

**HIS 委託試驗申請書-安全性試驗**  
**HIS APPLICATION FORM- Safety Study**

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請填妥此申請書,連同試驗物質(即樣品)/對照物質一併寄出。Please fill in the application form and send it with test article (sample) /control article.

<b>申請者(Applicant) :</b> <b>郵寄地址(Address) :</b> (請填寫郵遞區號 Zip Code)  <b>統一編號(Registration Add. I/V No) :</b> <b>電話(Tel) :</b> <b>Ext:</b> <b>傳真(Fax) :</b> <b>聯絡人(Contact Person) :</b> <b>E-mail:</b>	<b>發票公司名稱(Invoice To) :</b> <b>發票地址(Registration Address) :</b>  <b>統一編號(Registration Add. I/V No) :</b> <b>電話(Tel):</b> <b>Ext:</b> <b>傳真(Fax):</b> <b>聯絡人(Contact Person):</b> <b>E-mail:</b>
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無填寫上方右欄者,發票公司與申請者相同; If the Invoice title is the same as applicant, the above right column shall not be filled out

<b>1. 試驗/對照物質名稱</b> Test/Control Article Name	(若需退樣, 快遞費用由客戶負擔, If return, express charge will be paid by applicant directly)
<b>2. 報告型式 Report Type</b> (備註 9 Note9)	<input type="checkbox"/> 英文 English <input type="checkbox"/> 繁體中文 Mandarin <input type="checkbox"/> 簡體中文 Simplified Chinese <input type="checkbox"/> 電子檔 Soft Copy (免費 Free) <b>【本單位只提供一種型式報告, 若加發另一型式或有修訂需求, 需另收費。We only provide you one language report. If you want to have another report with different language or amendment requirement for protocol / report, extra charge will be paid by applicant directly.</b>
<b>3. 報告領取 Get Report</b>	<input type="checkbox"/> 自取 By Yourself <input type="checkbox"/> 限掛郵寄 By Mail <input type="checkbox"/> E-mail
<b>4. 特殊需求</b> Specific Requirement	<input type="checkbox"/> 吸水測試 <input type="checkbox"/> 請填寫 Please Specify : <input type="checkbox"/> 無 N.A. <small>**萃取條件:若有指定請申請者填寫於“特殊需求”中,無說明則由本單位依產品性質來判斷, 實驗後若對萃取條件有修改, 本單位會另外收取費用。Extraction Condition: Please fill in it in “Specific Requirement” if you have extraction condition, otherwise it will be decided by SGS. (Changing condition during or after test will be charged.)</small>
<b>5. 預定註冊權責機關</b>	<input type="checkbox"/> 行政院衛生福利部食品藥物管理署 TFDA <input type="checkbox"/> 農業委員會動植物防疫檢疫局 BAPHIQ <input type="checkbox"/> 經濟部工業局 IDB <input type="checkbox"/> 其他: <input type="checkbox"/> 無 N.A.

**委託試驗項目 (Test(s) Required) :**

01.  細胞毒性試驗 Cytotoxicity Test (Guidance: <sup>o</sup>  
 ISO 10993-5 :  MTT  Agar Diffusion  Colony Formation  Others (Please specify \_\_\_\_\_) or  
 USP87 :  Elution  Agar Diffusion  Direct Contact  Others (Please specify \_\_\_\_\_) or  
 Others (Please specify \_\_\_\_\_)
02.  血液相容性: 溶血試驗 Hemolysis Test (Guidance: ISO 10993-4, ASTM F756)  
 方法 Method:  直接接觸法 Direct contact  萃取法 Extract  兩者皆需 Both (為規範建議, Guidance Suggestion)
03.  內毒素試驗 Endotoxin Test, 動力呈色法 The Kinetic Chromogenic Assay (Guidance: USP< 85>) (ISO/IEC17025, OECD GLP)
04.  基因毒性試驗: 沙門氏菌基因回復突變試驗 Salmonella Reverse Mutation Test (Guidance: ISO 10993-3, OECD TG 471)
05.  基因毒性試驗: 體外哺乳動物細胞染色體異常試驗 Genotoxicity: In Vitro Mammalian Chromosomal Aberration Test (Guidance: ISO 10993-3, OECD TG 473)
06.  基因毒性試驗: 體外哺乳動物細胞基因突變試驗 Genotoxicity: In Vitro Mammalian Cell Gene Mutation Test (Guidance: ISO 10993-3, OECD TG 490)
07.  基因毒性試驗: 微核試驗 Genotoxicity: Micronucleus Test (Guidance: ISO 10993-3)
08.  植入試驗 Implant Study-\_\_\_\_\_ days with histopathology (Guidance: ISO 10993-6)  
 肌肉 Muscle  皮下 Subcutaneous  骨骼 Bone
09.  皮膚刺激試驗 Skin Irritation Test (Guidance: ISO 10993-23)
10.  眼刺激試驗 Ocular Irritation Test (Guidance: ISO 10993-23)
11.  皮內刺激試驗 Intracutaneous Irritation Test (Guidance: ISO 10993-23)
12.  皮膚敏感試驗(極大化法) Skin Sensitization Study (Maximization Test) (Guidance: ISO 10993-10)
13.  急性系統毒試驗/注射試驗 Acute Systemic Toxicity Study /Systemic Injection Test (Guidance: ISO 10993-11)
14.  重複劑量毒性 14 Day Repeat-Dose Systemic Toxicity Study (Guidance: ISO 10993-11)

15.  重複劑量毒性 28 Day Repeat-Dose Systemic Toxicity Study (Guidance: ISO 10993-11)  
 16.  急性口服毒性試驗 Acute Oral Toxicity Test: Limit (Guidance: ISO 10993-11)  
 17.  熱原試驗 Pyrogen Study (Guidance: USP <151>)  
 18.  Others (Please Specify) \_\_\_\_\_

以上所勾選之測試項目應遵循之規範 Click Quality Regulation Should be Followed:

ISO/IEC 17025;  GLP, Good Laboratory Practice 請擇一 Please Only Select One。(詳見備註及聲明 10, Please see Note and Statement 10)

請連同“試驗物質/對照物質資料表”一起完成。Please fill in the form “INFORMATION OF TEST ARTICLE/CONTROL ARTICLE”

備註及聲明 Note and Statement

- 本單位報告是遵循 SGS 服務通用條款規定製作，倘需此條款內容，請來電索取或至 [www.sgs.com/terms\\_and\\_conditions.htm](http://www.sgs.com/terms_and_conditions.htm) 網站查閱。All SGS services are rendered in accordance with the applicable SGS conditions of service available on request and accessible at [http://www.sgs.com/terms\\_and\\_conditions.htm](http://www.sgs.com/terms_and_conditions.htm)
- 開案確立後，除經本單位書面同意，不論測試結果為何，申請者仍有義務支付檢測費用。因此申請之金額單價較高，申請者應於樣品收樣兩週內支付 80% 費用，剩餘部份於收到報告電子檔時支付(發票會分開兩筆開立)，若有填寫發票公司，則付費相關事項由發票公司支付及承擔。After application form is signed, the applicant should have the obligation to pay the cost of testing regardless of the test results except SGS's extra agreement. Please pay 80% fee after we receive the test article/sample first, and the reminding will be paid after you receive the soft copy of final report.(we will give you total two invoices for the separate payment). The payment responsibility will be the one who receive the invoice.
- 除有特別約定外，當事人應於發票開立後 30 日內支付相關檢驗測試費用，若相關檢驗測試費用之給付逾期遲延，應自遲延日起至費用清償日止計算遲延利息，遲延利息以年利率百分之 12 計算。Unless otherwise agreed, the parties shall pay the expenses related to inspection and testing within 30 days after invoicing, if relevant inspection and testing fees overdue payment delay, delay interest should be calculated from the cost of the settlement date to ending date delay, delay interest at 12% per annum calculated.
- 若因本件檢驗及其檢驗費用涉訟時，雙方當事人同意以台灣台北地方法院為第一審管轄法院。If the inspection and testing fees were involved in lawsuit, the parties agreed to the Taipei District Court as court of first instance.
- 本委託試驗申請書經「申請者」及「本單位」雙方人員簽名確認後，視同本契約即刻生效。Commissioned by the test application "sponsor/ applicant" and "SGS Taiwan" on both sides signing confirmed, deemed the contract with immediate effect.
- 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。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.
- 若客戶選擇退樣，一致性及生物安全之責任，且快遞費用由客戶負擔。If applicant wants to return the sample, the retention, inconsistencies and biological safety related issue of test article/control article are the responsibility of the Sponsor. If return, express charge will be paid by applicant directly
- 申請廠商或試驗委託者有提供之試驗過程必要之(包含但不限於對照物質、管柱、與當次測試結果相關之計算數據)，應同步提供該合用性之 COA 或聲明書。The applicant or sponsor has to provide the necessary test process (including but not limited to the control article, the column, and the calculation data related to the test result), and the COA or declaration of the suitability should be provided simultaneously.
- 若需英文報告，試驗物質資料表請以英文方式填寫。If you want to have English report, please write down the English version form "INFORMATION OF TEST ARTICLE/CONTROL ARTICLE".
- 申請者同意其所填寫之“試驗物質/對照物質資料表”內容及此文件之註記事項。試驗報告之所有資料以“試驗物質/對照物質資料表”為主。試驗報告抬頭廠商與“試驗物質/對照物質資料表”上試驗委託者之資料相同。若需不同或申請者需於報告中揭露，請另加說明。The applicant agrees the fill in content and notes in the "INFORMATION OF TEST ARTICLE/CONTROL ARTICLE". The name of sponsor in the report will be the same as the information which written in the "INFORMATION OF TEST ARTICLE/CONTROL ARTICLE". All the information will be according to "INFORMATION OF TEST ARTICLE/CONTROL ARTICLE". If it is different or applicant wants to reveal in the protocol/ report, please clarify and elaborate on it.
- 申請者同意授權委託機構處理外部服務轉件事宜並同意本單位回報委託案部分資訊予 TAF、TFDA 與相關法規單位。\*表示外部服務項目。The sponsor/applicant agreed to authorize the test facility outsourcing the rest and giving the test related information to TAF, TFDA and related regulatory authority. \* stands for subcontract.
- 除 TAF 與 TFDA 要求外，申請者未指定試驗規範年版時，以受託機構之本單位最新版為主。In addition to TAF and TFDA requirements, the latest version will be adopted by test facility when the sponsor/applicant did not specify the test specification version.
- 報告的測試結果僅對委託者所送的當次試驗物質負責，不代表及涵蓋該廠商其他產品範疇。The results shown in this test report refer only to the test article(s) tested. not represent and cover the sponsor's other product categories.
- 本申請表主要適用於財務協定，當申請者以試驗委託者不一致，報告之試驗委託者以“試驗物質/對照物質資料表”為主。The Application Form is for financial issue agreement. All the information will be according to "INFORMATION OF TEST ARTICLE/CONTROL ARTICLE" as if applicant and sponsor is not the same.
- 此委託試驗申請書視同正式合約。The application form is considered as formal contract.
- 申請者若與試驗物質資料表之試驗委託者不同，申請者同意其提供或回覆給本單位之分析相關檢測資訊及物件，均經過試驗委託者同意。本單位提出之檢測報告，僅出具於申請者。If the applicant is different from the sponsor mentioned in the "INFORMATION OF TEST ARTICLE/CONTROL ARTICLE", the applicant agrees that the study-related information and test/control article provided or reply to SGS shall be agreed by the sponsor. The report submitted by SGS is only to the applicant.

申請者簽名 (Applicant signed):

Name/Date(YYYY.MM.DD)

報告號碼 (Report No.):

收樣日 Date in:

預出數據日 Date out:

(本欄為本單位填寫用)