

产品检测报告

Certificate Of Analysis

NMK-QR-QC-003A

Report No: 20200504

产品名称 Product Name	Panco Solv Capsule /Effecsulin Capsule 艾菲苏林胶囊	制令单号 #MO	#072	产品 SKU Product SKU	HCD_FD-04-004
产品规格 Product Spec.	90Capsules (63g)	批量 Quantity	480 瓶	产品批号 Lot No.	A200415A
生产日期 Mfg. Date	20200415	有效期至 Expired Date	20230414	报告日期 Report. Date	20200518

No.	Testing Item	Standard	Results	Adjudge
1	需氧菌总数 Total Aerobic Microbial Coun	≤ 1000 cfu/g	<10 cfu/g	☒ OK ; ☐ NG
2	酵母菌和霉菌 Total Combined Molds and Yeasts Count	≤ 100 cfu/g	<10 cfu/g	☒ OK ; ☐ NG
3	耐胆盐格兰阴性菌 Bile-tolerant Gram-negative bacteria	≤ 100 cfu/g	<10 cfu/g	☒ OK ; ☐ NG
4	金黄色葡萄球菌 Staphylococcus aureus	Negative	Not Detected	☒ OK ; ☐ NG
5	沙门氏菌 Salmonella Species	Negative	Not Detected	☒ OK ; ☐ NG
6	大肠杆菌 Escherichia coli	Negative	Not Detected	☒ OK ; ☐ NG
7	梭状芽胞杆菌 Clostridium Species	Negative	Not Detected	☒ OK ; ☐ NG
8	水分 Moisture	$\leq 10\%$	5.87%	☒ OK ; ☐ NG
9	灰分 Ash	$\leq 10\%$	5.20%	☒ OK ; ☐ NG
10	六氯环己烷 Hexachlorocyclohexane isomers	≤ 0.3 mg/kg	<0.002 mg/kg	☒ OK ; ☐ NG
11	滴滴涕 DDT	≤ 1.0 mg/kg	<0.009 mg/kg	☒ OK ; ☐ NG
12	对硫磷 Parathion	≤ 0.5 mg/kg	<0.01 mg/kg	☒ OK ; ☐ NG
13	甲醇残留 Methanol Residue	≤ 3000 mg/kg	Not Detected	☒ OK ; ☐ NG
14	乙醇残留 Ethanol Residue	≤ 5000 mg/kg	Not Detected	☒ OK ; ☐ NG
15	亚硝酸盐 Nitrite	≤ 10 mg/kg	Not Detected	☒ OK ; ☐ NG
16	重金属 Heavy Metal	≤ 20 mg/kg	Conform	☒ OK ; ☐ NG
17	铅 Lead	≤ 0.5 mg/kg	0.31mg/kg	☒ OK ; ☐ NG
18	砷 Arsenic	≤ 1.5 mg/kg	0.13mg/kg	☒ OK ; ☐ NG
19	总汞 Total Mecury	≤ 1.5 mg/kg	Not Detected	☒ OK ; ☐ NG
20	镉 Cadmium	≤ 0.5 mg/kg	0.04mg/kg	☒ OK ; ☐ NG
21	黄曲霉素 B1、B2、G1、G2 Aflatoxin B1、B2、G1、G2	≤ 20 μ g/kg	Not Detected	☒ OK ; ☐ NG
22	黄曲霉素 B1 Aflatoxin B1	≤ 5 μ g/kg	Not Detected	☒ OK ; ☐ NG
23	装量差异 Net weight	56.7~69.3g	Conform	☒ OK ; ☐ NG
24	崩解时限 Disintegration	30 分钟内全部崩解 All of the capsules disintegrate within 30min	Conform	☒ OK ; ☐ NG
25	包装标签 Packaging and Label	符合设计标准 Comply with design	Conform	☒ OK ; ☐ NG

Conclusion Comply with USP standard and contract, PASS: 该批产品符合 USP 标准及客户合同要求, 合格;

检验员 Q. C.: 郭强
2020-5-18

主管 Supervisor:

杨红娟
2020-5-18

需氧菌总数、霉菌和酵母、耐胆盐革兰阴性菌检测原始记录

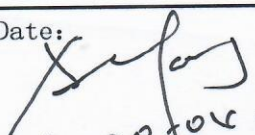
Total Aerobic Microbial Count, Combined Molds, Yeasts Count
& Bile-tolerant Gram-negative bacteria

产品名称 Product Name		Pancro Solv Capsule / Zeffesulin Capsule		产品编号 Product SKU		HCD-7D-04-004		
生产日期 Manufacturing Date		2020-04-15		批号 Lot No.		A200415A		
检验日期 Inspection Date		2020-04-21		批量 Quantity		—		
检测数量 Testing Quantity		60g		样品来源 Sample Source		车间		
检测依据 Based on		微生物限度检查作业指导书 Microbial Enumeration Tests SOP NMK-WI-QC-001						
样品 Sample	检测项目 Testing Item	1*10 ⁻¹		1*10 ⁻²		1*10 ⁻³		Result (CFU/g)
1:	需氧菌总数 Total Aerobic Microbial Count	1	1	0	0	0	0	0
	霉菌和酵母 Molds and Yeasts Count	0	0	0	0	0	0	0
	耐胆盐革兰阴性菌 Bile-tolerant Gram-negative bacteria	—		—		—		0
2:	需氧菌总数 Total Aerobic Microbial Count	0	0	0	0	0	0	0
	霉菌和酵母 Molds and Yeasts Count	2	2	0	0	0	0	0
	耐胆盐革兰阴性菌 Bile-tolerant Gram-negative bacteria	—		—		—		0
3:	需氧菌总数 Total Aerobic Microbial Count	0	0	0	0	0	0	0
	霉菌和酵母 Molds and Yeasts Count	0	1	0	0	0	0	0
	耐胆盐革兰阴性菌 Bile-tolerant Gram-negative bacteria	—		—		—		0
4:	需氧菌总数 Total Aerobic Microbial Count							
	霉菌和酵母 Molds and Yeasts Count							
	耐胆盐革兰阴性菌 Bile-tolerant Gram-negative bacteria							
5:	需氧菌总数 Total Aerobic Microbial Count							
	霉菌和酵母 Molds and Yeasts Count							
	耐胆盐革兰阴性菌 Bile-tolerant Gram-negative bacteria							
结果 Result	需氧菌总数 Total Aerobic Microbial Count	0 CFU/g						
	霉菌和酵母 Molds and Yeasts Count	15 CFU/g						
	耐胆盐革兰阴性菌 Bile-tolerant Gram-negative bacteria	0 CFU/g						

Prepared By/Date: Kuri Gai

2020-04-28

Approved By/Date:


 2020-04-28

金黄色葡萄球菌、梭状芽胞杆菌检测原始记录
Staphylococcus Aureus&Clostridium Species Testing Records

NMK-QR-QC-006A

产品名称 Product Name	Pancoro Solv Capsule/Effesulin capsule	产品编号 Product SKU	HCD-7D-04-004
生产日期 Manufacturing Date	2020-04-15	批号 Lot No.	A200415A
检验日期 Testing Date	2020-04-21	批量 Quantity	—
检测数量 Testing Quantity	30g	样品来源 Sample Source	车间
检测依据 Based on	微生物限度检查作业指导书 Microbial Enumeration Tests SOP (NMK-WI-QC-001)		

金黄色葡萄球菌/Staphylococcus aureus

		BP琼脂 Baird-Parker	革兰氏染色 Gram Stain	血浆凝固酶 Plasma-Coagulase	结果 Result
1: 10g	现象 appearance	无菌生长	/	/	未检出
	判定 Judge	无可疑菌			
2: 10g	现象 appearance	无菌生长			未检出
	判定 Judge	无可疑菌			
3: 10g	现象 appearance	无菌生长			未检出
	判定 Judge	无可疑菌			

梭状芽胞杆菌/Clostridium Species

		哥伦比亚琼脂培养基 Columbia Agar Medium	革兰氏染色 Gram Stain	芽孢染色 Spore staining	过氧化酶试验 Peroxidase Test	结果 Result
1: 10g	现象 appearance	无菌生长	/	/	/	未检出
	判定 Judge	无可疑菌				
2: 10g	现象 appearance	无菌生长				未检出
	判定 Judge	无可疑菌				
3: 10g	现象 appearance	无菌生长				未检出
	判定 Judge	无可疑菌				

结果 Result	金黄色葡萄球菌Staphylococcus Aureus	未检出
	梭状芽胞杆菌Clostridium Species	未检出

Recorder/Date: Yun Lan

2020-04-25

Assessor/Date:

2020-04-25

大肠杆菌、沙门氏菌检测原始记录

E • Coli & Salmonella Paratyphi Testing Records

NMK-QR-QC-005A

产品名称 Product Name	Pancro Solv Capsule / Effesol in Capsule		产品编号 Product SKU	HCD-7D-04-004
生产日期 Manufacturing Date	2020-04-15		批号 Lot No.	A200415A
检验日期 Inspection Date	2020-04-21		批量 Quantity	—
检测数量 Testing Quantity	303		样品来源 Sample Source	车间
检测依据 Test Standard	微生物限度检查作业指导书 Microbial Enumeration Tests SOP (NMK-WI-QC-001)			

大肠杆菌/E • Coli

		麦康凯琼脂培养基 MacConkey Agar Medium	革兰氏染色 Gram Stain	伊红美蓝琼脂培养基 Eosin-methyleneblue agar Medium	结果 Result
1:	现象 appearance	无菌生长	/	/	未检出
	判定 Judge	无可疑菌			
2:	现象 appearance	无菌生长			未检出
	判定 Judge	无可疑菌			
3:	现象 appearance	无菌生长			未检出
	判定 Judge	无可疑菌			

沙门氏菌/Salmonella paratyphi

		HE琼脂 Hektoen Enteric Agar Medium	革兰氏染色 Gram Stain	三糖铁琼脂培养基 Triple Sugar - Iron - Agar Medium	结果 Result		
1:	现象 appearance	无菌生长			未检出		
	判定 Judge	无可疑菌					
2:	现象 appearance	无菌生长			未检出		
	判定 Judge	无可疑菌					
3:	现象 appearance	无菌生长			未检出		
	判定 Judge	无可疑菌					
结果 Result		大肠杆菌 E • Coli			未检出		
		沙门氏菌Salmonella			未检出		

Recorder/Date: kun Cai

2020-04-24

Assessor/Date:

2020-04-24

水分、灰分检测原始记录

Moisture & Ash Testing Records

NMK-QR-QC-007A

产品名称 Product Name		Panoro Solo Capsule/Effectsu Capsule		产品编号 Product SKU		HCD 7D-04-004		
生产日期 Manufacturing Date		2020-04-15		批号 Lot No.		A200415A		
检验日期 Inspection Date		2020-04-22		批量 Quantity		—		
检测数量 Testing Quantity		16g		样品来源 Sample Source		¥700		
水分 Moisture	检测依据/Test Standard:		水分检测作业指导书 NMK-WI-QC-002					
	NO	供试品重m (g) Weiht m	称量瓶重m ₂ (g) Crucible weight		干燥后称量瓶+供试品重m ₁ (g) Weight after drying		结果X (%) Result	平均值 (%) Average Value
	1	1.9673	29.4421	29.4414	31.2985	31.2976	5.65	5.71
	2	1.9926	28.8874	28.8863	30.7654	30.7648	5.73	
	3	1.9865	28.6359	28.6351	30.5093	30.5084	5.70	
	4	1.9914	28.4116	28.4109	30.2884	30.2874	5.77	
	计算公式: $X = [m - (m_1 - m_2)] / m * 100$							
灰分 Ash	检测依据/Test Standard:		总灰分检测作业指导书 NMK-WI-QC-003					
	序号	供试品重m (g) Weiht m	坩埚重m ₂ (g) Crucible weigh		灰化后坩埚+灰分重m ₁ (g) Weight after drying		结果X (%) Result	平均值 (%) Average Value
	1	2.0461	19.4749	19.4748	19.5827	19.5826	5.27	5.21
	2	2.0329	22.2519	22.2518	22.3655	22.3654	5.19	
	3	2.0276	20.6330	20.6329	20.7370	20.7369	5.13	
	4	2.0348	17.5665	17.5664	17.6733	17.6732	5.25	
	计算公式: $X = (m_1 - m_2) / m * 100$							
备注/Note								

Recorder/Date:

Kurir Car

2020-04-23

Assessor/Date:

2020-04-23

重金属、亚硝酸盐检测原始记录

HEAVY METALS Heavy Metals&pH Detection Record Sheets

NMK-QR-QC-009A

产品名称 Product Name	Panoro Solu Capsule / Pheesulm Capsule			产品编号 Product SKU	H02-20-04-004		
生产日期 Manufacturing Date	2020-04-15			批号 Lot No.	A200415A		
检验日期 Testing Date	2020-04-23			批量 Quantity	—		
检测数量 Testing Quantity	6g			样品来源 Sample Source	车间		
重金属 Heavy Metal	检测依据/Test Standard: 重金属含量检测作业指导书 NMK-WI-QC-011						
	NO	样品质量 (g) Sample Weight	铅标准液浓度 $\mu\text{g/ml}$ lead standard solution	标准液使用量 ml usage amount	现象 (颜色对比) appearance	结果 (mg/kg) Result	平均值 average value (mg/kg)
	1	20461	10	1	轻标准管浅	120	120
	2	20329	10	1	轻标准管浅	120	
	3	20276	10	1	轻标准管浅	120	
亚硝酸盐 Nitrite	Test Standard: 亚硝酸盐检测作业指导书 NMK-WI-QC-009						
	标准曲线的绘制 Standard Curve						
	标准品含量/Assay						
	吸光值/ABS						
	标准曲线/Standard Curve :						
	供试品测定 Sample Testing						
	供试品质量/Weight m, g	1:	2:	3:			
	样液吸光值/ABS						
	测定用样液亚硝酸盐含量A, μg						
	测定用样液体积V ₁ , ml						
样液总体积/Total Volume V ₀							
供试品中亚硝酸盐含量X, mg/kg							
平均值/Average Value, mg/kg							
计算公式: $X = A \times 1000 / [m \times (V_1 / V_0) \times 1000]$							

Recorder/Date: Yun Cai

2020-04-24

Assessor/Date:

2020-04-24

净重、崩解时限原始记录 Net weight & Disintegration Testing Records

NMK-QR-QC-059A

产品名称 Product Name	Panco Solr Capsule				产品编号 Product SKU	HCO-F0-04-004						
生产日期 Manufacturing Date	2020-4-15				批号 Lot No.	A2004/5/1						
检验日期 Testing Date	2020-4-16				批量 Quantity	300g						
规格 Specification	90粒/瓶				样品来源 Sample	车间						
崩解时限 Disintegration	检测依据/Test Standard: 崩解度检测作业指导书											
	温度: 37±2℃											
	序号No	1	2	3	4	5	6					
	崩解时间 Time	8	8	7	7	7	7					
	序号No	7	8	9	10	11	12					
	崩解时间 Time	7	7	8	8	8	8					
	①空心胶囊（装满滑石粉）各粒均应在10 min 内崩解，如有 1粒不能崩解，应另取 6粒复试，均应符合规定；											
	②硬胶囊（产品）浸入0.05 Mol/L醋酸盐缓冲液（PH4.50±0.05）中，应在30分钟内全部崩解，如有1粒不能完全崩解，应另取12粒复试，均应符合规定											
	净重 Net Weight	包材平均质量 (g) Packing materials weigh	24.5				装量差异范围 (g/ml) Weight Variation			56.7~64.3		
		序号 No	1	2	3	4	5	6	7	8	9	10
毛重 Gross weight (g)		92.9	93.8	93.8	94.9	93.8	94.8	94.7	94.9	93.8	92.9	
净重 Net weight (g)		62.4	64.3	64.3	65.4	64.3	65.3	65.4	62.9	64.3	62.4	
序号 No		11	12	13	14	15	16	17	18	19	20	
毛重 Gross weight (g)		96.6	93.8	92.9	92	93.8	92.9	92.6	93.6	92.7	93.7	
净重 Net weight (g)		67.1	64.3	63.4	62.5	64.3	63.4	63.1	64.1	63.2	64.2	
平均重量 (g) Average weight		64.3										
感官 Attributes		符合要求										
备注 Remark												

Recorder/Date: Aidan
2020-4-16

Assessor/Date: [Signature]
2020-04-16

产品检测报告

Certificate Of Analysis

NMK-QR-QC-003A

Report No: 20200505

产品名称 Product Name	Effecsulin Capsule 艾菲苏林胶囊	制令单号 #MO	#072	产品 SKU Product SKU	HCD_FD-04-004
产品规格 Product Spec.	90Capsules (63g)	批量 Quantity	2424 瓶	产品批号 Lot No.	A200415A
生产日期 Mfg. Date	20200415	有效期至 Expired Date	20230414	报告日期 Report. Date	20200518

No.	Testing Item	Standard	Results	Adjudge
1	需氧菌总数 Total Aerobic Microbial Coun	≤ 1000 cfu/g	<10cfu/g	☒ OK ; ☐ NG
2	酵母菌和霉菌 Total Combined Molds and Yeasts Count	≤ 100 cfu/g	<10cfu/g	☒ OK ; ☐ NG
3	耐胆盐格兰阴性菌 Bile-tolerant Gram-negative bacteria	≤ 100 cfu/g	<10cfu/g	☒ OK ; ☐ NG
4	金黄色葡萄球菌 Staphylococcus aureus	Negative	<10cfu/g	☒ OK ; ☐ NG
5	沙门氏菌 Salmonella Species	Negative	Not Detected	☒ OK ; ☐ NG
6	大肠杆菌 Escherichia coli	Negative	Not Detected	☒ OK ; ☐ NG
7	梭状芽胞杆菌 Clostridium Species	Negative	Not Detected	☒ OK ; ☐ NG
8	水分 Moisture	$\leq 10\%$	5.87%	☒ OK ; ☐ NG
9	灰分 Ash	$\leq 10\%$	5.20%	☒ OK ; ☐ NG
10	六氯环己烷 Hexachlorocyclohexane isomers	≤ 0.3 mg/kg	<0.002mg/kg	☒ OK ; ☐ NG
11	滴滴涕 DDT	≤ 1.0 mg/kg	<0.009mg/kg	☒ OK ; ☐ NG
12	对硫磷 Parathion	≤ 0.5 mg/kg	<0.01mg/kg	☒ OK ; ☐ NG
13	甲醇残留 Methanol Residue	≤ 3000 mg/kg	Not Detected	☒ OK ; ☐ NG
14	乙醇残留 Ethanol Residue	≤ 5000 mg/kg	Not Detected	☒ OK ; ☐ NG
15	亚硝酸盐 Nitrite	≤ 10 mg/kg	Not Detected	☒ OK ; ☐ NG
16	重金属 Heavy Metal	≤ 20 mg/kg	Not Detected	☒ OK ; ☐ NG
17	铅 Lead	≤ 0.5 mg/kg	Conform	☒ OK ; ☐ NG
18	砷 Arsenic	≤ 1.5 mg/kg	0.31mg/kg	☒ OK ; ☐ NG
19	总汞 Total Mecury	≤ 1.5 mg/kg	0.13mg/kg	☒ OK ; ☐ NG
20	镉 Cadmium	≤ 0.5 mg/kg	Not Detected	☒ OK ; ☐ NG
21	黄曲毒素 B1、B2、G1、G2 Aflatoxin B1、B2、G1、G2	≤ 20 μ g/kg	0.04mg/kg	☒ OK ; ☐ NG
22	黄曲毒素 B1 Aflatoxin B1	≤ 5 μ g/kg	Not Detected	☒ OK ; ☐ NG
23	装量差异 Net weight	56.7~69.3g	Not Detected	☒ OK ; ☐ NG
24	崩解时限 Disintegration	30 分钟内全部崩解 All of the capsules disintegrate within 30min	Conform	☒ OK ; ☐ NG
25	包装标签 Packaging and Label	符合设计标准 Comply with design	Conform	☒ OK ; ☐ NG

Conclusion Comply with USP standard and contract, PASS; 该批产品符合 USP 标准及客户合同要求, 合格;

检验员 Q.C.: 郭端

2020-5-18

主管 Supervisor:

2020-5-18

NMK-QR-QC-004A

需氧菌总数、霉菌和酵母、耐胆盐革兰阴性菌检测原始记录
 Total Aerobic Microbial Count, Combined Molds, Yeasts Count
 & Bile-tolerant Gram-negative bacteria

产品名称 Product Name		Effeceulin Capsule		产品编号 Product SKU		H02-717-04-004	
生产日期 Manufacturing Date		2020-04-15		批号 Lot No.		A200415A	
检验日期 Inspection Date		2020-04-21		批量 Quantity		—	
检测数量 Testing Quantity		60g		样品来源 Sample Source		车间	
检测依据 Based on		微生物限度检查作业指导书 Microbial Enumeration Tests SOP NMK-WI-QC-001					

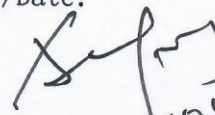
样品 Sample	检测项目 Testing Item	1×10^{-1}		1×10^{-2}		1×10^{-3}		Result (CFU/g)
1: 10g	需氧菌总数 Total Aerobic Microbial Count	0	0	0	0	0	0	<10
	霉菌和酵母 Molds and Yeasts Count	0	2	0	0	0	0	20
	耐胆盐革兰阴性菌 Bile-tolerant Gram-negative bacteria	—		—		—		<10
2: 10g	需氧菌总数 Total Aerobic Microbial Count	1	0	0	0	0	0	10
	霉菌和酵母 Molds and Yeasts Count	0	0	0	0	0	0	<10
	耐胆盐革兰阴性菌 Bile-tolerant Gram-negative bacteria	—		—		—		<10
3: 10g	需氧菌总数 Total Aerobic Microbial Count	0	0	0	0	0	0	<10
	霉菌和酵母 Molds and Yeasts Count	0	0	0	0	0	0	<10
	耐胆盐革兰阴性菌 Bile-tolerant Gram-negative bacteria	—		—		—		<10
4:	需氧菌总数 Total Aerobic Microbial Count							
	霉菌和酵母 Molds and Yeasts Count							
	耐胆盐革兰阴性菌 Bile-tolerant Gram-negative bacteria							
5:	需氧菌总数 Total Aerobic Microbial Count							
	霉菌和酵母 Molds and Yeasts Count							
	耐胆盐革兰阴性菌 Bile-tolerant Gram-negative bacteria							
结果 Result	需氧菌总数 Total Aerobic Microbial Count	<10 CFU/g						
	霉菌和酵母 Molds and Yeasts Count	20 CFU/g						
	耐胆盐革兰阴性菌 Bile-tolerant Gram-negative bacteria	<10 CFU/g						

Prepared By/Date:

Kuri Cai

2020-04-28

Approved By/Date:


 2020-04-28

金黄色葡萄球菌、梭状芽胞杆菌检测原始记录

Staphylococcus Aureus&Clostridium Species Testing Records

NMK-QR-QC-006A

产品名称 Product Name		Efficulim Capsule		产品编号 Product SKU		HVD-7D-04-004					
生产日期 Manufacturing Date		22-04-15		批号 Lot No.		A200415A					
检验日期 Testing Date		22-04-21		批量 Quantity		-					
检测数量 Testing Quantity		30g		样品来源 Sample Source		车间					
检测依据 Based on		微生物限度检查作业指导书 Microbial Enumeration Tests SOP (NMK-WI-QC-001)									
金黄色葡萄球菌/Staphylococcus aureus											
		BP琼脂 Baird-Parker		革兰氏染色 Gram Stain		血浆凝固酶 Plasma-Coagulase					
1: 10g	现象 appearance	无菌生长		/		未检出					
	判定 Judge	无可疑菌									
2: 10g	现象 appearance	无菌生长				/		未检出			
	判定 Judge	无可疑菌									
3: 10g	现象 appearance	无菌生长						/		未检出	
	判定 Judge	无可疑菌									
梭状芽胞杆菌/Clostridium Species											
		哥伦比亚琼脂培养基 Columbia Agar Medium		革兰氏染色 Gram Stain						芽孢染色 Spore staining	
						过氧化酶试验 Peroxidase Test					
1: 10g	现象 appearance	无菌生长		/		未检出					
	判定 Judge	无可疑菌									
2: 10g	现象 appearance	无菌生长				/		未检出			
	判定 Judge	无可疑菌									
3: 10g	现象 appearance	无菌生长						/		未检出	
	判定 Judge	无可疑菌									
结果 Result		金黄色葡萄球菌Staphylococcus Aureus								未检出	
		梭状芽胞杆菌Clostridium Species								未检出	

Recorder/Date: Kun Cai

22-04-21

Assessor/Date:

22-04-25

大肠杆菌、沙门氏菌检测原始记录

NMK-QR-QC-005A

E • Coli & Salmonella Paratyphi Testing Records

产品名称 Product Name		Efferesulin Capsule		产品编号 Product SKU	HAD 7D-04-024
生产日期 Manufacturing Date		22-04-15		批号 Lot No.	A200415A
检验日期 Inspection Date		22-04-21		批量 Quantity	—
检测数量 Testing Quantity		30 g		样品来源 Sample Source	车间
检测依据 Test Standard		微生物限度检查作业指导书 Microbial Enumeration Tests SOP (NMK-WI-QC-001)			
大肠杆菌/E • Coli					
		麦康凯琼脂培养基 MacConkey Agar Medium	革兰氏染色 Gram Stain	伊红美蓝琼脂培养基 Eosin-methyleneblue agar Medium	结果 Result
1: 10g	现象 appearance	无菌生长	/	/	未检出
	判定 Judge	无可疑菌			
2: 10g	现象 appearance	无菌生长			未检出
	判定 Judge	无可疑菌			
3: 10g	现象 appearance	无菌生长			未检出
	判定 Judge	无可疑菌			
沙门氏菌/Salmonella paratyphi					
		HE琼脂 Hektoen Enteric Agar Medium	革兰氏染色 Gram Stain	三糖铁琼脂培养基 Triple Sugar - Iron - Agar Medium	结果 Result
1: 10g	现象 appearance	无菌生长	/	/	未检出
	判定 Judge	无可疑菌			
2: 10g	现象 appearance	无菌生长			未检出
	判定 Judge	无可疑菌			
3: 10g	现象 appearance	无菌生长			未检出
	判定 Judge	无可疑菌			
结果 Result		大肠杆菌 E • Coli	未检出		
		沙门氏菌 Salmonella	未检出		

Recorder/Date: Kuri Car

22-04-24

Assessor/Date:

2020.06.24

水分、灰分检测原始记录

Moisture & Ash Testing Records

NMK-QR-QC-007A

产品名称 Product Name		Ettersulin Capsule		产品编号 Product SKU		NKD-7D-04-004	
生产日期 Manufacturing Date		2020-04-15		批号 Lot No.		A200415A	
检验日期 Inspection Date		2020-04-22		批量 Quantity		—	
检测数量 Testing Quantity		16g		样品来源 Sample Source		车间	
水分 Moisture	检测依据 Test Standard:		水分检测作业指导书 NMK-WI-QC-002				
	NO	供试品重 m (g) Weiht m	称量瓶重 m_2 (g) Crucible weight	干燥后称量瓶+供试品重 m_1 (g) Weight after drying		结果 X (%) Result	平均值 (%) Average Value
	1	1.9738	27.6097 27.6087	29.4692 29.4683		5.78	5.83
	2	1.9862	28.3987 28.3978	30.2679 30.2674		5.87	
	3	1.9765	28.6024 28.6012	30.4638 30.4627		5.82	
	4	1.9643	29.3231 29.3224	31.1727 31.1719		5.84	
	计算公式: $X = [m - (m_1 - m_2)] / m * 100$						
灰分 Ash	检测依据 / Test Standard:		总灰分检测作业指导书 NMK-WI-QC-003				
	序号	供试品重 m (g) Weiht m	坩埚重 m_2 (g) Crucible weigh	灰化后坩埚+灰分重 m_1 (g) Weight after drying		结果 X (%) Result	平均值 (%) Average Value
	1	2.0216	19.4670 19.4687	19.5717 19.5716		5.13	5.16
	2	2.0196	19.4688 19.4687	17.5735 17.5734		5.18	
	3	2.0463	21.9710 21.9709	22.0779 22.0778		5.22	
	4	2.0448	23.5335 23.5334	23.6375 23.6374		5.09	
	计算公式: $X = (m_1 - m_2) / m * 100$						
备注/Note							

Recorder/Date: Kuri Car

2020-04-23

Assessor/Date:

2020-06-23

重金属、亚硝酸盐检测原始记录

HEAVY METALS Heavy Metals&pH Detection Record Sheets

NMK-QR-QC-009A

产品名称 Product Name	Effeculin Capsule		产品编号 Product SKU	HWD-20-04-004			
生产日期 Manufacturing Date	2020-04-15		批号 Lot No.	A200415A			
检验日期 Testing Date	2020-04-23		批量 Quantity	—			
检测数量 Testing Quantity	6g		样品来源 Sample Source	F10			
重金属 Heavy Metal	检测依据/Test Standard: 重金属含量检测作业指导书 NMK-WI-QC-011						
	NO	样品质量 (g) Sample Weight	铅标准液浓度 $\mu\text{g/ml}$ lead standard solution	标准液使用量 ml usage amount	现象 (颜色对比) appearance	结果 (mg/kg) Result	平均值 average value (mg/kg)
	1	2.0196	10	1	较标准管浅	<20	<20
	2	2.0216	10	1	较标准管浅	<20	
	3	2.0463	10	1	较标准管浅	<20	
亚硝酸盐 Nitrite	Test Standard: 亚硝酸盐检测作业指导书 NMK-WI-QC-009						
	标准曲线的绘制 Standard Curve						
	标准品含量/Assay						
	吸光值/ABS						
	标准曲线/Standard Curve :						
	供试品测定 Sample Testing						
	供试品质量/Weight m, g	1:	2:	3:			
	样液吸光值/ABS						
	测定用样液亚硝酸盐含量A, μg						
	测定用样液体积V ₁ , ml						
样液总体积/Total Volume V ₀							
供试品中亚硝酸盐含量X, mg/kg							
平均值/Average Value, mg/kg							
计算公式: $X = A * 1000 / [m * (V_1 / V_0) * 1000]$							

Recorder/Date: Yuni Cai

2020-04-24

Assessor/Date:

2020-06-22

净重、崩解时限原始记录

Net weight & Disintegration Testing Records

NMK-QR-QC-059A

产品名称 Product Name	Effecsalin Capsule				产品编号 Product SKU	HCD-90-04-004					
生产日期 Manufacturing Date	2020.4.15.				批号 Lot No.	A200415A					
检验日期 Testing Date	2020.4.16				批量 Quantity	300kg					
规格 Specification	9粒/瓶				样品来源 Sample	车间					
崩解时限 Disintegration	检测依据/Test Standard: 崩解度检测作业指导书										
	温度: 37±2℃										
	序号No	1	2	3	4	5	6				
	崩解时间 Time	8	1	1	9	8	7				
	序号No	7	8	9	10	11	12				
	崩解时间 Time	8	8	8	1	8	8				
	①空心胶囊(装满滑石粉)各粒均应在10 min 内崩解, 如有 1粒不能崩解, 应另取 6粒复试, 均应符合规定;										
	②硬胶囊(产品)浸入0.05 Mol/L醋酸盐缓冲液(PH4.50±0.05)中, 应在30分钟内全部崩解, 如有1粒不能完全崩解, 应另取12粒复试, 均应符合规定										
净重 Net Weight	包材平均质量 (ml) Packing materials weigh	29.5.				装量差异范围 (g/ml) Weight Variation			56.1 ~ 69.3.		
	序号 No	1	2	3	4	5	6	7	8	9	10
	毛重 Gross weight (ml)	96.6	93.8	92.9	92	93.8	92.9	92.6	93.6	92.1	93.7
	净重 Net weight (ml)	67.1	64.3	63.4	62.5	64.3	63.4	63.1	64.1	63.2	64.2.
	序号 No	11	12	13	14	15	16	17	18	19	20
	毛重 Gross weight (ml)	92.9	93.8	93.8	94.9	93.8	94.8	94.9	93.8	91.9	92.9
	净重 Net weight (ml)	63.4	64.3	64.3	65.4	64.3	65.3	65.4	64.3	62.4	63.4
	平均重量 (ml) Average weight	64.3									
感官 Attributes	符合要求										
备注 Remark											

Recorder/Date:

2020.4.16

Assessor/Date:

2020.10.16

检测报告

报告编号	2120005623
REPORT NO	
样品名称	拜耳精灵 艾菲苏林胶囊
SAMPLE NAME	Pancro Solv Capsule/Effeecsulin Capsule
委托单位	厦门诺美康生物科技有限公司
CONSIGNOR	Super Health Care Bio.Technique(Xiamen) Co.,Ltd



厦门海关技术中心
Technology Center of Xiamen Customs

厦门海关技术中心
TECHNOLOGY CENTER OF XIAMEN CUSTOMS
检 验 报 告
TEST REPORT

报告编号: 2120005623
报告日期: 05/09/2020
第 1 页 共 1 页

委托单位: 厦门诺美康生物科技有限公司
CONSIGNOR: Super Health Care Bio.Technique(Xiamen) Co.,Ltd
申报品名 / 规格: 拜耳精灵 艾菲苏林胶囊
PRODUCT/ SPECIFICATION: Pancro Solv Capsule/Effecsulin Capsule
送样数量: 63g*3
AMOUNT OF CONSIGNMENT: 63g*3
样品状态及标识: 粉剂瓶装
委托方提供标识: HCD_FD-04-004
A200415A
SAMPLE STATUS AND IDENTIFICATION: Bottled powder.
Client provides identification: HCD_FD-04-004
A200415A
收样日期: 2020年04月27日
CONSIGNMENT DATE: 04/27/2020



检测结果 (TEST RESULTS):

项目 ITEM	样品 SAMPLE 拜耳精灵 艾菲苏林胶囊 Pancro Solv Capsule/Effecsulin Capsule	检测方法 METHOD
菌落总数 Aerobic plate count (CFU/g)	<100	GB 4789.2-2016
大肠菌群 Coliforms (MPN/g)	<0.3	GB 4789.3-2016
霉菌和酵母计数 Moulds and yeasts (CFU/g)	<10	GB 4789.15-2016
沙门氏菌 Salmonella (/25g)	未检出 Not detected	GB 4789.4-2016
金黄色葡萄球菌 Staphylococcus aureus (/25g)	未检出 Not detected	GB 4789.10-2016
大肠埃希氏菌 Escherichia coli (MPN/g)	<0.3	GB 4789.38-2012
六六六(mg/kg) HCH(mg/kg)	未检出(<0.002) ND(<0.002)	参照 GB/T 5009.19-2008
滴滴涕(mg/kg) DDT(mg/kg)	未检出(<0.009) ND(<0.009)	参照 GB/T 5009.19-2008
对硫磷(mg/kg) Parathion(mg/kg)	未检出(<0.01) ND(<0.01)	参照/T 0148-2011

备注: 上述检验结果仅对样品负责。

NOTE: The results are only responsible for the samples provided.



签发: 张士明

0091750



Test Report

XMF20-002066-02

Date: 22 May 2020

Client Name: Super Health Care Bio.Technique(Xiamen)Co.,Ltd

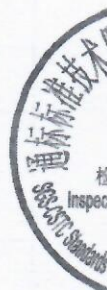
Client Address: B Area,Floor 3,No.20 Huli Industrial Park Meixi Dao,Tongan District,Xiamen,Fujian 361100 China

Sample Name: Pancro Solv Capsule/Effecsulin Capsule
Manufacturer: /
Sample Batch No.: A200415A
Production Date: 20200415

Above information and sample(s) was/were submitted and certified by the client, SGS quoted the information with no responsibility as to the accuracy, adequacy and/or completeness.

Date of Sample Received : 28 Apr 2020
Testing Period : 28 Apr 2020 - 22 May 2020
Test Requested : Selected test(s) as requested by client.
Test Method : Please refer to next page(s).
Test Result(s) : Please refer to next page(s).

Unless otherwise stated the results shown in this test report refer only to the items tested, and for clients internal use only, not to the society has the proof function. This document cannot be used for publicity, without prior written approval of the SGS.



scan to see the report



XMF20-002066-02

SGS Authorized Signature

SGS-CSTC Standards Technical Services Co.,Ltd. Xiamen Branch

Page 1 of 3



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Test Report

XMF20-002066-02

Date: 22 May 2020

Sample Description :

Specimen No.	SGS Sample ID	Description
1	XMF20-002066.002	Sample in bottle

Chemical test

Test Result(s) :

Test Item(s)	Unit	Test Method(s)	Test Result(s) 002	LOQ
Heavy Metal (as Pb)	mg/kg	General requirement No. 0821 of Ch.P.2015 Volume IV	<10	-
Moisture	g/100g	GB 5009.3-2016 I	5.87	-
*Aflatoxin B ₁	µg/kg	General requirement No. 2351 method I of Ch.P.2015 Volume IV	ND	2.0
*Aflatoxin B ₂	µg/kg	General requirement No. 2351 method I of Ch.P.2015 Volume IV	ND	2.0
*Aflatoxin G ₁	µg/kg	General requirement No. 2351 method I of Ch.P.2015 Volume IV	ND	2.0
*Aflatoxin G ₂	µg/kg	General requirement No. 2351 method I of Ch.P.2015 Volume IV	ND	2.0
*Aflatoxin(B ₁ +B ₂ +G ₁ +G ₂)	µg/kg	General requirement No. 2351 method I of Ch.P.2015 Volume IV	ND	-
*Arsenic (As)	mg/kg	Journal of AOAC international Vol 90,NO.3,2007	0.13	0.02
*Lead (Pb)	mg/kg	Journal of AOAC international Vol 90,NO.3,2007	0.31	0.02
*Mercury (Hg)	mg/kg	Journal of AOAC international Vol 90,NO.3,2007	ND	0.01
*Cadmium (Cd)	mg/kg	Journal of AOAC international Vol 90,NO.3,2007	0.04	0.02
Ash	g/100g	GB 5009.4-2016 Method I	5.2	-

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SGS-CSTC Standards Technical Services Co., Ltd.
Xiamen Branch: Testing Laboratory for Food and Feed Laboratory

No.31 Xianghong Road, Xiang'an Torch Industrial Zone, Xiamen, Fujian Province, China. 361101 t 400-691-0488 f (86-592) 5765386 www.sgs.com.cn
中国·福建·厦门·火炬(翔安)产业区翔虹路31号 邮编: 361101 t 400-691-0488 f (86-592) 5765386 e sgs.china@sgs.com

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Test Report

XMF20-002066-02

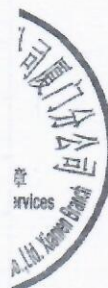
Date: 22 May 2020

Test Item(s)	Unit	Test Method(s)	Test Result(s)	LOQ
*Ethanol	mg/kg	In house method HS-GC-MS	002 ND	10
*Methanol	mg/kg	In house method HS-GC-MS	ND	20

Remark:

- 1.ND = Not Detected
- 2.LOQ = Limit of Quantitation
- 3.*Test item(s) was/were carried out by SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd. Laboratory.

*** End ***



SGS-CSTC Standards Technical Services Co.,Ltd. Xiamen Branch

Page 3 of 3



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