List of Tables

Table No.	Caption	Page No.
3.1	Patents involving different approaches for PR formulations	44
4.1	List of materials used in the research work	62
4.2	List of solvents/reagents used in the research work	64
4.3	List of equipments used in the research work	65
5.1	Calibration curve and regression equation of PRS obtained using UV spectrophotometric method	71
5.2	Accuracy data of PRS obtained using UV spectrophotometric method	72
5.3	Precision data of PRS obtained using UV spectrophotometric method	72
5.4	Ruggedness data of PRS obtained using UV spectrophotometric method	72
5.5	Summary of validation parameters of PRS UV spectrophotometric method	73
5.6	Chromatographic conditions for determination of PRS	75
5.7	Calibration curve and regression equation of PRS obtained using HPLC method	75
5.8	Accuracy data of PRS obtained using HPLC method	76
5.9	Precision data of PRS obtained using HPLC method	76
5.10	Ruggedness data of PRS obtained using HPLC method	76
5.11	Summary of validation parameters of PRS HPLC method	77
5.12	QTPP of desired PR formulation	79
5.13	List of ingredients and their respective concentrations employed for formulation of PRS core tablets	82
5.14	Identification of CQAs for desired compression-coated PR formulation	87
5.15	Initial risk analysis matrix for identification of impact of formulation ingredients on drug product attributes	89
5.16	Initial risk analysis matrix for identification of impact of unit operations on drug product attributes	89
5.17	Justifications for initial risk assessment of formulation variables on drug product attributes	90
5.18	Justifications for initial risk assessment of unit operations on drug product attributes	94
5.19	Risk assessment by FMEA analysis to identify criticality of failure modes	124
5.20	Selected formulation variables and their levels for CCD	126
5.21	Experimental matrix of CCD with measured responses	127
5.22	Estimated Regression Coefficients for lag time along with their p values	128
5.23	Analysis of variance (ANOVA) results of effect of HPMC and Coating levels on lag time	131
5.24	Composition of optimized PRS CCTs	132
5.25	Results of curing study for optimized PRS CCTs	136
5.26	Results of stability study for optimized PRS CCTs	137
5.27	Risk mitigation of failure modes after implementation of control strategy	138

5.28	Final and updated risk analysis matrix for identification of impact of	140
5.20	formulation ingredients on drug product attributes	140
5.29	Final and updated risk analysis matrix for identification of impact of unit	140
	operations on drug product attributes	110
5.30	Justifications for updated risk assessment of formulation variables on drug	141
	product attributes	
5.31	Justifications for updated risk assessment of unit operations on drug	142
	product attributes	
5.32	Chromatographic conditions for determination of MPR	147
5.33	Calibration curve and regression equation of MPR obtained using HPLC	148
	method	
5.34	Accuracy data of MPR obtained using HPLC method	149
5.35	Precision data of MPR obtained using HPLC method	149
5.36	Ruggedness data of MPR obtained using HPLC method	149
5.37	Summary of validation parameters of MPR HPLC method	150
5.38	List of ingredients and their respective concentrations employed for	150
	formulation of MPR core tablets	
5.39	Results of curing study for MPR CCTs	155
5.40	Results of stability study for MPR CCTs	155
5.41	Chromatographic conditions for determination of DIC	158
5.42	Calibration curve and regression equation of DIC obtained using HPLC	159
	method	
5.43	Accuracy data of DIC obtained using HPLC method	160
5.44	Precision data of DIC obtained using HPLC method	160
5.45	Ruggedness data of DIC obtained using HPLC method	160
5.46	Summary of validation parameters of DIC HPLC method	161
5.47	List of ingredients and their respective concentrations employed for	162
	formulation of DIC core tablets	
5.48	Flow property evaluation of DIC compression blends	163
5.49	Results of curing study for DIC CCTs	166
5.50	Results of stability study for DIC CCTs	167
5.51	Chromatographic conditions for determination of DIL	170
5.52	Calibration curve and regression equation of DIL obtained using HPLC	171
	method	
5.53	Accuracy data of DIL obtained using HPLC method	172
5.54	Precision data of DIL obtained using HPLC method	172
5.55	Ruggedness data of DIL obtained using HPLC method	172
5.56	Summary of validation parameters of DIL HPLC method	173
5.57	List of ingredients and their respective concentrations employed for	173
	formulation of DIL core tablets	
5.58	Flow property evaluation of DIL compression blends	175
5.59	Results of curing study for DIL CCTs	178
5.60	Results of stability study for DIL CCTs	179

5.61	Chromatographic conditions for determination of NIF	183
5.62	Calibration curve and regression equation of NIF HPLC method	184
5.63	Accuracy data of NIF obtained using HPLC method	185
5.64	Precision data of NIF obtained using HPLC method	185
5.65	Ruggedness data of NIF obtained using HPLC method	185
5.66	Summary of validation parameters of NIF HPLC method	186
5.67	List of ingredients and their respective concentrations employed for	187
	formulation of NIF core tablets	
5.68	Results of curing study for NIF CCTs	196
5.69	Results of stability study for NIF CCTs	197
5.70	Chromatographic conditions for determination of LOR	200
5.71	Calibration curve and regression equation of LOR obtained using HPLC	201
	method	
5.72	Accuracy data of LOR obtained using HPLC method	202
5.73	Precision data of LOR obtained using HPLC method	202
5.74	Ruggedness data of LOR obtained using HPLC method	202
5.75	Summary of validation parameters of LOR HPLC method	203
5.76	List of ingredients and their respective concentrations employed for	204
	formulation of LOR core tablets	
5.77	Results of curing study for LOR CCTs	211
5.78	Results of stability study for LOR CCTs	212
6.1	Animal grouping and dosing treatment of DIC pharmacokinetic study	232
6.2	% RSD of lag times for developed PCT and CCT formulations	237
6.3	Results of curing study for all six PCTs	238
6.4	Results of stability study for all six PCTs	238
6.5	Summary of pharmacokinetic parameters of DIC IR formulation and DIC PR formulation	240
6.6	BE parameters of DIC PR formulation with respect to DIC IR formulation at 90% CI	240