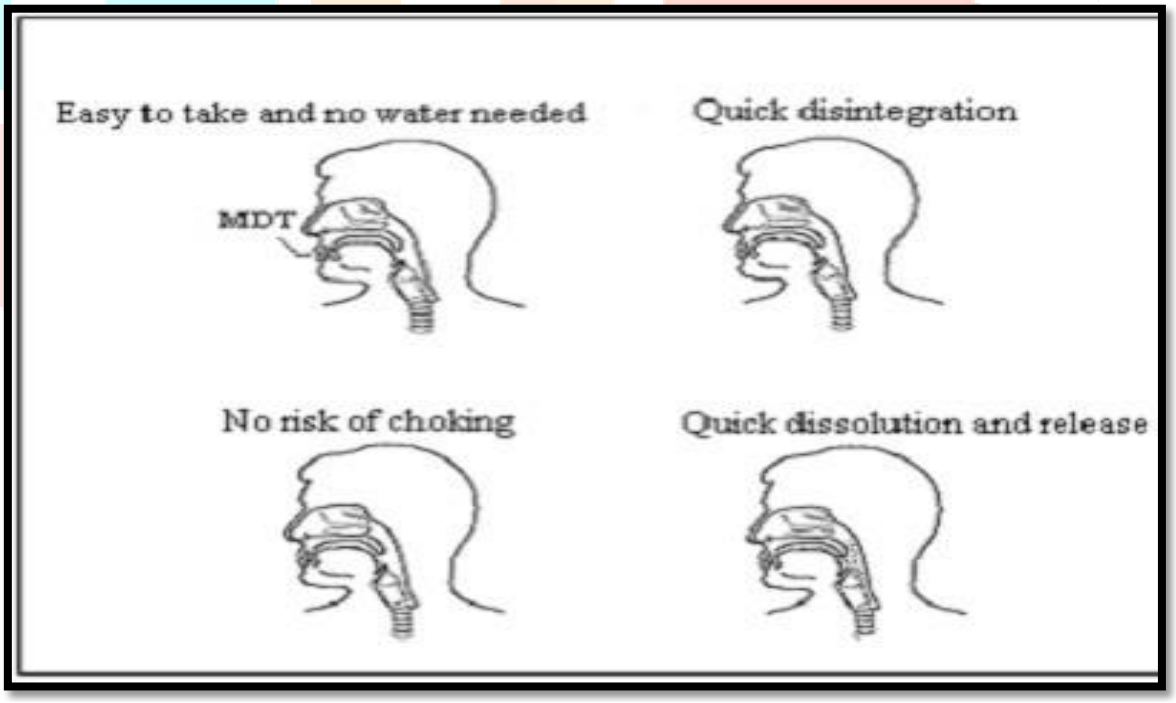


Fig.1:AdvantagesofODT

1.6Mechanismofactionof disintegrants

Thetabletbreakstoprimaryparticlesbyoneormoreofthemechanismslistedbelow:-

a. Bycapillaryaction
b. Byswelling
c. Becauseofheatofwetting
d. Duetoreleaseofgases
e. Byenzymaticaction
f. Duetodisintegratingparticle/particlerepulsiveforces
g. Dueto deformation

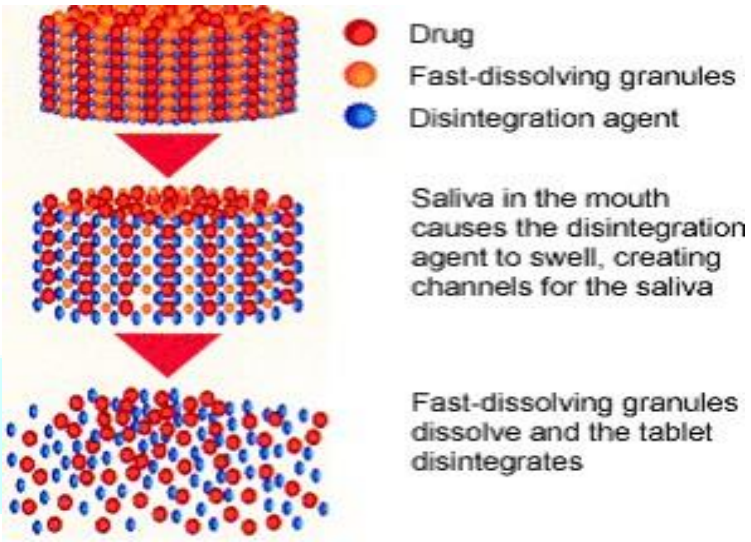


Fig.2:MechanismofActionofSuperdisintegrants

2. FormulationDevelopment

The mouth dissolving tablet prepared by superdisintegrant addition method. The tablets were formulated employing direct compression method using 8 mm biconcave punches. It is the process by which tablets are compressed directly from mixtures of the drug and excipients without preliminary treatment such as granulation.

Drug (10 mg), super disintegrants in different ratios and excipients were blended using mortar and pestle. The drugand the disintegrants were sieved through mesh # 120 before blending. The mixture was evaluated for angle of repose, bulk density and compressibility. The mixture was mixed with 1% magnesium stearate as lubricant and mint as flavoring agent. The powder blends were thencompressed byusingFluidpack multistationrotarytablet machine using8 mmpunch. The hardness was adjusted to 2-5 kg/cm2.

Table1.FormulationofMouth-disssolvingtablets

Ingredients(mg)	**F1**	**F2**	**F3**	**F4**	**F5**	**F6**	**F7**	**F8**	**F9**
Meclizine	25	25	25	25	25	25	25	25	25
MCC(PH-102)	14	14	14	14	14	14	14	14	14
Crosscarmellosesodium	9	13.5	18	-	-	-	-	-	-
Crosspovidone	-	-	-	9	13.5	18	-	-	-
Indion414	-	-	-	-	-	-	9	13.5	18
Povidone	1	1	1	1	1	1	1	1	1
PearlitolSD200	89	84.5	80	89	84.5	80	89	84.5	80
Aspartame	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s
Talcumpowder	1%	1%	1%	1%	1%	1%	1%	1%	1%
Mg.Stearate	1%	1%	1%	1%	1%	1%	1%	1%	1%

3. EvaluationStudiesofpowderparameters(Pre-Formulation):-

TableNo.2:PreformulationstudiesofVariousbatches

Batch	Angle of Repose(θ)/ ± SD	BulkDensity (g/cc)/ ±SD	Tapped Density (g/cc)/±SD	(%) Compressibility/±SD	Hausner's Ratio/±SD
F1	33.13^0±0.003	0.47± 0.007	0.54±0.003	14.23±1.601	1.16± 0.802
F2	32.55^0 ±0.201	0.44± 0.017	0.50±0.017	12.62±1.032	1.14± 0.010
F3	33.25^0 ±0.045	0.56 ±0.024	0.66±0.038	15.15± 1.926	1.16 ±0.802
F4	31.21^0 ±0.675	0.48 ±0.003	0.54 ±0.003	12.40± 0.954	1.14 ±0.010
F5	38.36^0 ±1.852	0.45 ±0.014	0.48 ±0.024	5.20± 1.590	1.06 ±0.017
F6	33.74^0 ±0.219	0.47 ±0.007	0.50 ±0.017	5.25± 1.573	1.06 ±0.017
F7	32.05^0 ±0.378	0.48 ±0.003	0.56 ±0.003	6.36± 1.180	1.14 ±0.010
F8	31.03^0 ±0.738	0.51 ±0.007	0.54 ±0.003	4.42± 1.866	1.04 ±0.024
F9	32.82^0 ±0.106	0.53 ±0.014	0.60 ±0.017	11.66± 0.692	1.13 ±0.007

4. EvaluationofTablet(Post-Formulation):-

TableNo.3:Physicalevaluationofformulatedtabletbatches

Parameter	F1	F2	F3	F4	F5	F6	F7	F8	F9
Thickness(mm)/± SD	2.61 ±0.00	2.64 ±0.01	2.63 ±0.01	2.62 ±0.01	2.64 ±0.01	2.61 ±0.00	2.51 ±0.02	2.52 ±0.02	2.54 ±0.01
Hardness (kg/cm^2)/±SD	3.6 ±0.17	3.2 ±0.19	2.9 ±0.07	3.4 ±0.10	3.1±0.00	3.4 ±0.10	3.2 ±0.19	2.9±0.07	2.5±0.21
Friability (%w/w)/±SD	0.21 ±0.11	0.73 ±0.06	1.16 ±0.21	0.53 ±0.00	0.41 ±0.04	1.07 ±0.18	0.12 ±0.14	0.32 ±0.07	0.33 ±0.07
Wettingtime(sec)/ ±SD	19 ±0.51	14 ±1.21	16 ±0.50	15 ±0.86	18 ±0.19	19 ±0.55	16 ±0.50	12 ±1.92	28 ±3.73
Disintgrationtime (sec)/± SD	25 ±0.86	21 ±0.54	22 ±0.19	27 ±1.57	24 ±0.51	25 ±0.86	23 ±0.15	17 ±1.96	19 ±1.25
Drugcontent (%w/v)/±SD	87.53 ±0.20	87.80 ±0.10	88.16 ±0.01	87.48 ±0.22	87.80 ±0.10	78.40 ±3.43	87.96 ±0.05	95.11 ±0.93	92.76 ±1.64
Dissolution (%w/v)/±SD	67.71± 5.83	81.32±1.02	69.0 ±5.38	89.43±1.84	85.53±0.46	87.93±1.31	89.98±2.03	95.48±3.98	91.68±2.63

TableNo.3:StandardCalibrationcurve

Conc.(mcg/ml)	Absorbance	±S.D.
0	0.0000	0.00
15	0.225	±0.036
30	0.285	±0.012
45	0.341	±0.01
60	0.401	±0.034
75	0.438	±0.049
90	0.523	±0.084

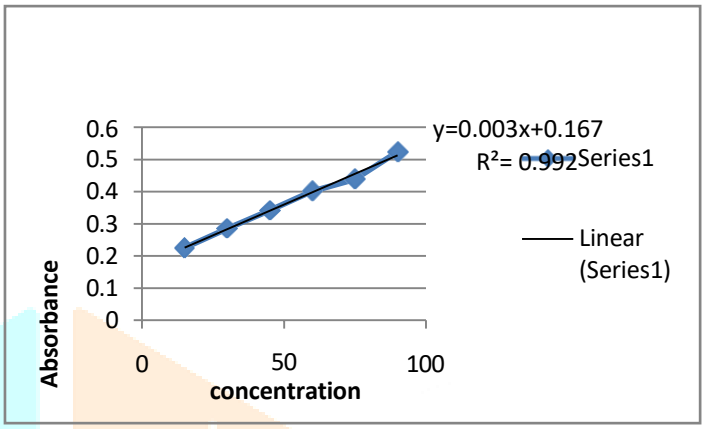


Fig.No.3:StandardcalibrationcurveofMECLIZINE

TableNo.4:Comparativestudyof%DrugreleasefromMouthdissolvingtabletofBatchF1,F2and F3

Timei n Min	%drugrelease		
	F1	F2	F3
30 sec	9.44	14.73	11.08
60 sec	20.41	29.76	21.87
90 sec	31.71	48.40	33.40
2	43.18	61.49	44.98
3	53.33	77.80	56.80
4	67.71	81.32	69.0

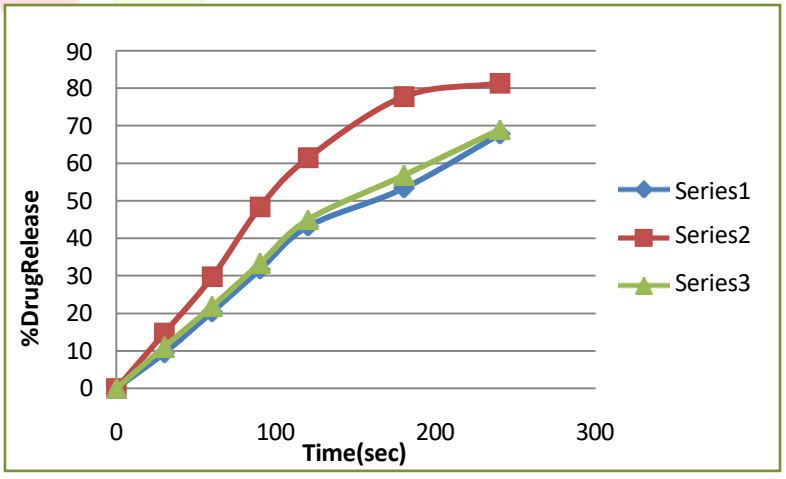
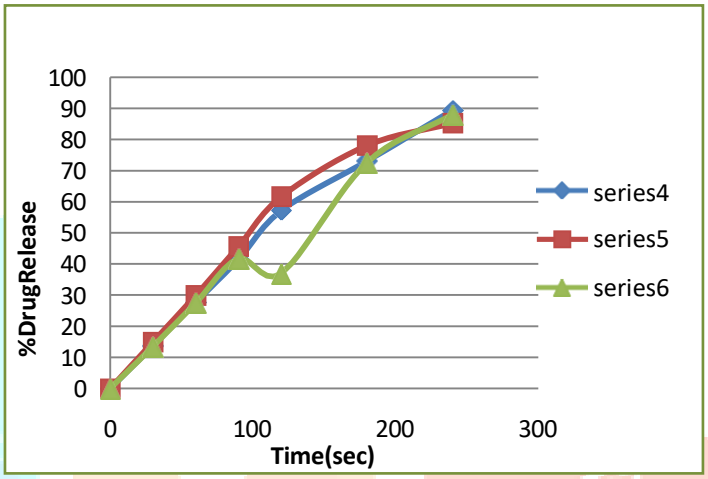


Fig.No.4:Comparativestudyof%Drugrelease(BatchF1,F2and F3)

TableNo.5:ComparativestudyofDrugreleasefromMouthdissolvingtabletofBatchF4,F5and F6

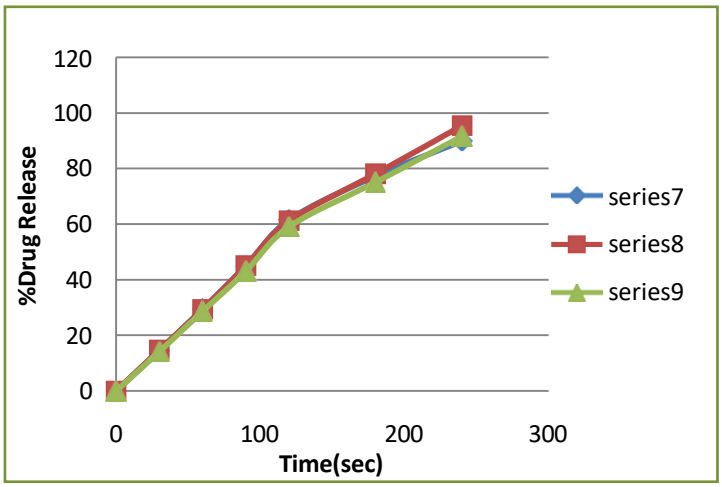
Timein Min	%drugrelease		
	F4	F5	F6
30 sec	13.72	14.96	13.5
60 sec	27.75	29.95	27.47
90 sec	41.55	45.7	41.73
2	57.26	61.71	36.96
3	73.12	78.1	72.6
4	89.43	85.3	87.93



FigNo.6:Comparativestudyof%Drugrelease(BatchF4,F5and F6)

TableNo.6:ComparativestudyofDrugreleasefromMouthdissolvingtabletofBatchF7,F8and F9

Timein Min	%drugrelease		
	F7	F8	F9
30 sec	14.58	14.73	14.17
60 sec	29.55	29.33	28.68
90 sec	45.0	45.08	43.13
2	61.61	61.28	59.17
3	77.36	78.16	75.15
4	89.98	95.48	91.68



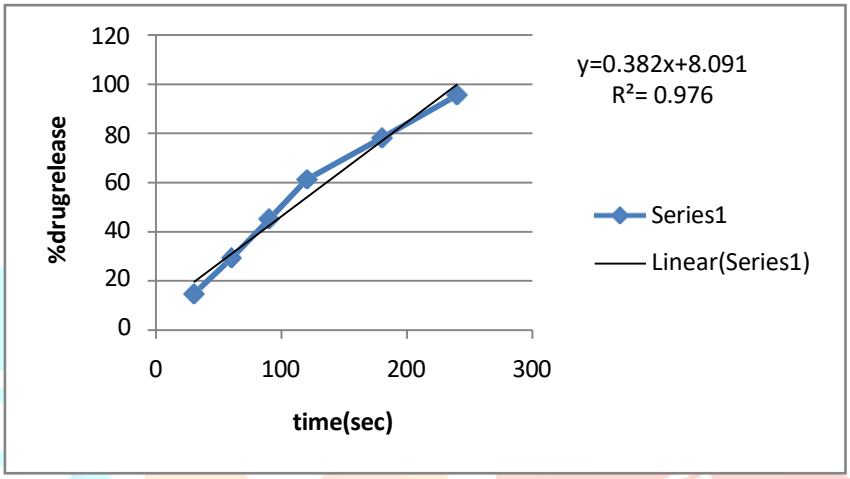
FigNo.7:Comparativestudyof%Drugrelease(BatchF7,F8and F9)

5. MechanismofReleasefromMatrixtablets:

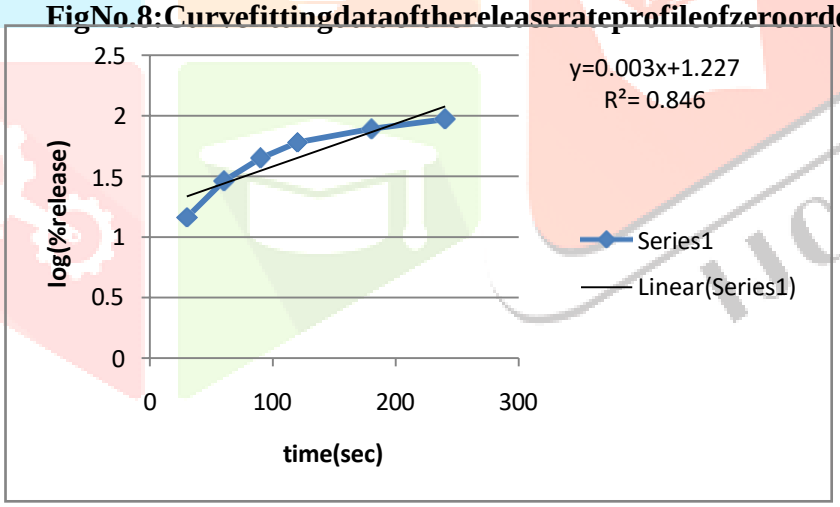
Fromthedataobtainedafterapplyingallsuitablemathematicalmodelswecanconclude thattheoptimizedformulationsselected are proposed to explain the mechanism of release of drug from formulation

Tableno.7:Drugreleasekineticstudyofoptimizedbatch

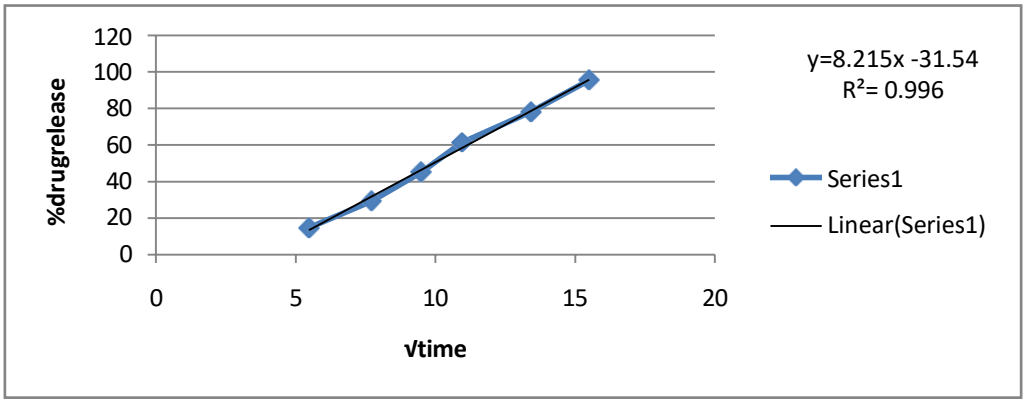
MODELS		F_8 (MECLIZINE)
Korsmeyer-peppas	n	0.987
Zeroorder	R	0.976
Firstorder	R	0.846
Higuchimodel	R	0.996
Bestfitmodel		Higuchi



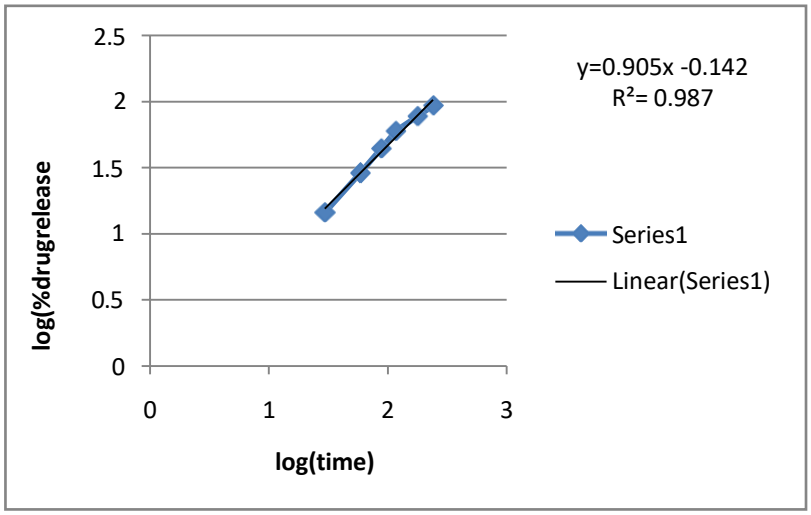
FigNo.8:Curvefittingdataofthereleaserateprofileofzeroorder.



FigNo.9:Curvefittingdataofthereleaserateprofileoffirstorder.



FigNo.10:CurvefittingdataofthereleaserateprofileofHiguchimodel



FigNo.11:CurvefittingdataofthereleaserateprofileofKorsmeyer-peppas

4. Conclusion

Inpresent studyMeclizine Mouthdisolvingtablet prepared usingdifferent types and concentrations of superdisintegrant by direct compression method which was confirmed by various characterization and evaluation studies. Indion 414 as superdisintegrant gives better result as compared to crosscarmellose sodium and crosspovidone. Tablets disintegrate within 30 sec in mouth having better mouth feel.

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