

List of Tables

Table No.	Description	Page No.
2.1.	Most commonly employed characterization techniques for CoCs.	36
2.2.	Most commonly employed characterization techniques for CD complexes and ternary CD complexes.	43
2.3.	Examples of commercialized HPBCD products.	46
2.4.	Most commonly employed characterization techniques for NCs.	55
2.5.	Examples of commercialized NC products.	59
2.6.	Formulation research works on Eze and their drawbacks.	69
2.7.	Examples of research works employing ND in CoC systems.	73
2.8.	Examples of research works employing HPBCD ternary systems.	74
2.9.	Examples of research works employing TPGS in NC systems.	79
2.10.	Examples of research works employing SLS in NC systems.	80
4.1.	List of chemicals.	89
4.2.	List of equipments.	91
4.3.	List of software.	93
5.1.	UV-VIS method validation parameters for pure Eze.	126
5.2.	UV-VIS method validation parameters for pure NA.	132
5.3.	UV-VIS method validation parameters for pure ND.	134
5.4.	FTIR data table presenting characteristic peak assignments of parent compounds of CoCs.	137
5.5.	PXRD patterns of parent compounds and CoCs showing the peak heights in counts (cts) at various diffraction angles ($2\theta^\circ$).	142
5.6.	Flow properties of parent compounds and CoCs. Data shown as Mean \pm SD (n = 3).	146
5.7.	Saturation solubility (n = 3) and dissolution (n = 6) results of pure Eze and CoCs. Data shown as Mean \pm SD.	147

5.8.	Stability study observations of optimized CoCs. Data shown as Mean±SD and n = 3 (n = 6 for dissolution data).	152
5.9.	HPLC-UV method validation parameters for analytical and bioanalytical Eze samples.	157
5.10.	Pharmacokinetic parameters derived for pure Eze and CoCs (n = 6). Data shown as Mean±SD.	159
5.11.	Percent reduction in the total cholesterol levels achieved by pure Eze and CoC formulations. Results were expressed as Mean±SD (n = 6).	168
6.1.	FTIR data table presenting characteristic peak assignments of parent compounds of Eze CD complexes.	197
6.2.	NMR data table presenting protonic shifts of Eze protons after binary and ternary complexation (chemical shifts values in ppm).	207
6.3.	Saturation solubility and log P values of pure Eze and Eze CD complexes. Data shown as Mean±SD (n = 3).	211
6.4.	Dissolution data of pure Eze and Eze CD complexes shown as Mean±SD (n = 6).	215
6.5.	Stability study performances of optimized ternary complexes. Data shown as Mean±SD and n = 3 (n = 6 for dissolution data).	218
6.6.	Pharmacokinetic parameters derived for pure Eze and optimized ternary complexes (n = 6). Data shown as Mean±SD.	220
6.7.	Percent reduction in the total cholesterol levels achieved by pure Eze and optimized ternary complex formulations. Results were expressed as Mean±SD (n = 6).	226
7.1.	Coded levels of the applied independent variables and constraints of the studied dependent variables of PBD.	241
7.2.	Coded levels of PBD when the independent variables were considered constant for one factor at a time analysis.	242
7.3.	Coded levels of the applied independent variables and constraints of the studied dependent variables of BBD.	244
7.4.	Coded levels of the applied independent variables and constraints of the studied dependent variables of CCD.	248
7.5.	PBD experimental runs.	258
7.6.	Percent contribution of each of the applied factors of the two level PBD factorial model to the variations in the response, PS of ANCs.	260
7.7.	ANOVA for the PBD factorial model for analysing the response, PS of ANCs.	260

7.8.	Statistics summary of the PBD factorial model for analysing the response, PS of ANCs.	261
7.9.	Percent contribution of each of the applied factors of the two level PBD factorial model to the variations in the response, PDI of ANCs.	264
7.10.	ANOVA for the PBD factorial model for analysing the response, PDI of ANCs.	264
7.11.	Statistics summary of the PBD factorial model for analysing the response, PDI of ANCs.	265
7.12.	Percent contribution of each of the applied factors of the two level PBD factorial model to the variations in the response, ZP of ANCs.	268
7.13.	ANOVA for the PBD factorial model for analysing the response, ZP of ANCs.	269
7.14.	Statistics summary of the PBD factorial model for analysing the response, ZP of ANCs.	269
7.15.	Optimization validation of PBD.	271
7.16.	BBD experimental runs.	272
7.17.	ANOVA data of sequential model sum of squares test applied to select an appropriate BBD model for analysing the response, PS of ANCs.	274
7.18.	ANOVA data of lack of fit test applied to select an appropriate BBD model for analysing the response, PS of ANCs.	274
7.19.	ANOVA for the selected response surface quadratic BBD model for analysing the response, PS of ANCs.	275
7.20.	Statistics summary of the quadratic response surface BBD model for analysing the response, PS of ANCs.	275
7.21.	ANOVA data of sequential model sum of squares test applied to select an appropriate BBD model for analysing the response, PDI of ANCs.	279
7.22.	ANOVA data of lack of fit test applied to select an appropriate BBD model for analysing the response, PDI of ANCs.	279
7.23.	ANOVA for the selected response surface quadratic BBD model for analysing the response, PDI of ANCs.	280
7.24.	Statistics summary of the quadratic response surface BBD model for analysing the response, PDI of ANCs.	280
7.25.	ANOVA data of sequential model sum of squares test applied to select an appropriate BBD model for analysing the response, ZP of ANCs.	284

7.26.	ANOVA data of lack of fit test applied to select an appropriate BBD model for analysing the response, ZP of ANCs.	284
7.27.	ANOVA for the selected response surface quadratic BBD model for analysing the response, ZP of ANCs.	285
7.28.	Statistics summary of the quadratic response surface BBD model for analysing the response, ZP of ANCs.	285
7.29.	CCD experimental runs.	290
7.30.	ANOVA data of sequential model sum of squares test applied to select an appropriate CCD model for analysing the response, PS of ESTNCs.	292
7.31.	ANOVA data of lack of fit test applied to select an appropriate CCD model for analysing the response, PS of ESTNCs.	292
7.32.	ANOVA for the selected response surface quadratic CCD model for analysing the response, PS of ESTNCs.	293
7.33.	Statistics summary of the quadratic response surface CCD model for analysing the response, PS of ESTNCs.	293
7.34.	ANOVA data of sequential model sum of squares test applied to select an appropriate CCD model for analysing the response, PDI of ESTNCs.	297
7.35.	ANOVA data of lack of fit test applied to select an appropriate CCD model for analysing the response, PDI of ESTNCs.	297
7.36.	ANOVA for the selected response surface quadratic CCD model for analysing the response, PDI of ESTNCs.	298
7.37.	Statistics summary of the quadratic response surface CCD model for analysing the response, PDI of ESTNCs.	298
7.38.	ANOVA data of sequential model sum of squares test applied to select an appropriate CCD model for analysing the response, ZP of ESTNCs.	303
7.39.	ANOVA data of lack of fit test applied to select an appropriate CCD model for analysing the response, ZP of ESTNCs.	303
7.40.	ANOVA for the selected response surface quadratic CCD model for analysing the response, ZP of ESTNCs.	304
7.41.	Statistics summary of the quadratic response surface CCD model for analysing the response, ZP of ESTNCs.	304
7.42.	Batches of NCs prepared during confirmatory trials and their PS, PDI, and ZP results (data shown as Mean±SD and n = 3).	310
7.43.	Saturation solubility (n = 3) and dissolution (n = 6) parameters of pure drug, PMs and optimized NCs (data shown as Mean±SD).	323

7.44.	Stability study data of optimized NC formulations. Data shown as Mean±SD and n = 3 (n = 6 for dissolution data).	329
7.45.	Pharmacokinetic parameters derived for pure Eze and optimized NCs (n = 6). Data shown as Mean±SD.	331
7.46.	Percent reduction in the total cholesterol levels achieved by pure drug suspension and optimized NCs. Results were expressed as Mean±SD (n = 6).	336
8.1.	Estimation of pharmacodynamic parameters.	355
8.2.	Dissolution graph data of pure Eze, Ezentia, and optimized formulations in 0.01 N HCl (pH 2) containing 0.45% w/v SLS. Results were expressed as Mean±SD (n = 6).	361
8.3.	Dissolution graph data of pure Eze, Ezentia, and optimized formulations in USP acetate buffer (pH 4.5) containing 0.45% w/v SLS. Results were expressed as Mean±SD (n = 6).	362
8.4.	Dissolution graph data of pure Eze, Ezentia, and optimized formulations in distilled water (measured pH 6.8) containing 0.45% w/v SLS. Results were expressed as Mean±SD (n = 6).	363
8.5.	Saturation solubility (n = 3) and dissolution (n = 6) parameters of pure drug, optimized formulations and Ezentia (data shown as Mean±SD).	364
8.6.	Dissolution (n = 6) parameters of pure drug, optimized formulations and Ezentia (data shown as Mean±SD) in other media.	364
8.7.	Pharmacokinetic parameters compared for pure Eze, Ezentia, Ezentia suspension and optimized formulations (n = 6). Data shown as Mean±SD.	371
8.8.	Percent relative bioavailability values (n = 6). Data shown as Mean±SD.	372
8.9.	Plasma drug concentration – time graph data of pure Eze, Ezentia, Ezentia suspension and optimized formulations up to 24 h. Data shown as Mean±SD (n = 6).	375
8.10.	Order of pharmacodynamic performance of the treatment groups.	378
8.11.	Percent decrease in total plasma cholesterol levels.	385
8.12.	Percent decrease in plasma triglyceride levels.	386
8.13.	Percent increase in plasma HDL levels.	387
8.14.	Percent decrease in plasma LDL levels.	388
8.15.	Percent decrease in plasma VLDL levels.	389
8.16.	Percent decrease in Atherogenic Coefficient.	390

8.17.	Percent decrease in Atherogenic Index of Plasma.	391
8.18.	Percent decrease in CHOLINDEX.	392
8.19.	Percent decrease in Cardiac Risk Ratio or Castelli's Risk Index I.	393
8.20.	Percent decrease in Castelli's Risk Index II.	394
8.21.	First phase dose reduction efficiency studies – order of performance.	405
8.22.	Second phase dose reduction efficiency studies – order of performance.	406