

检测报告

报告编号: ASH20-006953-01

发布日期: 2020-07-16

客户名称: 中船重工(沈阳)抗微生物科技有限公司
客户地址: 辽宁省沈阳市和平区十三纬路 23-5 号
样品名称: 抗微生物助剂
样品批号: /
生产日期: /
生产商: /

以上样品及信息由客户提供及确认, SGS 不承担证实客户提供信息的准确性、适当性和(或)完整性责任。

SGS 相关号: XMF20-000636

样品接收日期: 2020 年 03 月 05 日

检测周期: 2020 年 03 月 05 日 - 2020 年 07 月 09 日

检测要求: 根据客户要求进行检测

检测方法: 请参见下一页

检测结果: 请参见下一页

除非另有说明, 本检测结果仅与被检测物品有关。仅供客户内部使用, 不对社会具有证明作用。未经检验机构书面同意, 委托人不得擅自使用检测结果进行不当宣传。

结论:

在本实验条件下, 样品 (抗微生物助剂) 经五株标准菌株测定后, 无论加和未加 S9 均为阴性, 不具有致基因突变作用。



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检测样品描述:

样品编号	SGS 样品 ID	描述
1	ASH20-006953.001	浅棕色液体

检测结果:

1. 检测方法: GB/T 21786-2008
2. 检测项目: 鼠伤寒沙门氏菌回复突变试验
3. 菌株名称: 组氨酸营养缺陷型鼠伤寒沙门氏菌 TA1535、TA97、TA98、TA100 和 TA102 一组五株标准测试菌株
4. 菌株生物学特性: 经鉴定, 5 种菌株在本实验条件下均符合其生物学特性
5. 阴性对照: 无菌水、二甲基亚砜 (DMSO)
6. 阳性对照:
 - S9: 敌克松、叠氮钠;
 - +S9: 2-氨基芴、1,8-二羟基蒽醌、环磷酰胺;
7. 代谢活化系统: 大鼠肝 S9
8. 样品前处理: 按客户要求样品经十万分之一进行稀释后作为原液, 再以无菌水为溶剂经过滤除菌后分别配制成各剂量组浓度。
9. 剂量设计: 分别在加和不加 S9 的情况下选择 0.05mg/皿、0.16mg/皿、0.50mg/皿、1.58 mg /皿和 5.00mg/皿共计 5 个剂量组为正式试验剂量, 选择 0.32mg/皿、0.63mg/皿、1.25mg/皿、2.50mg/皿、5.00mg/皿共计 5 个剂量组为验证试验剂量, 同时再设空白对照、阴性对照和阳性对照组
10. 试验方法: 菌株经增菌培养制得增菌液后进行平板掺入, 2.0mL 顶层培养基分装于试管中, 于 45°C 水浴保温, 然后每管依次加入受试样品 0.1mL、增菌液 0.1mL 和 S9 混合液 0.5mL(需代谢活化时)混匀。迅速倾入底层培养基上, 使其均匀分布, 水平放置待顶层培养基凝固后, 将平板翻转, 37°C 培养 48h。计数每皿回变菌落数。
11. 结果:

阴性对照和阳性对照试验的回复突变数在被接受的范围内, 因此认为本试验有效。
在加和不加 S9 的情况下, 样品对菌株没有可观察到的毒性。
在加和不加 S9 的情况下, 样品未引起任一种菌株回复突变菌落数的显著增加。经验证试验确证样品依然为阴性。

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附表 1 鼠伤寒沙门氏菌回复突变试验结果-正式试验(个/皿,x±s)

S9	组别		剂量 (μg/皿)	TA97	TA98	TA100	TA102	TA1535
- S9	空白对照组		/	104±4.7	32±1.2	119±1.0	253±11.4	9±0.0
	阴性对照组 (无菌水)		/	96±2.5	29±0.6	122±3.5	247±2.1	12±1.2
	阴性对照组 (DMSO)			109±6.1	32±1.2	130±6.4	257±8.6	10±0.6
	样品组		50	108±10.6	30±0.6	129±9.2	251±11.2	11±2.6
			160	107±13.6	32±1.7	126±9.3	239±10.5	13±0.6
			500	106±5.3	31±2.6	124±5.3	233±10.1	12±1.2
			1580	107±9.8	30±1.2	122±5.8	246±2.0	9±0.0
			5000	101±6.0	30±1.5	122±8.6	230±2.3	13±0.6
	阳性对照组	敌克松	50μg/plate	2644±94.1	1093±70.2	/	896±98.1	/
	照组	叠氮钠	1.5μg/plate	/	/	2831±81.6	/	636±127.0
- S9	空白对照组		/	105±4.6	31±2.3	117±6.1	258±3.2	13±0.0
	阴性对照组 (无菌水)		/	113±4.0	29±0.6	122±9.3	264±5.5	12±0.6
	阴性对照组 (DMSO)			97±2.1	29±1.7	127±5.9	251±3.2	10±1.2
	样品组		50	110±2.5	31±1.5	123±7.0	244±6.7	8±0.6
			160	110±6.5	32±2.3	126±4.7	258±7.6	11±2.9
			500	106±6.1	31±3.0	128±3.2	245±13.5	10±2.1
			1580	108±6.7	28±0.6	123±7.6	235±6.4	13±0.6
			5000	105±8.2	29±1.0	129±3.5	246±11.6	11±0.0
	阳性对照组	2-氨基芴	10μg/plate	1167±55.2	2280±47.0	1178±54.4	/	/
		1,8-二羟基蒽醌	50μg/plate	/	/	/	1124±74.1	/
		环磷酰胺	200μg/plate	/	/	/	/	467±30.6

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附表 2 鼠伤寒沙门氏菌回复突变试验结果-验证试验(个/皿,x±s)

S9	组别		剂量 (μg/皿)	TA97	TA98	TA100	TA102	TA1535
-S9	空白对照组		/	108±10.7	30±0.0	125±9.5	252±6.7	9±0.0
	阴性对照组 (无菌水)		/	105±9.0	32±1.2	123±4.9	237±3.2	13±0.6
	阴性对照组 (DMSO)			105±1.5	32±1.0	122±9.3	241±11.4	12±0.6
	样品组		10	98±3.1	31±1.5	127±8.1	248±6.2	10±1.5
			40	103±7.4	29±1.0	118±3.2	238±10.1	9±0.6
			200	103±4.5	29±1.2	116±3.5	243±4.5	11±1.2
			1000	111±6.1	29±0.6	123±6.0	246±6.7	11±0.0
			5000	104±2.9	29±0.6	125±5.5	238±8.5	12±1.2
	阳性对照组	敌克松	50μg/plate	2707±83.3	1147±61.1	/	889±43.1	/
	照组	叠氮钠	1.5μg/plate	/	/	2752±58.9	/	692±72.3
-S9	空白对照组		/	112±2.1	32±1.2	120±2.0	242±17.0	9±0.0
	阴性对照组 (无菌水)		/	108±6.7	31±0.6	130±6.6	243±3.6	11±0.6
	阴性对照组 (DMSO)			116±5.5	30±0.0	138±2.6	260±6.5	12±1.2
	样品组		10	107±0.6	29±1.2	126±2.5	250±8.5	12±0.6
			40	103±8.4	29±0.0	122±10.6	249±6.1	12±1.2
			200	100±6.0	30±0.6	129±9.2	251±9.6	9±1.0
			1000	112±3.1	28±0.6	128±3.1	253±11.0	10±2.3
			5000	111±4.5	29±1.0	121±7.6	229±3.5	11±1.0
	阳性对照组	2-氨基芴	10μg/plate	1157±67.7	2227±50.3	1184±65.5	/	/
		1,8-二羟基蒽醌	20μg/plate	/	/	/	1227±50.3	/
		环磷酰胺	200μg/plate	/	/	/	/	463±48.4

备注:

1. 检测项目由宁波出入境检验检疫局检验检疫技术中心实验室执行。

*** 结束***

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