

LIST OF TABLES

TABLE NO.	TITLE	PAGE NO.
3.1	Digestive enzymes and their functions	16
3.2	Pharmacopoeial specifications for fungal alpha amylase	27
3.3	Pharmacopoeial specifications for β -cyclodextrin	45
3.4	Physical characteristics of cyclodextrin	47
3.5	Pharmacopoeial specifications for cellulose acetate phthalate	52
3.6	In vitro folding aids	55
4.1	Oral liquid formulation Batch Co-L-1 and Co-L-2 without addition of cofactor and refolding aid	98
4.2	Oral liquid formulation Batch Co-L-3 to Co-L-5 with addition of refolding aid	99
4.3	Oral liquid formulation with cofactor calcium chloride	100
4.4	Oral liquid formulation with cofactor calcium gluconate	101
4.5	Oral liquid formulation with cofactor calcium lactate	102
4.6	Oral liquid formulation with cofactor calcium propionate	103
4.7	Dry syrup formulation Batch Co-DS-1 and Co-DS-2 prepared by wet granulation method	106
4.8	Dry syrup formulation Batch Co-DS-3 and Co-DS-4 prepared by dry mixing method	107
4.9	Oral drop formulations Batch Co-D-1 to Co-D-4	111
4.10	Hard gelatin capsule formulation Batch Co-C-1 and Co-C-2	112
4.11	Enteric sugar coated tablet- Batch ES-T-1-tablet core formula	123
4.12	Enteric sugar coated tablet - Batch ES-T-1-enteric coating formula	123
4.13	Enteric sugar coated tablet- Batch ES-T-1-sugar coating formula	124
4.14	Matrix tablet formulation Batch ES-MT-1 to ES-MT-4-core tablet formulation	129
4.15	Matrix tablet formulation Batch ES-MT-5 to ES-MT-7-core tablet formulation	130
4.16	Matrix tablet Batch ES-MT-7- sugar coating formula	131

4.17	Fungal alpha amylase enteric pellets formulation-Batch ES-P-1	134
4.18	Pepsin nonenteric Pellets formulation- Batch NES-P-1	135
4.19	Hard gelatin capsule containing enteric pellets of amylase and nonenteric pellets of pepsin- Batch ESP-C-1	135
4.20	Enteric coated powder of amylase- Batch ECP-1 and ECP-2	137
4.21	Enteric coated amylase and pepsin hard gelatin capsule formulation- Batch ECP-C-1	139
4.22	Enteric coated amylase and pepsin tablet- Batch ECP-T-1	141
4.23	Enteric coated amylase and pepsin dry syrup formulation- Batch ECP-DS-1	143
4.24	Oral liquid formulation with inclusion complex Batch IC-L-1 and IC-L-2	148
4.25	Oral liquid formulation with inclusion complex Batch IC-L-3 and IC-L-4	149
5.1	Results from accuracy study of radial diffusion method for fungal alpha amylase	160
5.2	Results of precision study of radial diffusion method for fungal alpha amylase	161
5.3	Results of linearity study of radial diffusion method for fungal alpha amylase	162
5.4	Results of ruggedness study of radial diffusion method for fungal alpha amylase	163
5.5	Results of robustness study of radial diffusion method for fungal alpha amylase	164
5.6	Results of analytical solution stability of radial diffusion method for fungal alpha amylase	165
5.7	Initial analysis of market brands of fungal alpha amylase	169
5.8	Near expiry analysis of market brands of fungal alpha amylase	169
5.9	Effect of pH on fungal alpha amylase activity	170
5.10	Stability data cum characterization of fungal alpha amylase powder	172
5.11	Stability data of fungal alpha amylase in mixed phosphate buffer pH 7.0	173
5.12	Effects of salts on fungal alpha amylase activity	174

5.13	% Activity of fungal alpha amylase recovered in presence of disodium EDTA	183
5.14	Stability cum characterization of oral liquid formulation without addition of cofactor and refolding aid- Batch Co-L-1 and Co-L-2	186
5.15	Stability cum characterization of oral liquid formulation with refolding aid -Batch Co-L- 3 to Batch Co-L- 5	187
5.16	Stability cum characterization of oral liquid formulation with refolding aid -Batch Co-L- 6 to Batch Co-L- 8	188
5.17	Stability cum characterization of oral liquid formulation with refolding aid -Batch Co-L- 9 to Batch Co-L- 11	189
5.18	Stability cum characterization of oral liquid formulation with refolding aid- Batch Co-L- 12 to Batch Co-L- 14	190
5.19	Stability cum characterization of oral liquid formulation with refolding aid- Batch Co-L- 15 to Batch Co-L- 17	191
5.20	Stability cum characterization of oral liquid formulation with refolding aid- Batch Co-L- 18 to Batch Co-L- 20	192
5.21	Stability cum characterization of oral liquid formulation with refolding aid -Batch Co-L- 21	193
5.22	Characterization of dry syrup batches Co-DS-1 to Co-DS-4	196
5.23	Characterization cum stability of reconstituted dry syrup Batch Co-DS-1 to Co-DS-4 at 30°C	197
5.24	Stability study data of dry syrup -Batch Co-DS-1 and Co-DS-2	198
5.25	Stability study data of dry syrup -Batch Co-DS- 3 and Co-DS- 4	199
5.26	Stability cum characterization of oral drop formulations-Batch Co-D-1 and Co-D-2	202
5.27	Stability cum characterization of oral drop formulations-Batch Co-D- 3 and Co-D- 4	203
5.28	Characterization of capsule blend-Batch Co-C-1 and Batch Co-C-2	206
5.29	Characterization of hard gelatin capsule-Batch Co-C-1 and Batch Co-C-2	207
5.30	Stability study of hard gelatin capsule- Batch Co-C- 1 and Co-C- 2	208
5.31	In-vitro stability of fungal alpha amylase at pH 1.2	211
5.32	In-vitro stability of fungal alpha amylase at different pH 1.2 – 5.0 – 6.8	212

5.33	In-vitro stability of fungal alpha amylase at different pH 3.0 – 5.0 – 6.8	213
5.34	In-vitro stability of fungal alpha amylase at different pH 4.0 – 5.0 – 6.8	214
5.35	In-vitro stability of fungal alpha amylase at different pH 5.0 – 6.8	215
5.36	Fungal alpha amylase market sample in-vitro stability in Gut	216
5.37	Evaluation of granules prepared for enteric sugar coated tablet	221
5.38	Evaluation of uncoated tablets prepared for enteric sugar coated tablet	222
5.39	Evaluation of enteric tablets prepared for enteric sugar coated tablet	223
5.40	Evaluation of enteric sugar coated tablet	224
5.41	Stability study data of enteric sugar coated -Batch ES-T-1	226
5.42	Evaluation of granules prepared for sugar coated matrix tablets- Batch ES-MT-1 to ES-MT-4	231
5.43	Evaluation of granules prepared for sugar coated matrix tablets- Batch ES-MT-5 to ES-MT-7	232
5.44	Evaluation of uncoated tablets prepared for sugar coated matrix tablets- Batch ES-MT-1 to ES-MT-7	233
5.45	Fungal alpha amylase release from uncoated matrix tablets Batch ES-MT-1 to ES-MT-7 at buffer stage	234
5.46	Evaluation of sugar coated matrix tablets - ES-MT-7	236
5.47	Stability data of sugar coated matrix tablets	237
5.48	Evaluation of fungal alpha amylase enteric coated pellets	241
5.49	Evaluation of pepsin uncoated pellets	242
5.50	Evaluation of hard gelatin capsule containing fungal alpha amylase enteric coated pellets and pepsin uncoated pellets	243
5.51	Stability study of hard gelatin capsule containing fungal alpha amylase enteric coated pellets and pepsin uncoated pellets -Batch ESP-C-1	246
5.52	Evaluation of enteric coated fungal alpha amylase powder Batch ECP-1 and ECP-2	250
5.53	Particle size analysis of enteric coated powder of fungal alpha amylase Batch ECP-1 and ECP-2	252

5.54	Characterization of hard gelatin capsule blend containing enteric coated fungal alpha amylase and pepsin powder-Batch ECP-C-1	259
5.55	Characterization of hard gelatin capsule containing enteric coated fungal alpha amylase and pepsin powder-Batch ECP-C-1	260
5.56	Stability study of hard gelatin capsule containing enteric coated fungal alpha amylase and pepsin powder-Batch ECP-C-1	261
5.57	Evaluation of granules prepared for tablets containing enteric coated fungal alpha amylase and pepsin powder-Batch ECP-T-1	264
5.58	Evaluation of tablets containing enteric coated fungal alpha amylase and pepsin powder-Batch ECP-T-1	265
5.59	Stability study of tablets containing enteric coated fungal alpha amylase and pepsin powder-Batch ECP-T-1	266
5.60	Evaluation of dry syrup containing enteric coated fungal alpha amylase and pepsin powder Batch ECP-DS-1	269
5.61	Evaluation of reconstituted dry syrup containing enteric coated fungal alpha amylase and pepsin powder Batch ECP-DS-1 and stability at 30°C	270
5.62	Stability study of dry syrup containing enteric coated fungal alpha amylase and pepsin powder Batch ECP-DS-1	271
5.63	Aggregation inhibition of fungal alpha amylase by beta-cyclodextrin	274
5.64	Recovery of fungal alpha amylase activity in excess of initial activity	276
5.65	Effect of enzyme concentration on inclusion complex	277
5.66	Effect of stirring time on inclusion complex	278
5.67	Effect pH and temperature on inclusion complex	279
5.68	Effect of ionic strength on inclusion complex	280
5.69	Stability cum characterization of oral liquid prepared with inclusion complex of fungal alpha amylase with beta-cyclodextrin Batch IC-L-1 and IC-L-2	293
5.70	Stability cum characterization of oral liquid prepared with inclusion complex of fungal alpha amylase with beta-cyclodextrin Batch IC-L-3 and IC-L-4	294
5.71	RMS deviation data for lowest energy minimized structures	300
5.72	Residues of fungal alpha amylase in contact with beta-cyclodextrin found out by Ligand Protein Contacts (LPC) analysis	304

5.73	List of putative hydrogen bonds between beta-cyclodextrin and fungal alpha amylase given by Ligand Protein Contacts (LPC) analysis	305
------	--	-----
