



## List of Tables

Table No.	Title	Page
Table 2.1	Differences between emulsions and microemulsions	27
Table 2.2	Rationale for developing and using medicated microemulsions	28
Table 2.3	Comparison for mouse models of AD	53
Table 3.1	Experimental conditions for halobetasol propionate by UV method	106
Table 3.2	Optimization conditions for tetrazolium blue method	107
Table 3.3	Experimental conditions for halobetasol propionate by HPLC method	109
Table 3.4	Experimental conditions for tacrolimus by HPLC method (Methanol: water)	110
Table 3.5	Experimental conditions for tacrolimus by HPLC method (Acetonitrile: water)	110
Table 3.6	Absorbance of halobetasol propionate (zero order) at 239nm	112
Table 3.7	Accuracy and precision of halobetasol propionate estimation by UV method	114
Table 3.8	Optimization of tetrazolium blue reagent volume	114
Table 3.9	Optimization of heating temperature	115
Table 3.10	Optimization of heating time at 90°C	115
Table 3.11	Calibration curve of halobetasol propionate by tetrazolium blue method	115
Table 3.12	Accuracy and precision of Halobetasol propionate estimation by tetrazolium blue method	117
Table 3.13	Calibration of halobetasol propionate by HPLC method	117
Table 3.14	System suitability for halobetasol propionate estimation	118
Table 3.15	Accuracy and precision of halobetasol propionate estimation by HPLC	119
Table 3.16	Calibration of tacrolimus by HPLC method	119
Table 3.17	System suitability for halobetasol propionate estimation	120
Table 3.18	Accuracy and precision of Tacrolimus estimation by HPLC	121
Table 3.19	Calibration of tacrolimus by HPLC method	121
Table 3.20	System suitability for tacrolimus estimation	122

Table 3.21	Accuracy and precision of Tacrolimus estimation by HPLC	122
Table 3.22	Calibration plot of serum IgE levels in mice by ELISA	123
Table 4.1	Solubility of HP in excipients	138
Table 4.2	Solubility of Tac in excipients	139
Table 4.3	3 <sup>2</sup> Factorial design for HP System1	142
Table 4.4	Checkpoint batches for HP system1	144
Table 4.5	3 <sup>2</sup> Factorial design for HP System 2	145
Table 4.6	Checkpoint batches for HP system 2	147
Table 4.7	3 <sup>2</sup> Factorial design for HP System 3	148
Table 4.8	Checkpoint batches for HP system 3	150
Table 4.9	Optimized HP formulations	150
Table 4.10	Characterization of HPMEC 0.035% and HPMEC 0.05%	151
Table 4.11	3 <sup>2</sup> Factorial design for Tac System 1	154
Table 4.12	Checkpoint batches for Tac system 1	156
Table 4.13	3 <sup>2</sup> Factorial design for Tac system 2	157
Table 4.14	Checkpoint batches for Tac system 2	159
Table 4.15	3 <sup>2</sup> Factorial design for Tac system 3	160
Table 4.16	Checkpoint batches for Tac system 3	162
Table 4.17	Optimized Tac formulations	162
Table 4.18	Characterization of TacMEC 0.1%	163
Table 4.19	Accelerated Stability Study of HP ME and Tac ME	167
Table 4.20	Stability study of HP MEs	168
Table 4.21	Stability study of Tac MEs	169
Table 4.22	Stability study of HPMEC 0.035%, HPMEC 0.05% and TacMEC 0.1%	170
Table 5.1	<i>In vitro</i> diffusion study of HP formulations	191
Table 5.2	Diffusion coefficient and regression coefficients of HP formulations	192
Table 5.3	Skin retention data of HP formulation through rodent skin and human cadaver skin	192
Table 5.4	<i>In vitro</i> diffusion study of Tac formulations	194
Table 5.5	Diffusion coefficient and regression coefficients of Tac formulations	195
Table 5.6	Skin retention data of Tac formulation through rodent skin and human cadaver skin	195
Table 6.1	Observations of animals during the course of sub-acute dermal toxicity study	212
Table 6.2	Hematology Findings at Day 14	213
Table 6.3	Number of mast cells	218
Table 6.4	Optical Density and relative viability by MTT assay	218

Table 7.1	Primer sequences and PCR conditions for genes investigated under semi quantitative mRNA expression studies	232
Table 7.2	Comparative dermatitis score in mice during the course of study after elicitation with inducing agent (TNCB) and treatment with different formulations	235
Table 7.3	Ear swelling response in mice recorded 3 h and 24 h post application of formulations	237
Table 7.4	Comparative serum total IgE levels during the course of study after sensitization and elicitation with hapten (TNCB) and treatment with different HP formulations	238
Table 7.5	Mast cell numbers during the course of study after sensitization and elicitation with hapten (TNCB) and treatment with different formulations	242
Table 7.6	Cytokine gene expression by RT-PCR at the end of study on day 35. The expression level is expressed as a ratio to internal reference beta-actin expression	245
Table 7.7	Comparative dermatitis score in mice during the course of study after elicitation with inducing agent (TNCB) and treatment with different formulations	247
Table 7.8	Comparative serum total IgE levels during the course of study after sensitization and elicitation with hapten (TNCB) and treatment with different formulations	248
Table 7.9	: Ear swelling response in mice recorded 3 h post application of formulations	249
Table 7.10	Ear swelling response in mice recorded 24 h post application of formulations	250
Table 7.11	Mast cell numbers during the course of study after sensitization and elicitation with hapten (TNCB) and treatment with different formulations	251
Table 7.12	Cytokine gene expression levels by RT -PCR at the end of study on day 35. The expression level is expressed as a ratio to internal reference beta-actin expression	254
Table 8.1	Disease severity score comparison between the two groups	289
Table 8.2	Change in key signs and symptoms during the course of study for Group 1: HPMEC (0.035%)	289
Table 8.3	Change in key signs and symptoms during the course of study for Group 2: HP cream (0.05%)	290
Table 8.4	Change in key signs and symptoms during the course of study for Group 1A: Microemulsion based placebo cream	290

Table 8.5	Change in key signs and symptoms during the course of study for Group 2A: Plain placebo cream	291
Table 8.6	Percentage reduction in signs and symptoms at the end of treatment (21 days)	291
Table 9.1	Experimental conditions for simultaneous evaluation of HP and Tac	305
Table 9.2	Compatibility between HP and Tac in accelerated studies as evaluated by physical appearance and HPLC	307
Table 9.3	Characterization of HP (0.035%) + Tac (0.1%) ME based combination cream	309
Table 9.4	<i>In vitro</i> diffusion study of HP, Tac and Combination formulations	309
Table 9.5	Skin retention data of HP, Tac and Combination formulation through rodent skin and human cadaver skin	310
Table 9.6	Comparative dermatitis score in mice during the course of study after elicitation with inducing agent (TNCB) and treatment with different formulations	312
Table 9.7	Comparative serum total IgE levels during the course of study after sensitization and elicitation with hapten (TNCB) and treatment with different formulations	313
Table 9.8	Ear swelling response in mice recorded 3 h post application of formulations	314
Table 9.9	Ear swelling response in mice recorded 24 h post application of formulations	315
Table 9.10	Cytokine gene expression levels by RT –PCR at the end of study on day 35	317
Table 9.11	Stability Study of Combination ME Cream	318