合同编号 Contract No.:

技 术 服 务 合 同

Technical Service Contract

项目名称：MLC1501 产品合作开发

Project Name: MLC1501 Product Co-Development

委 托 人:

(甲方)　新加坡莫利亚克公司

Entrustor:

(Party A) Moleac Pte Ltd.

受 托 人:

(乙方)　神威药业集团有限公司

Entrustee:

(Party B) Shineway Pharmaceutical Group Ltd.

技 术 服 务 合 同

Technical Service Contract

服务委托方 Services Entrustor:

名称：新加坡莫利亚克公司

Name: Moleac Pte Ltd.

地址 Address: Helios #09-08, 11 Biopolis Way, Singapore 138667

电话 Tel: +65 62113710

以下简称“甲方”或“Moleac”

Hereinafter referred to as "Party A" or "Moleac"

服务提供方 Services Provider:

名称：神威药业集团有限公司

Name: Shineway Pharmaceutical Group Ltd.

地址：中国河北省石家庄市栾城区石栾大街 168 号

Address: No.168, Shiluan St.,Luancheng, Shijiazhuang, Hebei, China

电话 Tel: +86-311-88030066

以下简称“乙方”或“神威”

Hereinafter referred to as "Party B" or "Shineway".

Together Parities A and B are hereinafter referred to as "the parties"

背景：甲方是一家专门从事药物研制和市场开发的新加坡公司，已在新加坡和其他若干国家研制了 MLC1501 产品。MLC1501 是一种植物提取物。它由四种草药组合而成：（a）黄芪，（b）川芎，（c）当归，（d）远志。此产品已经在若干国家申请到了专利保护。乙方是一家通过中国国家食品药品监督管理局 GMP 认证和 PIC/s-GMP 认证的药品生产制造企业。神威声明自身具备依照本合同提供 Moleac 所需技术服务的能力。双方建立了长期友好合作关系。

Background: Party A is a Singapore company specialized in drug development and commercialization, who has developed the product MLC1501. MLC1501 is a botanical extract. It is prepared by combining four herbs: (a) Radix Astragali, (b) Rhizoma Chuanxiong, (c) Radix Angelicae sinensis, and (d) Radix Polygalae. It is filed several patents applications and obtained patent rights in several markets. Party B is a drug manufacturer who has obtained a GMP certificate issued by the State Food and Drug Administration of the PRC as well as a PIC/s-GMP certificate. Shineway declares that it has the capability for providing the Technical Services (as defined in Article 1 hereinafter) required by Moleac pursuant to this Contract. Both parties have established a long-term friendly cooperation relationship.

依据《中华人民共和国合同法》的规定，甲方特此委托乙方为 MLC1501 的研

制提供生产技术服务。经双方协商，同意签订本合同并遵守以下条款。

According to the *"PRC Contract Law"*, Party A hereby entrusts Party B to provide Technical Services for the development of MLC1501, and both parties agree to sign this contract and to abide by the following articles.

第一条 本项委托的技术服务内容、方式和要求

Article 1, Technical Services content, method and requirements of this entrustment

（一）技术服务内容

A. Technical services content

1、完成 MLC1501 产品 QC 分析方法的研发和方法确认/验证，以及质量标准的建立及验证

1. Finish MLC1501 QC analytical method development and method confirmation/validation, as well as the specification establishment and confirmation.

2、完成 MLC1501 产品生产工艺开发和工艺确认以及验证

2. Finish MLC1501 product manufacturing process development and process confirmation /validation.

3、提供 MLC1501 所用 4 位药材满足 GACP 的文件证明

3. Provide supporting documents for 4 herbs used in MLC1501 compliant with GACP

（二）技术提交方式

B. Technology Delivery Mode

要求 Requirements:

1、提交 QC 分析方法报告和验证文件报告，以及质量标准建立报告

1. Provide Specification Verification and Analytical Method Validation Report; as well as the specification establishment report

2. 提交 MLC1501 样品、生产工艺开发和工艺确认文件

2. Provide MLC1501 Samples, Manufacturing Process Development and Process Validation Protocol

3. 提交 MLC1501 所用 4 位药材满足 GACP 的文件证明

3. Provide supporting documents to demonstrate 4 herbs used in MLC1501 compliant with GACP

本合同附件 1 中总结了乙方将根据本合同提供成果的清单。

Appendix 1 attached hereto summarizes the list of deliverables to be provided by Party B pursuant to this Contract.

（三）完成时间要求

C. Requirements for Completion Schedule

双方应根据有待乙方提供的每一种服务，商定技术服务的完成时间。具体时间参考第 6 条。

Both Parties shall agree in writing on the completion schedule of the Technical Services based on each type of service to be provided by Party B. Refer to Section 6, for the details of timeline.

第二条 知识产权

Article 2: Intellectual Property (IP) Rights

双方认可Moleac对MLC1501完全享有全部知识产权。神威不拥有Moleac对于MLC1501享有的任何知识产权的任何利益、所有权或权利，亦不得获得或注册任何上述利益、所有权或权利。神威对Moleac创作和提供的包装设计、布图、设计、标识、模切及相关材料不得拥有或获得任何财产利益。

Both parties acknowledge that all IP rights regarding MLC1501 are exclusively owned by Moleac. Shineway does not have, and shall not acquire or register, any interest, title or right in any IP relating to MLC1501, its preparation and/or use. Furthermore, Shineway does not have, and shall not acquire any property interest in the artwork, layout, designs, logos, die cuts and related materials created by either party relating to MLC1501.

神威在此认可MLC1501完全是Moleac的产品，有关MLC1501的专有技术、注册商标、获取专利或其相应申请权（视情况而定）的所有权以及任何其他知识产权均应属于并始终属于Moleac。神威承诺在本合同有效期内及其后，不采取或协助采取任何旨在获得或注册有关Moleac的专有技术及其他知识产权的任何财产权利的行动. 此外，神威承诺不试图以神威或任何第三方的名义取得与MLC1501有关的任何专利，在神威或任何第三方的名称中注册与Moleac拥有的商标相同或容易引起混淆的相似商标， 包括MLC1501在内的中药，或以Shineway或任何第三方的名义获得与MLC1501相关的任何其他知识产权。

Shineway hereby acknowledges that MLC1501 is Moleac's exclusive property, and that the ownership of all know-how, registered trademarks and granted patents and corresponding application rights (as the case may be), as well as any other IP rights in respect of MLC1501, shall belong to and remain vested in Moleac. During the term of this Contract and indefinitely thereafter, Shineway undertakes not to take any action, nor to assist in any such actions, to acquire or register any property rights in respect of the know-how and other IP rights of Moleac relating to MLC1501. In addition, Shineway undertakes not to attempt to obtain in Shineway's or any third party's name, any patents relating to MLC1501, register in Shineway's or any third party's name any trademarks that are identical to or confusingly similar to trademarks owned by Moleac relating to combinations of traditional Chinese medicines, including MLC1501, or obtain in Shineway's or any third party's name any other

IP rights that relate to MLC1501.

神威承诺与Moleac进行沟通，并允许Moleac拥有充分权利查阅和拥有根据本合同在技术服务期间产生的有关 MLC1501的任何和所有新成果、数据信息、记录、专有技术和其他信息。

Shineway undertakes to communicate to Moleac, and allow Moleac to have full access to, and ownership of, any and all new results, data information, records, know-how and other information generated during the Technical Services undertaken pursuant to this Contract.

第三条 工作条件和协作事项

Article 3. Working Condition and Cooperative Items

1、研究用样品将由甲方确定，甲方将提供对照品、经费及受试样品资料。

1. Samples used in studies will be determined by Party A. Party A will provide Reference Standard or fees, and documents on the tested samples necessary for completion of the Technical Services.

2、乙方将提供实验室、生产车间、检验室、分析及人员。

2. Party B will provide laboratories, workshops, testing chambers, analytical analysis and personnel necessary for completion of the Technical Services.

第四条 期限、地点和方式

Article 4: Term, Location and Mode

本合同的有效期为 2018 年 7 月 15 日至 2020 年 12 月 31 日，将在神威药业集团有限公司履行。

This contract will take effect on place Jul 15, 2018 and continue through Dec 31, 2020

第五条 验收标准

Article 5: Acceptance Standard.

甲方将验收乙方提供的技术服务文件和报告。乙方对真实性负责。甲方应向乙方出具验收证明并签字盖章。

Technical Service protocol and report provided by Party B will be inspected by Party A and accepted if meeting the acceptance criteria. Party B is responsible for authenticity. Party A shall issue a proof of acceptance with signature and stamp to Party B.

本合同服务项目的保证期为一年。在保证期内发现服务质量和数据真实性不符合验收标准的，乙方负责返工或者采取补救措施。但因甲方使用不当、操作不当或甲方自身其他原因引起的情况除外。

The warranty period for the Technical Service items for this Contract is one year. In the warranty period, if the quality of service and the data authenticity does not meet

acceptance criteria, Party B is responsible for taking remedial measures to meet acceptance criteria, except when the failure is due to misuse, improper handling or other own reasons of Party A.

第六条 项目实施、价格及支付方式

Article 6: Project Implementation, price and payment terms.

(一) 项目实施

根据技术服务内容，在各项目启动前，甲方应书面通知乙方，明确技术项目方式和要求，此后，乙方应在甲方提供的文件上签字，包括项目竣工的时间安排，这应是项目启动的一项先决条件。

A: Project implementation:

According to the contents of the technical services, Party A shall notify Party B in writing before the launch of each project, including specifying the technical project mode and requirements, The project will only be launched after Party B has signed the document provided by Party A, including a timeline for completion of the project.

（二）项目价格

B. Price of the Project:

1、MLC1501 产品 QC 分析方法的研发和方法确认/验证，以及质量标准的建立及验证

MLC1501 QC analytical method development and method confirmation/validation, as well as the specification establishment and confirmation.

Actions List	Timeline/Cost
Develop USP method to replace CP method for Finished Product general batch release testing. Translate UPS monograms and setup SOPs, perform method validation/confirmation for critical analytical methods (eg. Microbial test) 对最终产品的质量标准中通用项目的放行检测方法，开发 USP 方法以代替 CP 方法。翻译 USP 通则并制定 SOPs，对关键的分析方法进行方法确认或验证，如微生物限度研究。	- Timeline/时间: 10 working days /10 个工作日 - Cost/报价: 235000 RMB/人民币
To develop analysis method and set up specification for additional markers for drug substance and drug product. Minimally, one marker is representative of one herb. To perform method validation for newly development analysis method and existing method in meeting ICH requirement.	- Timeline/时间: 67 working days /67 个工作日 - Cost/报价: 500000 RMB/人民币

为干膏粉中间物和最终产品开发更多标示物的检测方法. 以及指标成分含量标准建立。至少每味药材都有对应的标示物。还有对新的标示物分析方法和现有的标示物进行方法学验证以满足 ICH 的要求。	
Take the 4 raw herbs retention sample from last MLC1501 batch (BN17062311), and perform fingerprint analysis, which will be set as the reference/criteria for selecting raw material for future batches. 以 BN17062311 批产品的留样药材为研究对象，为今后原药材批次建立指纹图谱参照标准。 Develop fingerprint method for drug substance (dry extract powder) and drug product (finished product). 开发原料药（干膏粉）和药品（成品）的指纹图谱法。	- Timeline/时间: 70 working days /70 个工作日 - Cost/报价: 590000 RMB/人民币

2、MLC1501 生产工艺开发和工艺确认。

MLC 1501 manufacturing process development and process validation.

Actions List （任务单）	Timeline & Cost (时间表和报价)
Based on current process, design experiment to improve the understanding of processes. To identify the critical process parameters to achieve the batch to batch consistency based on IND specifications. By referring the in-process quality control (IPQC) mentioned in IND, to evaluate IPQC by designing experiment. 根据当前工艺，设计实验来提高对工艺的理解。 根据 IND 规范确定关键工艺参数以实现批次间的一致性。 通过参考 IND 中提到的过程质量控制（IPQC）。	- Timeline/时间: 80 working days / 80 个工作日 - Cost/报价: 175000 RMB/人民币

3、MLC1501 所用 4 位药材满足 GACP 的文件证明。

Supporting documents for 4 herbs used in MLC1501 compliant with GACP

Actions List （任务单）	Timeline & Cost (时间表和报价)
Based on Shineway's experience with GACP certification of two herbs (Radix Ophiopogonis & Lonicera japonica), develop the documents to demonstrate the four herbs used for MLC1501 (Radix Astragali, Rhizoma Chuanxiong, Radix Angelicae Sinensis, Radix Polygalae) are following	待商定 To be discussed

same process and meeting GACP requirement. 根据 Shineway 在两种草药（麦冬和金银花）的 GACP 认证方面的经验，开发文件以证明用于 MLC1501 的四种草药（黄芪川芎，当归，远志）均符合 GACP 要求。	

4、以上 1、2、3 项根据服务内容改变，实施前双方可做调整。制定任务进度表，双方签字确认

4. The 1st, 2nd and 3rd items mentioned above can be adjusted before implementation according to the service content adjustment. Confirmation is signed by both parties.

(三) 支付方式

C. Payment Terms

在上述第六条第（一）款所述的文件经认可并签字后 30 天内，甲方应预付每一项目商定的服务费的 40%。在乙方交付技术报告的 30 天内，甲方应支付服务费的 30%。甲方在 60 天内会付清余下的 30%服务费。如甲方有异议，应以书面方式提出。乙方收到书面意见之后，立即修改直至甲方认可为止。但不影响付款。

Party A shall pre-pay 40% of the service fee agreed upon for each project within 30 days after confirmation and signing of the document referred to in 6.1 above. Party A shall pay the 30% within 30 days after Party B has delivered the Technical Service protocols/reports. The balance 30% will be paid by Party A within 60 days. If Party A has any doubt on the deliverables, should feedback to Party B in written. Party B will immediately make remediation after the feedback is received. Payment will not be impacted.

第七条 违约赔偿

Article 7: Breach of Contract

违反本合同约定的，违约方应按照《中华人民共和国合同法》有关规定承担违约责任。

The defaulting party shall bear the liability for breach of contract in accordance with the relevant provisions of the PRC Contract Law.

(一) 若乙方违反任何应履行服务协议的义务，乙方应：

If Party B does not fulfill any aspect of its obligations with respect to the Technical Services herein, Party B Shall:

1、按照甲方要求完成乙方违反合同义务的子项目。

1. Comply with Party A's requirements to finish the sub-project in respect of which Party B is in breach of its obligations: and

2、赔偿该子项目商定的服务费的 30%。

2. Pay a compensation amounting to 30% of the Service Fee agreed upon for said sub-project.

(二) 乙方在被授权履行本合同义务外以任何方式使用甲方提供的保密信息，或违反第二条规定的有关尊重甲方知识产权的义务，乙方应立即遵守甲方的要求，停止未经授权的活动并尽可能改正违约行为。 甲方也有权：

If Party B uses information provided in confidence by Party A in any manner except as authorized to fulfill its obligations under this Contract, or if Party B breaches its obligations with respect to Moleac's Intellectual Property as set out in Article 2, Party B shall comply immediately with Party A's request to cease the unauthorized activity and cure the breach where possible. Party A shall also have the right to:

1. 立即终止合同

1. Terminate the Contract forthwith and

2. 通过中华人民共和国法院寻求因违反合同的损害赔偿金和任何其他可用补救办法

2. Seek a damages award for the breach of contract and any other available remedy through the PRC courts

(三) 若甲方违反第五、六条约定，甲方应：

If Party A breaches Article 5 and 6, Party A shall:

1、按照乙方要求对违约行为进行补救，付清项目所有服务费。

1. Comply with Party B's requirements to remedy the breach, and pay off all the service fees of the project; and

2、赔偿违约的子项目服务费的 30%。

2. Pay a compensation amounting to Party B of 30% of the Service Fee of the breached sub-project.

第八条 争议的解决

Article 8: Dispute Settlement

在履行或终止本合同的过程中发生的任何争议，应首先通过友好协商解决。双方未能友好解决的，该争议应提交至中国国际经济贸易仲裁委员会（北京），由三名仲裁员依据其仲裁规则最终解决。仲裁地点应为中国北京。仲裁裁决应具有终局性，对双方均有约束力。仲裁费将由败诉方承担，除非仲裁庭裁定不同的承担方式。

Any disputes arising during the course of performance or termination of this Contract shall be settled first through friendly negotiation. If the parties fail to reach an amicable settlement, the dispute shall be submitted to the China International Economic and Trade Arbitration

Commission, Beijing, to be definitively settled by three arbitrators in accordance with its own rules for arbitration. The place of arbitration shall be Beijing, China. The arbitral award shall be final and binding upon both parties. The arbitration fee will be borne by the losing party unless the arbitral tribunal arbitrates a different manner of commitment.

第九条 其它

Article 9: Others

1、 本合同履行过程中，经双方同意可补充修改本合同，需双方另行签订补充协议。

1. During the course of performance of this Contract, this Contract can be supplemented or amended with the consent of both Parties, subject to a separate supplementary agreement being signed by both Parties.

2、本合同未包括的服务项目将由双方批准并签字生效，视为本合同的组成部分。

2. The service items excluded from this Contract will be approved and signed by both Parties and shall be regarded as a part of this Contract.

3、如本合同中英文版本有差异，以英文文本为准。

3. When there is discrepancy between Chinese and English versions, the text in English shall prevail.

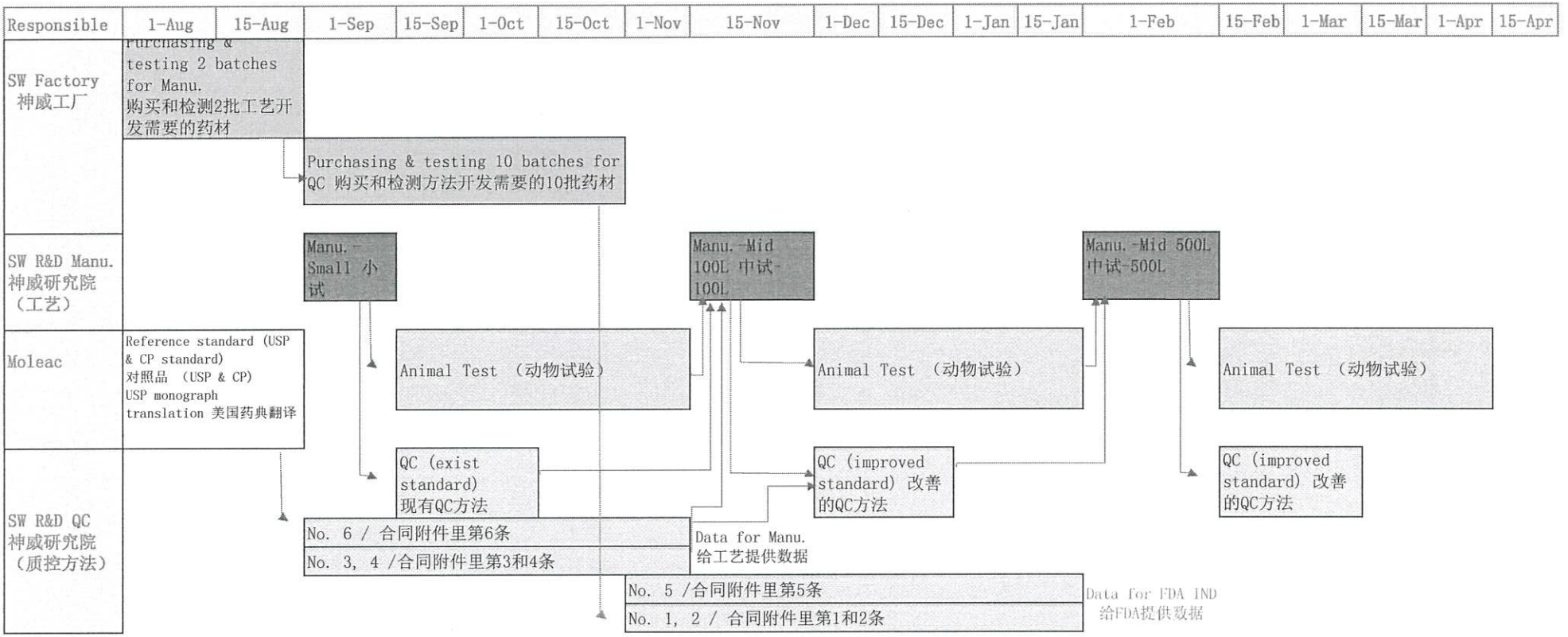
4、神威研发中心应为该项目指定一名项目经理。双方应每两周举行一次电话会议以便进行项目更新，以确保项目顺利进行

4. Shineway should appoint a project manager from R&D center for this project. Two parties should held biweekly teleconferences for project updates in order to ensure the project being carried out smoothly.

甲方：新加坡莫利亚克公司	乙方：神威药业集团有限公司
PARTY A: MOLEAC PTE LTD	PARTY B: SHINEWAY PHARMACEUTICAL GROUP LTD
被授权人：	被授权人：
Authorized person: DAVID PICARD	Authorized person:
签字盖章：	签字盖章：
Signature and seal:	Signature and seal:
日期：	日期： 2018-08-22
Date: 2018-09-20	Date:

附件 1 Appendix 1：

编号 S/N	技术服务成果 *Technical Service Deliverables*
1	General batch release testing (e.g. Water Content; Average fill weight; Disintegration time; Microbial Limit; Aflatoxin), need follow USP method instead of CP method. 一般放行检验（例如水含量;平均填充重量;崩解时间;微生物限制;黄曲霉毒素）需要遵循 USP 方法而不是 CP 方法。
2	Batch release test for Raw herb – Radix Astragli need follow USP method instead of CP method. 黄芪原药材的放行检验 -需要遵循 USP 方法而不是 CP 方法。
3	To develop/improve analysis method for additional markers for drug substance and drug product. Minimally, one marker is representative of one herb. 研发新的标志物和改进现有的分析方法。 至少每一种原药材都有表征标示物。
4	To perform method validation for newly developed markers analysis method and existing method (astragaloside IV) in meeting ICH requirements 对新开发的标示物分析方法和现有标示物的分析方法（黄芪甲苷 IV）进行方法验证以符合 ICH 要求
5	Develop fingerprint method and establish QC batch releasing criteria for 4 individual raw materials – raw herb & slices 为 4 种原药材和饮片分别开发指纹图谱并建立 QC 放行标准
6	Develop fingerprint method and establish QC batch releasing criteria for drug substance (dry extract powder) and drug product (finished product) 为中间物（干膏粉）和最终产品（成品）开发指纹图谱并建立 QC 放行标准
7	Provide supporting documents for 4 herbs used in MLC1501 compliant with GACP 为符合 GACP 的 MLC1501 中使用的 4 种草药提供支持性文件
8	Provide the samples, manufacturing details and conclusion from small scale trial – 3 batches 提供小规模试验（3 批）样品，制造细节和结论
9	Provide the samples, manufacturing details and conclusion from middle scale trial (100L extraction tanks) – 3 batches 提供中试试验（100L 提取罐；3 批）样品，制造细节和结论
10	Provide the samples, manufacturing details and conclusion from big scale trial (500L extraction tanks) – 3 batches 提供大试试验（ 5 00L 提取罐；3 批）样品，制造细节和结论
11	Provide the samples, manufacturing details and conclusion from commercial scale trial (3000L extraction tanks) – 1 batch 提供试生产（ 1 批）样品，制造细节和结论
12	Provide the optimal manufacturing process parameters and in-process control critical process parameters 提供最佳制造工艺参数和过程控制关键工艺参数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SW Factory 神威工厂
Purchasing & testing 2 batches for Manu. 购买和检测2批工艺开发需要的药材
Purchasing & testing 10 batches for QC 购买和检测方法开发需要的10批药材
SW R&D Manu. 神威研究院（工艺）
Manu.-Small 小试
Manu.-Mid 100L 中试-100L
Manu.-Mid 500L 中试-500L
Moleac
Reference standard (USP & CP standard) 对照品 (USP & CP) USP monograph translation 美国药典翻译
Animal Test （动物试验）
Animal Test （动物试验）
Animal Test （动物试验）
SW R&D QC 神威研究院（质控方法）
QC (exist standard) 现有QC方法
QC (improved standard) 改善的QC方法
QC (improved standard) 改善的QC方法
No. 6 / 合同附件里第6条
No. 3, 4 /合同附件里第3和4条
Data for Manu. 给工艺提供数据
No. 5 /合同附件里第5条
No. 1, 2 / 合同附件里第1和2条
Data for FDA IND 给FDA提供数据