

申請資料の目次
ディレグラ配合錠

1	1
2	2
3	3
4	4
5	5
6	6
7	7
8	8
9	9
10	10
11	11
12	12
13	13
14	14
15	15
16	16
17	17
18	18
19	19
20	20
21	21
22	22
23	23
24	24
25	25
26	26
27	27
28	28
29	29
30	30
31	31
32	32
33	33
34	34
35	35
36	36
37	37
38	38
39	39
40	40
41	41
42	42
43	43
44	44
45	45
46	46
47	47
48	48
49	49
50	50
51	51
52	52
53	53
54	54
55	55
56	56
57	57
58	58
59	59
60	60
61	61
62	62
63	63
64	64
65	65
66	66
67	67
68	68
69	69
70	70
71	71
72	72
73	73
74	74
75	75
76	76
77	77
78	78
79	79
80	80
81	81
82	82
83	83
84	84
85	85
86	86
87	87
88	88
89	89
90	90
91	91
92	92
93	93
94	94
95	95
96	96
97	97
98	98
99	99
100	100

第三部 目次

3.2.S 原薬（塩酸プソイドエフェドリン）
3.2.S.1 General Information
3.2.S.1.1 Nomenclature
3.2.S.1.2 Structure
3.2.S.2 Manufacture
3.2.S.2.1 Manufacturer
3.2.S.2.2 Description of Manufacturing Process and Process Controls
3.2.S.2.3 Control of Materials
3.2.S.2.4 Controls of Critical Steps and Intermediates
3.2.S.2.6 Manufacturing Process Development
3.2.S.6 Container Closure Systems
3.2.P 製剤（ディレグラ配合錠，錠剤）
3.2.P.1 Description and Composition of the Drug Product
3.2.P.2 Pharmaceutical Development
3.2.P.2.1 Components of the drug product
3.2.P.2.2 Drug product
3.2.P.2.3 Manufacturing process development
3.2.P.2.4 Container closure system
3.2.P.2.5 Microbiological attributes
3.2.P.2.6 Compatibility
3.2.P.3 Manufacture
3.2.P.3.1 Manufacturer(s)
3.2.P.3.2 Batch Formula
3.2.P.3.3 Description of Manufacturing Process and Process Controls
3.2.P.3.4 Controls of Critical Steps and Intermediates
3.2.P.3.5 Process Validation and/or Evaluation
3.2.P.4 Control of Excipients (compendial)
3.2.P.4.1 Specification
3.2.P.4.2 Analytical procedures
3.2.P.4.3 Validation of Analytical Procedures
3.2.P.4.4 Justification of specifications
3.2.P.4 Control of Excipients (Carnauba wax)

第四部 目次

4 Nonclinical Study Reports
4.2 Study Reports
4.2.2 Pharmacokinetics
4.2.2.1 Analytical Methods and Validation Reports
4.2.2.1-1 Validation of a high performance liquid chromatographic method using tandem mass spectrometry detection for the determination of fexofenadine in human EDTA K3 plasma
4.2.2.1-2 Validation of a high performance liquid chromatographic method using tandem mass spectrometry detection and automated extraction for the determination of pseudoephedrine in human EDTA plasma
4.2.3 Toxicology
4.2.3.1 Single Dose Toxicity
4.2.3.1-1 The effect of terfenadine on the acute oral toxicity of pseudoephedrine hydrochloride in rats
4.2.3.1-2 Determination of comparative oral minimum lethal dose of a sustained release form of d-pseudoephedrine versus the raw form of d-pseudoephedrine in the dog
4.2.3.1-3 Determination of comparative oral minimum lethal dose of sustained release capsule versus immediate release capsule of d-pseudoephedrine
4.2.3.2 Repeat Dose Toxicity
4.2.3.2-1 Range finding study with a terfenadine/pseudoephedrine hydrochloride combination in rats
4.2.3.2-2 Three month oral toxicity study of a terfenadine/pseudoephedrine hydrochloride combination in rats
4.2.3.2-3 Subacute (30-day) oral toxicity of novafed 120 in New Zealand white rabbits
4.2.3.2-4 Subacute (30-day) oral toxicity of novafed 120 (d-pseudoephedrine HCl) in mongrel dogs
4.2.3.2-5 Subacute (39-day) oral toxicity of novafed 120 (d-pseudoephedrine HCL) in beagle dog
4.2.3.2-6 Three month oral toxicity of a terfenadine/pseudoephedrine hydrochloride in dogs
4.2.3.5 Reproductive and Developmental Toxicity
4.2.3.5.2 Embryofetal development
4.2.3.5.2-1 Teratology study with a terfenadine/pseudoephedrine hydrochloride combination in rats
4.2.3.5.2-2 Teratology study with a combination of terfenadine/pseudoephedrine hydrochloride combination in rabbits
4.3 Literature References

第五部 目次

5 Clinical Study Reports
5.2 Tabular Listing of All Clinical Studies
5.3 Clinical study reports and related information
5.3.1 Reports of Biopharmaceutic Studies
5.3.1.2 Comparative BA and Bioequivalence (BE) Study Reports
5.3.1.2-1 A double-blind, randomized, 5-day repeated-dose, dose ascending, crossover bioavailability, safety and tolerability study of fexofenadine and pseudoephedrine fixed-dose combination tablet in comparison with the marketed Allegra tablet in Japanese healthy male subjects
5.3.3 Reports of Human Pharmacokinetic (PK) Studies
5.3.3.4 Extrinsic Factor PK Study Reports
5.3.3.4-1 An open-label, randomized, single-dose, two-treatment crossover study, to investigate the potential food effect on the bioavailability of fixed dose combination formulation of fexofenadine hydrochloride and pseudoephedrine hydrochloride in Japanese healthy male subjects
5.3.3.4-2 Effect of pseudoephedrine on the pharmacokinetics of fexofenadine
5.3.5 Reports of Efficacy and Safety Studies - allergic rhinitis
5.3.5.1 Study Reports of Controlled Clinical Studies Pertinent to the Claimed Indication
5.3.5.1-1 季節性アレルギー性鼻炎患者に対して、フェキソフェナジン塩酸塩 60 mg / 塩酸プソイドエフェドリン 60 mg 配合剤又はフェキソフェナジン塩酸塩 60 mg / 塩酸プソイドエフェドリン 120 mg 配合剤を 1 日 2 回投与したときの 2 週間の有効性及び安全性の検討（ランダム化、二重盲検、フェキソフェナジン塩酸塩 60 mg 1 日 2 回投与対照、並行群間比較試験）
5.3.5.1-2 A comparative study of the safety and efficacy of a twice-daily fexofenadine HCl 60 mg pseudoephedrine HCl 120 mg combination versus its components alone in the management of ragweed seasonal allergy
5.3.6 Reports of Postmarketing Experience
Post-Marketing Safety Information on Allegra FDC (fexofenadine / pseudoephedrine combination)
PERIODIC SAFETY UPDATE REPORT for FEXOFENADINE HYDROCHLORIDE, FEXOFENADINE HCL/PSEUDOEPHEDRINE HCL, FEXOFENADINE HCL/PHENYLEPHRINE HCL
5.3.7 CRF and individual patient listings
5.3.7-1 用量設定の根拠となった主要な試験及び主要な有効性の検証試験の症例一覧表
5.3.7-2 実施された全ての臨床試験において副作用が観察された症例の一覧表
5.3.7-4 実施された全ての臨床試験において臨床検査値異常が観察された症例の一覧表
5.4 Literature References