台檢工業科技股份有限公司
SGS Taiwan Industrial Services Ltd.

INFORMATION OF☒TEST ARTICLE/☐CONTROL ARTICLE

Sponsor Company Name	**Test/Control Article No.** It will be labeled by SGS sample receiving personnel.
Sponsor Address	
Sponsor Telephone Number	
Name of Test Article/ Control Article	
Type	☐ Medical Devices，Category: ☐ Surface Device ☐ External Communicating Device: Circulating Blood：☐Yes☐No ☐ Implant Device ☐ Gas Pathways ☐ Other Type：_____ ☐ Food; ☐ Cosmetics Products ; ☐ Industrial Chemicals; ☐ Pesticide Products; ☐ Drug; ☐ Others：_____
Amount (Note 2)	A、Quantity/Unit:_____ B、☐One Test (No Retention)☐Two Test (For Retention) C、Packing Condition: ☐In Bulk ☐Intact Packing
Sterilization	Has been Sterilized ☐NO ☐YES, If Yes, Please Select the Following Method, ☐EO Sterilization☐Gamma Sterilization☐Steam Sterilization☐Other_____
Expiry Date (Note 3)	☐Expiry Date:_____._____._____(YYYY.MM.DD) ☐Not Provided.
Batch/Lot Number	☐ _____ ☐Not Provided.
Model Number	☐ _____ ☐Not Provided.
Description	A、 Major Components:_____ B、 Purity:_____ C、 Concentration:_____ D、 Stability：_____ E、 Color :_____ F、 Solvent and Solubility ：_____ G、 External Features: ☐Regular ☐Irregular ☐Liquid ☐Powder ☐Granule ☒Flat ☐Other:_____ H、 Thickness：_____mm/pcs or ☐ Not Available. I、 Surface Area*： ☐ _____cm^2/ pcs： ☐Human Contact Portions ☐All side or ☐ Not Available. *According to FDA guidance, determine the appropriate amount of test material by using surface area to extractant volume ratios. Mass to extractant volume ratios should only be used if surface area cannot be calculated, or if use of mass will result in a larger sample. In addition, the test will be performed directly with the surface area provided by the sponsor. ISO10993-12, No-patient contacting portions of the medical device should be exclude either physically from test sample extracts or exclusion of the surface area in the calculation of the extraction ratio.
Attachment(Note 4)	☐Certificate of Analysis ☐Material Safety Data Sheet ☐Stability Test Result ☐Others：_____ ☐No Attachment (Note4)
Storage Condition	☐Room Temperature☐2~8℃☐-10~-25℃☐Protect from Light ☐Others：_____

Can be Cut(Note5)	☐Yes ☐No ☐N.A(Liquid, Gel, Powder)
Testing parts	☐Whole Article ☐Determine by SGS ☐Specific Parts/Please Describe：_____
Extraction	Ratio： ☐No Extraction ☐By Surface Area：☐(3±10%)cm^2/mL☐(6±10%)cm^2/mL ☐By Weight：☐(0.1±10%)g/mL☐(0.2±10%)g/mL ☐Other：_____
	Condition： ☐(37±1)℃ (24±2)Hours ☐(37±1)℃ (72±2)Hours ☐(50±2)℃ (72±2)Hours ☐Other：_____
Source	A、Location of Origin：_____ B、Manufacturer/Supplier：_____ C、Manufacture Date：_____
Article Return (Note6)	☐No ☐Yes, only for un-used test article ☐Other：_____
Others	

Note1. All information in the form including the blanks which can't be provided are disclosure and should taken responsibility by the sponsor.
Note2. If the test follow GLP, should provide extra amount of the test/control article with the same lot for retention. If sponsor doesn't provide the retention of test article/control article, the retention of a reserved test article/control article from each lot/batch of test article /control article is the responsibility of the Sponsor.
Note3. For retention, if the effective period is less than SGS SOP definition, the test article/control article will be retained till the expiry date. If the expiry date is longer than SGS SOP definition, the test article/control article will be retained for the period of SGS SOP definition only. If the expiry date remained incomplete, it mentions that sponsor will agree that test facility will determine the earliest date, e.g. Exp. Date: 2020(YYYY), sponsor didn't identify the MM/DD, the expiration date should be 2020.01.01.
Note4. Sponsor should determinate, document and confirm the identity, strength, purity, stability, composition, method of synthesis, fabrication, derivation or other characteristics of the test article/control article before study. If the sponsor cannot provide the information, determination and documentation of the test article/control article are the responsibility of the Sponsor.
Note5. The test article/control article which has been destroyed or cutting will be discarded after the end of experiment unless applicant/sponsor have extra requirement. If the sponsor does not agree or have special requirements, should take the initiative to inform test facility and state the application prior to test. If related losses incurred because applicant/sponsor didn't inform, we will not be liable.
Note6. If sponsor wants to return the sample, the retention, inconsistencies and biological safety related issue of test article/control article are the responsibility of the Sponsor.
Note7. Note 'N/A' or 'N.A'if not applicable. Do not leave blank.
Note8. Test article and control article should be filled individually in "INFORMATION OF TEST ARTICLE/CONTROL ARTICLE".
Note9. GLP test：(1) Corrections and additions to a final report should be in the form of amendments. Amendments should clearly specify the reason for the corrections or additions. Lot number, test article photos and raw data cannot be amended by sponsor's requirement. (2)One protocol only can generate one report except for translation version. If the report with more than two languages version, we only issue English version protocol. We only issue amendment or additional language GLP report within three years and non-GLP report within one year. (3)The GLP compliance statement will state that we follow TFDA GLP and TAF OECD GLP norm unless sponsor's requirement. SGS Taiwan Ltd. UTIS have acquired Good Laboratory Practice Statement of Compliance from TFDA and TAF .
Note10. Please write down it carefully and in detail. "INFORMATION OF TEST ARTICLE/CONTROL ARTICLE" will be placed in the protocol and report along with a copy of this official document. If the information is not clear, we will exclude them from GLP statement.
Note11. The results shown in this test report refer only to the test article(s) tested.
Note12. If the sponsor is different from the applicant mentioned in the application form, the sponsor agrees that the study-related information, test/control article and application form provided or reply to SGS shall be agreed by the sponsor. The report submitted by SGS is only to the applicant.

Sponsor's Representative Signature/ Date：_____

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☒試驗物質/☐對照物質資料表

試驗委託者名稱	**試驗/對照物質編號** 此欄由本單位之收樣人員標示
試驗委託者地址	
試驗委託者電話	
試驗物質/對照物質名稱	
類別	☐醫療器材，分類: ☐接觸體表醫材 ☐體外連通醫材: 循環血液：☐是☐否 ☐植入醫材 ☐呼吸器 ☐其他類別：_____ ☐食品; ☐化粧品; ☐工業化學品; ☐農藥及環境用藥; ☐藥品; ☐其他：_____
數量(註2)	A、 數量/單位：_____ B、☐1次之測試使用(不留樣) ☐2次以上之測試使用(留樣用) C、包裝情況：☐散裝☐完整包裝
滅菌	產品是否已滅菌☐否☐是 (如勾選“是”，請再勾選下方滅菌方法) 滅菌方法是☐EO滅菌☐Gamma滅菌☐蒸汽滅菌☐其他_____
有效期限(註3)	☐有效期限 : 西元_____年_____月_____日 ☐無有效期限可提供
批號	☐ _____ ☐無可提供
型號	☐ _____ ☐無可提供
樣品描述	A、 主成分:_____ B、 純度:_____ C、 濃度:_____ D、 穩定度:_____ E、 顏色:_____ F、 適合之溶劑及其溶解度：_____ G、 型態: ☐規則☐不規則☐液狀☐粉狀☐顆粒☐片狀☐其他：_____ H、 厚度 _____mm/件 or ☐不適用 I、 表面積*: ☐_____cm^2/件：☐接觸人體部位 ☐全面積 or ☐不適用 *依據FDA指引，試驗物質萃取適當比例主要取決於表面積，唯有表面積無法計算或是大件樣品得以使用重量做為萃取比例計算。另試驗將以試驗委託者提供之表面積逕自進行測試。ISO10993-12，醫療器材非患者接觸部分應在試驗物質萃取中排除，或於萃取率計算排除表面積。
檢附之文件(註4)	☐分析證明☐安全資料表☐安定性測試結果☐其他：_____ ☐無附件(註4)
儲存環境	保存條件 ：☐室溫☐2~8℃☐-10~-25℃☐避光☐其他_____

試驗物質能否破壞(註5)	☐可破壞 ☐不可破壞 ☐不適用(液體，膠狀，粉狀)
測試部位	☐全樣品測試 ☐ 由本實驗室判斷 ☐指定測試部位/請描述：_____
萃取	比例： ☐不需萃取 ☐以面積萃取：☐(3±10%)cm^2/mL☐(6±10%)cm^2/mL ☐以重量萃取：☐(0.1±10%)g/mL☐(0.2±10%)g/mL ☐其他：_____
	條件： ☐(37±1)℃(24±2)小時☐(37±1)℃72±2)小時 ☐(50±2)℃(72±2)小時 ☐其他：_____
來源	A、原產地：_____ B、製造/供應商：_____ C、製造日期：_____
退樣(註6)	☐不須退還☐未使用過的試驗物質需退還☐其他：_____
其他	

註1. 本資料表所有資訊包含未填列事項由試驗委託者揭露並負責。未填列事項即代表試驗委託者無法提供此資訊並負責。

註2. 若此試驗依循GLP，試驗物質/對照物質除送來夠一次檢測量外，仍應再留一份同批號且可供一次試驗用的試驗物質/對照物質，若試驗委託者無法提供試驗/對照物質每批具代表性之儲備試驗/對照物質，其留存由試驗委託者自行存放負責。

註3. 針對有留樣量之試驗物質/對照物質，試驗物質/對照物質之有效期限少於本單位之留樣保存期限則以試驗委託者提供之有效期限為主；若試驗物質/對照物質之有效期限大於本單位之留樣保存期限，以本單位之有效期限為主。若有效期限填寫不完整，將以當年或當月之最早期限為主，例如有效期限僅填寫2020年，其有效期限將定義委託者同意為2020.01.01。

註4. 試驗委託者需於試驗前確認試驗物質/對照物質的本質，其包含試驗委託者提供之批次、純度、濃度、成份、合成、製造方法、來源、安定性或其他可適當定義本質的特徵之文件，若試驗委託者無法提供或正本之保存為試驗委託者的責任。

註5. 貴客戶所提供的測試試驗物質/對照物質，本單位依檢測目的暨專業領域鑑別判斷，針對破壞性檢測樣品進行破壞，減損與破壞將於試驗後丟棄，若委託者不同意或有特殊要求時，應主動於申請檢測前告知並載明於申請書，若因委託者未告知而產生相關損失，本單位將不負賠償責任。

註6. 若試驗委託者選擇退樣，則需自行負擔試驗物質一致性及生物安全之責任。

註7. 若此空格不適用，請填寫N/A或N.A，勿留空白處。

註8. 若有試驗物質或對照物質應分別填寫“試驗物質資料表或對照物質資料表”.

註9. GLP試驗注意事項：(1)修訂試驗計畫書與報告之更正與添加會以修訂方式為之，將會清楚於修訂試驗計畫書與修訂報告中呈現。批號、照片、原始數據不得修改。(2)一份試驗計畫書只能出一份報告，唯因不同語言之翻譯版不在此限。同時出具兩種以上語言之GLP報告，僅出具單一語言(英文)之計畫書。三年後不得加發或修訂報告。 (3) GLP之試驗委託者申請進行試驗時，以本單位遵循之TFDA GLP及TAF OECD GLP規範之聲明為主，若有特例試驗委託者需於相關文件中另行說明，SGS超微量工業安全實驗已取得TFDA GLP及TAF OECD GLP符合性登錄證書。

註10. 請試驗委託者確實填寫資訊，“試驗物質/對照物質資料表”將呈現在試驗計畫書及報告;請務必確認填寫內容無誤並簽署，如未填寫或填寫不確實，計畫書/報告中將於聲明中書寫排除。

註11. 報告的測試結果僅對委託者所送的當次試驗物質負責。

註12. 試驗委託者若與申請書之申請者不同，試驗委託者同意由申請者提供或回覆給本單位之分析相關檢測資訊物件及簽署之申請書內容，均經過試驗委託者同意。本單位提出之檢測報告，僅出具于申請者。

試驗委託者代表簽名/日期：_____