オファコルカプセル 50 mg
に関する資料

第 1 部：申請書等行政情報及び添付文書
に関する情報

1.12　添付資料一覧

本資料に記載された情報に係る権利及び内容の責任は、株式会社レクメドに帰属するものであります。当該情報を適正使用以外の営利目的に本資料を利用することはできません。

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添付資料番号	表題	評価／参考
3.1	第3部（モジュール3）目次	
3.2	データ又は報告書	
3.2.S manufacturer: ICE S.p.A.	原薬（Drug Substance）	
3.2.S.1	一般情報（General Information）	
3.2.S.1.1	名称（Nomenclature）	参考資料
3.2.S.1.2	構造（Structure）	参考資料
3.2.S.1.3	一般特性（General Properties）	参考資料
3.2.S.2	製造（Manufacturer）	
3.2.S.2.1	製造業者（Manufacturer）	評価資料
3.2.S.2.2	製造方法及びプロセス・コントロール（Description of Manufacturing Process and Process Controls）	評価資料
3.2.S.2.3	原材料の管理（Control of Materials）	評価資料
3.2.S.2.4	重要工程及び重要中間体の管理（Controls of Critical Steps and Intermediates）	評価資料
3.2.S.2.5	プロセス・バリデーション／プロセス評価（Process Validation and/or Evaluation）	評価資料
3.2.S.2.6	製造工程の開発の経緯（Manufacturing Process）	評価資料
3.2.S.3	特性（Characterisation）	
3.2.S.3.1	構造その他の特性の解明（Elucidation of Structure and other Characteristics）	参考資料
3.2.S.3.2	不純物（Impurities）	参考資料
3.2.S.4	原薬の管理（Control of Drug Substance）	
3.2.S.4.1	規格及び試験方法（Specification）	評価資料
3.2.S.4.2	試験方法（Analytical Procedures）	評価資料
3.2.S.4.3	試験方法のバリデーション（Validation of Analytical Procedures）	評価資料
3.2.S.4.4	ロット分析（Batch Analyses）	評価資料
3.2.S.4.5	規格及び試験方法の妥当性（Justification of Specification）	評価資料
3.2.S.5	標準品又は標準物質（Reference standards or materials）	参考資料
3.2.S.6	容器及び施栓系 （Container closure system）	評価資料
3.2.S.7	安定性 （Stability）	
3.2.S.7.1	安定性のまとめ及び結論（Stability summary and conclusions）	評価資料
3.2.S.7.2	承認後の安定性試験計画の作成及び実施（Post approval stability protocol and stability commitment）	評価資料
3.2.S.7.3	安定性データ （Stability data）	評価資料
3.2.S manufacturer: LAB-SERVICE S.A.	原薬（Drug Substance）	
3.2.S.1	一般情報（General Information）	
	該当資料なし	-
3.2.S.2	製造（Manufacturer）	
3.2.S.2.1	製造業者（Manufacturer）	評価資料
3.2.S.2.2	製造方法及びプロセス・コントロール（Description of Manufacturing Process and Process Controls）	評価資料
3.2.S.2.3	原材料の管理（Control of Materials）	評価資料

添付資料番号	表題	評価／参考
3.2.S.2.4	重要工程及び重要中間体の管理（Controls of Critical Steps and Intermediates）	評価資料
3.2.S.2.5	プロセス・バリデーション／プロセス評価（Process Validation and/or Evaluation）	評価資料
3.2.S.2.6	製造工程の開発の経緯（Manufacturing Process）	
	該当資料なし	-
3.2.S.3	特性（Characterisation）	
	該当資料なし	-
3.2.S.4	原薬の管理（Control of Drug Substance）	
3.2.S.4.1	規格及び試験方法（Specification）	評価資料
3.2.S.4.2	試験方法（Analytical Procedures）	評価資料
3.2.S.4.3	試験方法のバリデーション（Validation of Analytical Procedures）	評価資料
3.2.S.4.4	ロット分析（Batch Analyses）	評価資料
3.2.S.4.5	規格及び試験方法の妥当性（Justification of Specification）	評価資料
3.2.S.5	標準品又は標準物質（Reference standards or materials）	評価資料
3.2.S.6	容器及び施栓系 （Container closure system）	評価資料
3.2.S.7	安定性 （Stability）	
3.2.S.7.1	安定性のまとめ及び結論（Stability summary and conclusions）	評価資料
3.2.S.7.2	承認後の安定性試験計画の作成及び実施（Post approval stability protocol and stability commitment）	評価資料
3.2.S.7.3	安定性データ （Stability data）	評価資料
3.2.P	製剤（DRUG PRODUCT）	
3.2.P.1	製剤及び処方 （Description and composition of the Drug Product）	評価資料
3.2.P.2	製剤開発の経緯（Pharmaceutical development）	評価資料
3.2.P.3	製造（Manufacture）	
3.2.P.3.1	製造者（Manufacturer(s)）	評価資料
3.2.P.3.2	製剤処方（Batch Formula）	評価資料
3.2.P.3.3	製造工程及びプロセス・コントロール（Description of Manufacturing Process and Process Controls）	評価資料
3.2.P.3.4	重要工程及び重要中間体の管理（Controls of Critical Steps and Intermediates）	評価資料
3.2.P.3.5	プロセス・バリデーション／プロセス評価（Process Validation and/or Evaluation）	評価資料
3.2.P.4	添加剤の管理（Control of excipients）	
3.2.P.4.1	規格及び試験方法（Specifications）	評価資料
3.2.P.4.2	試験方法（Analytical procedures）	評価資料
3.2.P.4.3	試験方法のバリデーション（Validation of analytical procedures）	評価資料
3.2.P.4.4	規格及び試験方法の妥当性（Justification of specification）	評価資料
3.2.P.4.5	ヒト又は動物起源の添加剤（Excipients of human or Animal origin）	評価資料
3.2.P.4.6	新規添加剤（Novel excipients）	–
3.2.P.5	製剤の管理（Control of Drug Product）	
3.2.P.5.1	規格及び試験方法（Specification(s)）	評価資料
3.2.P.5.2	試験方法（Analytical Procedures）	評価資料
3.2.P.5.3	試験方法のバリデーション（Validation of Analytical Procedures）	評価資料
3.2.P.5.4	ロット分析（Batch Analyses）	評価資料

添付資料番号	表題	評価／参考
3.2.P.5.5	不純物の特性（Characterisation of Impurities）	評価資料
3.2.P.5.6	規格及び試験方法の妥当性（Justification of Specification(s)）	評価資料
3.2.P.6	標準品及び標準物質（Reference standard or materials）	評価資料
3.2.P.7	容器及び施栓系（Container Closure system）	評価資料
3.2.P.8	安定性（Stability）	
3.2.P.8.1	安定性のまとめ及び結論（Stability Summary and Conclusion）	評価資料
3.2.P.8.2	承認後の安定性試験計画の作成及び実施（Post-approval Stability Protocol and Stability Commitment）	評価資料
3.2.P.8.3	安定性データ（Stability Data）	評価資料
3.2.A	その他	
3.2.A.1	製造施設及び設備	–
3.2.A.2	外来性感染性物質の安全性評価	評価資料
3.2.A.3	新規添加剤	評価資料
3.2R	各極の要求資料	評価資料
3.3	参考文献	
3.3-1	Alvaro, D., Cantafora, A., Attili, A. F., Corradini, S. G., De Luca, C., Minervini, G., . Angelico, M. (1986). Relationships between bile salts hydrophilicity and phospholipid composition in bile of various animal species. : Comp Biochem Physiol B 83(3):551-4	–
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3.3-5	Merck Publishing Group. (2006a). The Merck Index: An Encyclopedia of Chemicals, Drugs, and Biologicals (14 th ed.). Cholic Acid: Merck & Co. Inc.	–
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3.3-7	Miki, K., & Kasai, N. (1990). Crystal Structure of Cholic Acid with No Guest Molecules. : Acta Cryst. C46:2442-5	–
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3.3-11	Sung, J. Y., Shaffer, E. A., & Costerton, J. W. (1993). Antibacterial Activity of Bile Salts Against Common Biliary Pathogens Effects of Hydrophobicity of the Molecule and in the Presence of Phospholipids. : Digestive Diseases and Sciences 38(11):2104-12	–

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3.3-13	Waterhous, D. V., Barnes, S., & Muccio, D. D. (1985). Nuclear magnetic resonance spectroscopy of bile acids. Development of two-dimensional NMR methods for the elucidation of proton resonance assignments for five common hydroxylated bile acids, and their parent bile acid, 5 beta-cholanoic acid. : J Lipid Res 26(9):1068-78	–
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4.1	第4部（モジュール4）目次	
4.2	試験報告書	
4.2.1	薬理試験	
4.2.1.1	効力を裏付ける試験	
4.2.1.1-1	Araya, Z; Sjöberg, H; Wikvall, K Different effects on the expression of CYP7 and CYP27 in rabbit liver by cholic acid and cholestyramine. Biochem Biophys Res Commun. 1995; 216(3): 868-73	参考資料
4.2.1.1-2	Borgström, B; Barrowman, J; Krabisch, L; Lindström, M; Lillienau, J Effects of cholic acid, 7 beta-hydroxy- and 12 beta-hydroxy isocholic acid on bile flow, lipid secretion and bile acid synthesis in the rat. Scand J Clin Lab Invest. 1986; 46(2): 167-75	参考資料
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4.2.1.1-8	Hall, R; Kok, E; Javitt, N B Bile acid synthesis: down-regulation by monohydroxy bile acids. Faseb J. 1988; 2(2): 152-6	参考資料
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4.2.1.1-10	Klaassen, C. D. Species differences in the choleretic response to bile salts. J Physiol. 1972; 224(2): 259-69	参考資料
4.2.1.1-11	Kwekkeboom, J; Princen, H M; Voorthuizen, E M; Kempen, H J Bile acids exert negative feedback control on bile acid synthesis in cultured pig hepatocytes by suppression of cholesterol 7 alpha-hydroxylase activity. Hepatology. 1990; 12(5): 1209-15	参考資料

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4.2.1.2	副次的薬理試験	
	該当資料なし	-
4.2.1.3	安全性薬理試験	

添付資料番号	表題	評価／参考
4.2.1.3-1	Colpaert, C G; Vandenbroucke, M P; Andries, L J; Van Marck, E A; Brutsaert, D L Role of endocardial endothelium in the positive inotropic effect of cholic acid in isolated myocardium. J Cardiovasc Pharmacol. 1992; 20 Suppl 12: S179-82	参考資料
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4.2.1.3-7	Szkudlinski, J. Further studies on the properties of bile acids. II. Effect of bile acids on the reactivity of adrenergic and cholinergic receptors in rat intestine. Acta Physiol Pol. 1984; 35(5-6): 500-8	参考資料
4.2.1.4	薬力学的薬物相互作用試験	
	該当資料なし	-
4.2.2	薬物動態試験	
4.2.2.1	分析法及びバリデーション報告書	
	該当資料なし	-
4.2.2.2	吸収	
4.2.2.2-1	Carrella, M; Dietschy, J M Comparison of the effects of cholic acid and chenic acid feeding on rates of cholesterol synthesis in the liver of the rat. Am J Dig Dis. 1977; 22(4): 318-26	参考資料
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4.2.2.3-1	Hassan, A S; Subbiah, M T Bile acids in the fetal rat: effect of maternal bile duct ligation. Steroids. 1980; 36(6): 709-15	参考資料
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4.2.2.4	代謝	
	該当資料なし	-
4.2.2.5	排泄	
4.2.2.5-1	Lindstedt, S; Norman, A On the excretion of bile acid derivatives in feces of rats fed cholic acid-2414C and chenodesoxycholic acid-2414C; bile acids and steroids 19. Acta Physiol Scand. 1955; 34(1): 1-10	参考資料
4.2.2.6	薬物動態学的薬物相互作用	
4.2.2.6-1	Azer, S A; Stacey, N H Differential effects of cyclosporin A on transport of bile acids by rat hepatocytes: relationship to individual serum bile acid levels. Toxicol Appl Pharmacol. 1994; 124(2): 302-9	参考資料
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4.2.2.7	その他の薬物動態試験	
	該当資料なし	-
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5.3.4	臨床薬力学（PD）試験報告書	
5.3.4.1	健康被験者におけるPD試験及びPK/PD試験報告書	
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5.3.4.2	患者におけるPD試験及びPK/PD試験報告書	
	該当資料なし	-
5.3.5	有効性及び安全性試験報告書	
5.3.5.1	申請する適応症に関する比較対照試験報告書	
	該当資料なし	-
5.3.5.2	非対照試験報告書	
5.3.5.2-1	日本人先天性胆汁酸代謝異常症患者（小児を含む）を対象とした第III相試験及び製造販売後臨床試験	評価資料
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5.3.5.2-4	Balistreri, W. F., 1999. Inborn errors of bile acid biosynthesis and transport. Novel forms of metabolic liver disease., : Gastroenterol Clin North Am 28(1): 145-72, vii	参考資料
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	該当資料なし	-
5.3.5.4	その他の臨床試験報告書	
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