

Test report No. shd1718

SURGICAL HAND DISINFECTION (EN 12791)

Name of the product:	Chemisept GEL
Batch number:	198251017
Order number:	17030
Manufacturer:	Chemi-Pharm Ltd.
Client, representative:	Chemi-Pharm Ltd., Põllu 132, Tallinn, 10917, ESTONIA Maris Millner, +372-51-77-090
Date of delivery:	15.01.2018
Test material conditions:	No specific features, sample in the manufacturers tare
Storage conditions:	In room temperature, dark
Active substance – conc.:	Ethyl alcohol 72,5% wt, isopropyl alcohol 7.5% wt
Appearance of the product:	Transparent liquid
Test concentration:	Ready to use
Contact time:	90 sec
Interfering substance:	-
Neutralizer:	Polysorbate 80 30g/l; saponin 30 g/l, lecithin 3 g/l
Rinsing liquid:	-
Test organisms:	Normal skin flora
Testing method:	EVS-EN 12791:2016+A1:2017 Chemical disinfectants and antiseptics – Surgical hand disinfection – Test method and requirements (phase 2, step2)
Testing date:	12.02.2018-20.02.2018
Results:	look appendix 1-10



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Head of laboratory, microbiologist
Date of test report: 23.02.2018

Appendix 1

Validations and controls

Neutralizer

validation:

The selected neutralizer is tested according to EN 13727:2012 + A2:2015 for *P.aeruginosa* ATCC 15442, *S. aureus* ATCC 6538, *E. hirae* ATCC 10541, *E. coli* K12, NCTC 10538 and according to EN 13624:20123 for *C. albicans* ATCC 10231. The neutralizer fulfilled all the criteria and passed the controls, therefore, the neutralizer is suitable for test.

P. aeruginosa ATCC 15442:

Validation suspension N_{vo}			Experimental conditions control (A)			Neutralizer control (B)			Method validation (C)		
V_{C1}	54	$\bar{x} = 52.5$	V_{C1}	37	$\bar{x} = 40.5$	V_{C1}	28	$\bar{x} = 32$	V_{C1}	50	$\bar{x} = 47.5$
V_{C2}	51		V_{C2}	44		V_{C2}	36		V_{C2}	45	
30 $\leq \bar{x} N_{vo} \leq 160$? yes X; no $\square$			$\bar{x}$ A is $\geq 0,5 \bar{x} N_{vo}$? yes X; no $\square$			$\bar{x}$ B is $\geq 0,5 \bar{x} N_{vo}$? yesX; no $\square$			$\bar{x}$ C is $\geq 0,5 \bar{x} N_{vo}$? yes X; no $\square$		

Test suspension and test

Testsuspension: N and N_0	N	V_{C1}	V_{C2}	$\bar{x}_{wm} = 2.31 \times 10^9$; $\log N = 9.36$ $N_0 = N/100$; $\log N_0 = 7.36$ $7,17 \leq \log N_0 \leq 7,70$; yesX; no ☐
	10^{-7}	223	241	
	10^{-8}	24	21	

S. aureus ATCC 6538

Validation suspension N_{vo}			Experimental conditions control (A)			Neutralizer control (B)			Method validation (C)		
V_{C1}	47	$\bar{x} = 43.5$	V_{C1}	36	$\bar{x} = 33.5$	V_{C1}	28	$\bar{x} = 31$	V_{C1}	36	$\bar{x} = 33$
V_{C2}	40		V_{C2}	31		V_{C2}	34		V_{C2}	30	
30 ≤ $\bar{x} N_{vo}$ ≤ 160 ? yes X; no □			$\bar{x} A$ is ≥ 0,5 $\bar{x} N_{vo}$? yes X; no □			$\bar{x} B$ is ≥ 0,5 $\bar{x} N_{vo}$? yesX; no □			$\bar{x} C$ is ≥ 0,5 $\bar{x} N_{vo}$? yes X; no □		

Test suspension and test

Testsuspension: N and N_0	N	V_{C1}	V_{C2}	$\bar{x}_{wm} = 2.03 \times 10^9$; $\log N = 9.31$ $N_0 = N/100$; $\log N_0 = 7.31$ $7,17 \leq \log N_0 \leq 7,70$; yesX; no ☐
	10^{-7}	195	207	
	10^{-8}	20	24	

E. hirae ATCC 10541

Validation suspension N_{vo}			Experimental conditions control (A)			Neutralizer control (B)			Method validation (C)		
V_{C1}	49	$\bar{x} = 41$	V_{C1}	42	$\bar{x} = 42$	V_{C1}	38	$\bar{x} = 31.5$	V_{C1}	34	$\bar{x} = 36.5$
V_{C2}	33		V_{C2}	42		V_{C2}	25		V_{C2}	39	
$30 \leq \bar{x} N_{vo} \leq 160$? yes X;no ☐			$\bar{x} A$ is $\geq 0,5 \bar{x} N_{vo}$?yes X;no ☐			$\bar{x} B$ is $\geq 0,5\bar{x} N_{vo}$? yesX; no ☐			$\bar{x} C$ is $\geq 0,5 \bar{x} N_{vo}$? yes X; no ☐		

Test suspension and test

Testsuspension: N and N_0	N	V_{C1}	V_{C2}	$\bar{x}_{wm} = 1.87 \times 10^9$; $\log N = 9.28$ $N_0 = N/100$; $\log N_0 = 7.28$ $7,17 \leq \log N_0 \leq 7,70$; yes X; no ☐
	10^{-7}	180	199	
	10^{-8}	16	20	

E. coli K12, NCTC 10538

Validation suspension N_{vo}			Experimental conditions control (A)			Neutralizer control (B)			Method validation (C)		
V_{C1}	37	$\bar{x} = 34$	V_{C1}	26	$\bar{x} = 23.5$	V_{C1}	22	$\bar{x} = 23.5$	V_{C1}	32	$\bar{x} = 29.5$
V_{C2}	31		V_{C2}	21		V_{C2}	25		V_{C2}	27	
30 ≤ $\bar{x} N_{vo}$ ≤ 160 yes X; no ☐			$\bar{x} A$ is ≥ 0,5 $\bar{x} N_{vo}$? yesX;no ☐			$\bar{x} B$ is ≥ 0,5 $\bar{x} N_{vo}$? yesX;no ☐			$\bar{x} C$ is ≥ 0,5 $\bar{x} N_{vo}$? yes X; no ☐		

Test suspension and test

Testsuspension: N and N_0	N	V_{C1}	V_{C2}	$\bar{x}_{wm} = 1.60 \times 10^9$; $\log N = 9.21$ $N_0 = N/100$; $\log N_0 = 7.21$ $7,17 \leq \log N_0 \leq 7,70$; yes X; no ☐
	10^{-7}	152	166	
	10^{-8}	17	18	

C. albicans ATCC 10231

Validation suspension N_{vo}			Experimental conditions control (A)			Neutralizer control (B)			Method validation (C)		
V_{C1}	62	$\bar{x} = 59.5$	V_{C1}	49	$\bar{x} = 45.5$	V_{C1}	38	$\bar{x} = 41.5$	V_{C1}	48	$\bar{x} = 52.5$
V_{C2}	57		V_{C2}	42		V_{C2}	45		V_{C2}	57	
$30 \leq \bar{x} N_{vo} \leq 160$? yes X; no ☐			$\bar{x} A$ is $\geq 0,5 \bar{x} N_{vo}$? yes X; no ☐			$\bar{x} B$ is $\geq 0,5 \bar{x} N_{vo}$? yes X; no ☐			$\bar{x} C$ is $\geq 0,5 \bar{x} N_{vo}$? yes X; no ☐		

Test suspension and test

Test suspension:	N	V_{C1}	V_{C2}	$\bar{x}_{wm} = 2.28 \times 10^8$; $\log N = 8.36$
N and N_0	10^{-6}	217	239	$N_0 = N/100$; $\log N_0 = 6.36$
	10^{-7}	25	20	$6,17 \leq \log N_0 \leq 6,70$; yes X; no ☐

Quality control on soft soap:

The soft soap met the quality criteria:

1. Identity: when sulphuric acid (10%) was added to an undiluted soft soap solution the free fatty acids separated out as a dense white precipitate which, when gently heated, melted into oily droplets and collected on the surface of the liquid.
2. Purity: 1g of soft soap dissolved in 2.0ml of warm water into clear liquid.
3. Alcohol-insoluble substances: 2.5g of soft soap contained 3 mg of alcohol-insoluble substances which meets the criterion (must be <5mg)
4. Loss on drying: 39,0% which is less than the maximum of 45% and therefore, passed the test.
5. Determination of content: after following the procedures described in EN12791 standard, the residue of soft soap weighed 1.173g, which meets the quality criterion (shall weight 1.125g to 1.25g, corresponding to a content of 45.0% to 50,0% of fatty acids)

Quality control of surgical gloves

Quality control of surgical gloves was carried out on the instructions given in EN12791. The tested gloves did not show any microbial growth, meaning the gloves were sterile and free from any microbial activity.

Appendix 2

Reference surgical hand disinfection procedure – Experimental results

Preparation: "RP" Reference [propan-1-ol 60% (v/v)]

Date of test: 12.02.2018 - 20.02.2018

Application: Rubbing hands during 3 min

Volunteer		Hand	Number of cfu per plate from dilution 10 ^x								
RP			Prevalues			Immediate postvalues			3h Postvalues		
No	Sequence	left or right	-1	-2	-3	0	-1	-2	0	-1	-2
1	PP>RP	l	>330	>330	<u>81</u>	<u>105</u>	18	4			
		r	>330	>330	<u>76</u>				<u>92</u>	15	3
2	PP>RP	l	>330	>330	<u>100</u>				<u>103</u>	<u>10</u>	3
		r	>330	>330	<u>91</u>	<u>128</u>	16	1			
3	PP>RP	l	>330	>330	<u>87</u>	<u>119</u>	8	2			
		r	>330	>330	<u>104</u>				<u>99</u>	13	2
4	PP>RP	l	>330	>330	<u>76</u>				<u>93</u>	11	0
		r	>330	>330	<u>61</u>	<u>82</u>	<u>8</u>	0			
5	PP>RP	l	>330	>330	<u>116</u>	<u>68</u>	19	4			
		r	>330	>330	<u>90</u>				<u>54</u>	8	0
6	PP>RP	l	>330	>330	<u>84</u>				<u>89</u>	12	2
		r	>330	>330	<u>97</u>	<u>100</u>	14	2			
7	PP>RP	l	>330	>330	<u>42</u>	<u>74</u>	10	1			
		r	>330	>330	<u>36</u>				<u>55</u>	8	1
8	PP>RP	l	>330	>330	<u>72</u>				<u>62</u>	<u>6</u>	0
		r	>330	>330	<u>60</u>	<u>49</u>	7	0			
9	PP>RP	l	>330	>330	<u>46</u>	<u>106</u>	14	2			
		r	>330	>330	<u>37</u>				<u>84</u>	10	2
10	PP>RP	l	>330	>330	<u>92</u>				<u>91</u>	11	0
		r	>330	>330	<u>51</u>	<u>99</u>	6	0			
11	PP>RP	l	>330	>330	<u>64</u>	<u>84</u>	5	0			
		r	>330	>330	<u>85</u>				<u>71</u>	14	3
12	PP>RP	l	>330	>330	<u>101</u>				<u>41</u>	6	0
		r	>330	>330	<u>75</u>	<u>58</u>	9	3			
13	RP >PP	l	>330	<u>138</u>	16	<u>73</u>	5	0			
		r	>330	<u>116</u>	16				<u>59</u>	8	1
14	RP >PP	l	>330	>330	<u>64</u>				<u>79</u>	15	4
		r	>330	>330	<u>87</u>	<u>82</u>	14	4			
15	RP >PP	l	>330	>330	<u>106</u>	<u>94</u>	15	3			
		r	>330	>330	<u>113</u>				<u>104</u>	22	5
16	RP >PP	l	>330	<u>291</u>	32				<u>54</u>	8	2
		r	>330	>330	<u>37</u>	<u>70</u>	10	2			
17	RP >PP	l	>330	>330	<u>54</u>	<u>113</u>	17	5			
		r	>330	>330	<u>85</u>				<u>92</u>	14	3
18	RP >PP	l	>330	>330	<u>88</u>				<u>28</u>	5	0
		r	>330	>330	<u>50</u>	<u>33</u>	2	0			
19	RP >PP	l	>330	>330	<u>42</u>	<u>81</u>	<u>8</u>	2			
		r	>330	>330	<u>51</u>				<u>68</u>	10	2
20	RP >PP	l	>330	>330	<u>49</u>				<u>61</u>	4	0
		r	>330	>330	<u>71</u>	<u>75</u>	11	2			
21	RP >PP	l	>330	<u>174</u>	19	<u>107</u>	16	5			
		r	>330	<u>205</u>	28				<u>83</u>	6	0
22	RP >PP	l	>330	>330	<u>126</u>				<u>51</u>	9	2
		r	>330	>330	<u>120</u>	<u>77</u>	6	0			
23	RP >PP	l	>330	>330	<u>79</u>	<u>42</u>	3	0			
		r	>330	>330	<u>109</u>				<u>30</u>	5	0
24	RP >PP	l	>330	>330	<u>115</u>				<u>53</u>	7	0
		r	>330	>330	<u>101</u>	<u>85</u>	<u>9</u>	3			

Underlined = count used for further computation

Highlighted = indicates adjacent dilutions used for computation

Appendix 3

Surgical hand rub procedure with test product – Experimental results

Preparation: "PP" Chemisept GEL

Date of test: 12.02.2018 - 20.02.2018

Application: 2 x 3 ml, 90 s

Volunteer			Number of cfu per plate from dilution 10 ^x								
PP		Hand	Prevalues			Immediate postvalues			3h Postvalues		
No	Sequence	left or right	-1	-2	-3	0	-1	-2	0	-1	-2
1	RP >PP	l	>330	>330	<u>93</u>	<u>87</u>	12	2			
		r	>330	>330	<u>85</u>				<u>74</u>	5	0
2	RP >PP	l	>330	>330	<u>122</u>				<u>42</u>	8	2
		r	>330	>330	<u>154</u>	<u>61</u>	7	3			
3	RP >PP	l	>330	>330	<u>63</u>	<u>101</u>	18	3			
		r	>330	>330	<u>49</u>				<u>92</u>	<u>9</u>	2
4	RP >PP	l	>330	>330	<u>38</u>				<u>104</u>	15	1
		r	>330	>330	<u>51</u>	<u>122</u>	13	5			
5	RP >PP	l	>330	>330	<u>106</u>	<u>39</u>	5	0			
		r	>330	>330	<u>84</u>				<u>44</u>	13	2
6	RP >PP	l	>330	>330	<u>117</u>				<u>75</u>	4	1
		r	>330	>330	<u>136</u>	<u>88</u>	14	2			
7	RP >PP	l	>330	>330	<u>59</u>	<u>61</u>	8	0			
		r	>330	>330	<u>41</u>				<u>73</u>	11	2
8	RP >PP	l	>330	>330	<u>75</u>				<u>22</u>	4	0
		r	>330	>330	<u>84</u>	<u>34</u>	5	0			
9	RP >PP	l	>330	>330	<u>44</u>	<u>133</u>	16	3			
		r	>330	>330	<u>67</u>				<u>107</u>	14	2
10	RP >PP	l	>330	>330	<u>106</u>				<u>99</u>	6	0
		r	>330	>330	<u>81</u>	<u>116</u>	20	4			
11	RP >PP	l	>330	>330	<u>124</u>	<u>73</u>	11	3			
		r	>330	>330	<u>165</u>				<u>26</u>	2	0
12	RP >PP	l	>330	>330	<u>120</u>				<u>22</u>	<u>2</u>	1
		r	>330	>330	<u>103</u>	<u>25</u>	<u>3</u>	1			
13	PP>RP	l	>330	<u>184</u>	<u>22</u>	<u>49</u>	8	3			
		r	>330	<u>142</u>	<u>16</u>				<u>41</u>	7	2
14	PP>RP	l	>330	>330	<u>59</u>				<u>88</u>	13	3
		r	>330	>330	<u>74</u>	<u>109</u>	16	5			
15	PP>RP	l	>330	>330	<u>104</u>	<u>53</u>	8	0			
		r	>330	>330	<u>119</u>				<u>37</u>	5	0
16	PP>RP	l	>330	<u>254</u>	<u>28</u>				<u>76</u>	<u>8</u>	2
		r	>330	<u>233</u>	<u>20</u>	<u>85</u>	11	0			
17	PP>RP	l	>330	>330	<u>99</u>	<u>69</u>	10	4			
		r	>330	>330	<u>72</u>				<u>52</u>	8	0
18	PP>RP	l	>330	>330	<u>61</u>				<u>36</u>	2	0
		r	>330	>330	<u>84</u>	<u>47</u>	2	0			
19	PP>RP	l	>330	<u>163</u>	<u>20</u>	<u>91</u>	15	4			
		r	>330	>330	<u>34</u>				<u>108</u>	18	4
20	PP>RP	l	>330	>330	<u>68</u>				<u>75</u>	12	3
		r	>330	>330	<u>90</u>	<u>66</u>	9	2			
21	PP>RP	l	>330	>330	<u>42</u>	<u>129</u>	15	4			
		r	>330	>330	<u>58</u>				<u>85</u>	21	5
22	PP>RP	l	>330	>330	<u>142</u>				<u>48</u>	<u>5</u>	0
		r	>330	>330	<u>116</u>	<u>61</u>	8	0			
23	PP>RP	l	>330	>330	<u>84</u>	<u>28</u>	4	0			
		r	>330	>330	<u>91</u>				<u>39</u>	5	0
24	PP>RP	l	>330	>330	<u>138</u>				<u>65</u>	3	0
		r	>330	>330	<u>106</u>	<u>71</u>	14	2			

Underlined = count used for further computation

Highlighted = indicates adjacent dilutions used for computation

Appendix 4

List of computed lg values and lg reductions

Preparation: "RP" Reference [propan-1-ol 60% (v/v)]

Volunteer No	Sequence	Immediate effect			3h effect		
		lg Prevalues	lg Postvalues	lg Reduction	lg Prevalues	lg Postvalues	lg Reduction
1	RP > PP	4.91	3.02	1.89	4.88	2.96	1.92
2	RP > PP	4.96	3.11	1.85	5.00	3.01	1.99
3	RP > PP	5.02	3.08	1.86	5.02	3.00	2.02
4	RP > PP	4.88	2.91	1.87	4.88	2.97	1.91
5	RP > PP	4.95	2.83	2.23	4.95	2.73	2.22
6	RP > PP	4.92	3.00	1.99	4.92	2.95	1.97
7	RP > PP	4.56	2.87	1.75	4.56	2.74	1.82
8	RP > PP	4.86	2.69	2.09	4.86	2.79	2.07
9	RP > PP	4.57	3.03	1.64	4.57	2.92	1.64
10	RP > PP	4.96	3.00	1.71	4.96	2.96	2.00
11	RP > PP	4.93	2.92	1.88	4.93	2.85	2.08
12	RP > PP	5.00	2.76	2.11	5.00	2.61	2.39
13	PP > RP	4.06	2.86	1.28	4.06	2.77	1.29
14	PP > RP	4.81	2.91	2.03	4.81	2.90	1.91
15	PP > RP	5.05	2.97	2.05	5.05	3.02	2.04
16	PP > RP	4.46	2.85	1.72	4.46	2.73	1.73
17	PP > RP	4.93	3.05	1.68	4.93	2.96	1.97
18	PP > RP	4.94	2.52	2.18	4.94	2.45	2.50
19	PP > RP	4.71	2.91	1.72	4.71	2.83	1.88
20	PP > RP	4.69	2.88	1.98	4.69	2.79	1.90
21	PP > RP	4.31	3.03	1.21	4.31	2.92	1.39
22	PP > RP	5.10	2.89	2.19	5.10	2.71	2.39
23	PP > RP	5.04	2.62	2.27	5.04	2.48	2.56
24	PP > RP	5.06	2.93	2.07	5.06	2.72	2.34
Mean		4.82	2.90	1.89	4.82	2.82	2.00
Standard deviation		0.26	0.14	0.27	0.26	0.16	0.31
N		24	24	24	24	24	24

Appendix 5

List of computed lg values and lg reductions

Preparation: "PP" Chemisept GEL

Volunteer	Sequence	Immediate effect			3h effect		
No		lg Prevalues	lg Postvalues	lg Reduction	lg Prevalues	lg Postvalues	lg Reduction
1	PP>RP	4.97	2.94	2.03	4.93	2.87	2.06
2	PP>RP	5.19	2.79	2.40	5.09	2.62	2.46
3	PP>RP	4.80	3.00	1.80	4.69	2.96	1.73
4	PP>RP	4.71	3.09	1.62	4.58	3.02	1.56
5	PP>RP	5.03	2.59	2.43	4.92	2.64	2.28
6	PP>RP	5.13	2.94	2.19	5.07	2.88	2.19
7	PP>RP	4.77	2.79	1.99	4.61	2.86	1.75
8	PP>RP	4.92	2.53	2.39	4.88	2.34	2.53
9	PP>RP	4.64	3.12	1.52	4.83	3.03	1.80
10	PP>RP	4.91	3.06	1.84	5.03	3.00	2.03
11	PP>RP	5.09	2.86	2.23	5.22	2.41	2.80
12	PP>RP	5.01	2.41	2.61	5.08	2.34	2.74
13	RP >PP	4.26	2.69	1.57	4.15	2.61	1.54
14	RP >PP	4.87	3.04	1.83	4.77	2.94	1.83
15	RP >PP	5.02	2.72	2.29	5.08	2.57	2.51
16	RP >PP	4.37	2.93	1.44	4.40	2.88	1.52
17	RP >PP	5.00	2.84	2.16	4.86	2.72	2.14
18	RP >PP	4.92	2.67	2.25	4.79	2.56	2.23
19	RP >PP	4.21	2.96	1.25	4.53	3.03	1.50
20	RP >PP	4.95	2.82	2.13	4.83	2.88	1.96
21	RP >PP	4.62	3.11	1.51	4.76	2.93	1.83
22	RP >PP	5.06	2.79	2.28	5.15	2.68	2.47
23	RP >PP	4.92	2.45	2.48	4.96	2.59	2.37
24	RP >PP	5.03	2.85	2.17	5.14	2.81	2.33
Mean		4.85	2.83	2.02	4.85	2.76	2.09
Standard deviation		0.26	0.20	0.38	0.26	0.22	0.39
N		24	24	24	24	24	24

Appendix 6

Test for sequence effects

Test of sequence of IgR "Immediate effect"

	Sequence		Absolute difference
Procedure	RP>PP	PP>RP	[RP>PP]-[PP>RP]
	Mean s.d.N	Mean s.d.N	
RP (Propan-1-ol 60% v/v)	1.91 0.17 12	1.87 0.35 12	
PP	1.95 0.41 12	2.09 0.34 12	
Difference of Means			
RP - PP	0.04	0.22	0.18
s.d. standard deviation			

Test of sequence of Ig R "3-hours effect"

	Sequence		Absolute difference
Procedure	RP>PP	PP>RP	[RP>PP]-[PP>RP]
	Mean s.d.N	Mean s.d.N	
RP (Propan-1-ol 60% v/v)	2.00 0.19 12	1.99 0.41 12	
PP	2.02 0.37 12	2.16 0.41 12	
Difference of Means			
RP - PP	0.02	0.17	0.15
s.d. standard deviation			

"RP>PP" means: RP tested before PP and

"PP>RP" means: PP tested before RP

Appendix 7

Individual differences of IgRs between RP and PP for immediate and 3 h effects

Volunteer	Immediate effect			3h effect		
	RP	PP	Difference RP-PP	RP	PP	Difference RP-PP
1	1.89	2.03	-0.14	1.92	2.06	-0.14
2	1.85	2.40	-0.55	1.99	2.46	-0.47
3	1.86	1.80	0.06	2.02	1.73	0.29
4	1.87	1.62	0.25	1.91	1.56	0.35
5	2.23	2.43	-0.20	2.22	2.28	-0.06
6	1.99	2.19	-0.20	1.97	2.19	-0.22
7	1.75	1.99	-0.24	1.82	1.75	0.07
8	2.09	2.39	-0.30	2.07	2.53	-0.46
9	1.64	1.52	0.12	1.64	1.80	-0.16
10	1.71	1.84	-0.13	2.00	2.03	-0.03
11	1.88	2.23	-0.35	2.08	2.80	-0.72
12	2.11	2.61	-0.50	2.39	2.74	-0.35
13	1.28	1.57	-0.29	1.29	1.54	-0.25
14	2.03	1.83	0.20	1.91	1.83	0.08
15	2.05	2.29	-0.24	2.04	2.51	-0.47
16	1.72	1.44	0.28	1.73	1.52	0.21
17	1.68	2.16	-0.48	1.97	2.14	-0.17
18	2.18	2.25	-0.07	2.50	2.23	0.27
19	1.72	1.25	0.47	1.88	1.50	0.38
20	1.98	2.13	-0.15	1.90	1.96	-0.06
21	1.21	1.51	-0.30	1.39	1.83	-0.44
22	2.19	2.28	-0.09	2.39	2.47	-0.08
23	2.27	2.48	-0.21	2.56	2.37	0.19
24	2.07	2.17	-0.10	2.34	2.33	0.01

Acceptance criteria for test results

a) number of complete test results: 24

b) overall mean

of individual Ig prevalences RP (immediate/3 h effect): 4.82/4.82 (req. min 3.5/min 3.5)

of individual Ig prevalences PP (immediate/3 h effect): 4.85/4.85 (req. min 3.5/min 3.5)

c) absolute differences of mean between RP and PP

c1) between groups RP>PP and PP<RP, immediate effect: 0.18 (<2.0)

c2) between groups PP>RP and RP<PP, immediate effect: 0.15 (<2.0)

d) all quotients of two adjacent dilutions used for computation i.e. counts highlighted in tables appendix 2 and appendix 3 are between 5 and 15

All acceptance criteria are fulfilled.

Appendix 8

Computation of the Hodges – Lehmann 97.5 upper confidence limit

Computation of the Hodges Lehmann 97.5 upper confidence limit for immediate effect

Sorted differences of RP-PP (descending order)	Mean pairwise differences $(d_i + d_{ij}) / 2$										
	0.47	0.28	0.25	0.20	0.12	0.06	-0.07	-0.09	-0.10	-0.13	-0.14
0.47	0.47/1										
0.28	0.38/2	0.28/6									
0.25	0.36/3	0.27/7	0.25/9								
0.2	0.34/4	0.24/10	0.23/11	0.20/14							
0.12	0.30/5	0.20/13	0.19/17	0.16/23	0.12/28						
0.06	0.27/8	0.17/20	0.16/22	0.13/27	0.09/37	0.08/38					
-0.07	0.20/12	0.11/31	0.09/36	0.07/45	0.03/55	0.01/65	-0.07				
-0.09	0.19/15	0.10/32	0.08/39	0.06/46	0.02/64	0/71	-0.08	-0.09			
-0.1	0.19/16	0.09/35	0.08/40	0.05/41	0.01/67	-0.01/79	-0.09	-0.1	-0.1		
-0.13	0.17/18	0.08/41	0.06/47	0.03/56	-0.01/77	-0.02	-0.1	-0.11	-0.12	-0.13	
-0.14	0.17/19	0.07/43	0.06/48	0.03/57	-0.01/78	-0.03	-0.11	-0.12	-0.12	-0.14	-0.14
-0.15	0.16/21	0.07/44	0.05/50	0.03/58	-0.02	-0.03	-0.11	-0.12	-0.13	-0.14	-0.15
-0.2	0.14/24	0.04/52	0.03/59	0/68	-0.04	-0.06	-0.14	-0.15	-0.15	-0.17	-0.17
-0.2	0.14/24	0.04/53	0.02/62	0/69	-0.04	-0.06	-0.14	-0.15	-0.15	-0.17	-0.17
-0.21	0.13/26	0.04/54	0.02/63	0/70	-0.05	-0.06	-0.14	-0.15	-0.16	-0.17	
-0.24	0.12/29	0.02/60	0.01/66	-0.02/82	-0.06	-0.08	-0.16	-0.17	-0.17		
-0.24	0.12/30	0.02/61	0/72	-0.02	-0.06	-0.08	-0.16	-0.17			
-0.29	0.09/33	-0.01/74	-0.02/81	-0.05	-0.09	-0.1	-0.18				
-0.3	0.09/34	-0.01/75	-0.03	-0.05	-0.09	-0.11					
-0.3	0.08/42	-0.01/76	-0.03	-0.05	-0.09						
-0.35	0.06/49	-0.04	-0.05	-0.08							
-0.48	-0.01/73	-0.1	-0.12								
-0.5	-0.02/80	-0.02									
-0.55	-0.04										

The median of the difference between RP-PP is between 12th and 13th value: $[(-0.15) + (-0.2)] / 2 = (-0.175)$ The numbers after the values represent ranks.

The mean pairwise differences that do not exceed the median (here -0.175) are computed. The critical values for Wilcoxin's matched-pair signed-ranks test the entry for $n=24$ and a one-sided $P=0.025$ level of significance the critical value is 81. Hence $c = 81 + 1 = 82$. The pairwise differences are sorted in descending order. The 82nd value is -0.02. Hence, the Hodges – Lehmann upper one-sided 97.5% confidence limit for the difference in IgRs between RP and PP is -0.02, which is below the agreed inferiority margin of 0.75.

Therefore, the hypothesis of inferiority of the immediate effect of PP versus RP can be rejected.

Appendix 9

Computation of the Hodges Lehmann 97.5% upper confidence limit for the 3 h effect

Sorted differences of RP-PP (descending order)	Mean pairwise differences $(d_i + d_j) / 2$										
	0.38	0.35	0.29	0.27	0.21	0.19	0.08	0.07	0.01	-0.03	-0.06
0.38	0.38/1										
0.35	0.37/2	0.35/3									
0.29	0.34/4	0.32/6	0.29/10								
0.27	0.33/5	0.31/7	0.28/11	0.27/14							
0.21	0.30/8	0.28/12	0.25/15	0.24/17	0.21/23						
0.19	0.29/9	0.27/13	0.24/16	0.23/20	0.20/24	0.19/27					
0.08	0.23/18	0.22/21	0.19/26	0.18/31	0.15/40	0.14/41	0.08/63				
0.07	0.23/19	0.21/22	0.18/30	0.17/32	0.14/42	0.13/46	0.08/64	0.07/75			
0.01	0.20/25	0.18/27	0.15/39	0.14/43	0.11/58	0.10/59	0.04	0.04	0.01		
-0.03	0.18/28	0.16/35	0.13/45	0.12/47	0.09/62	0.08/65	0.03	0.02	-0.01	-0.03	
-0.06	0.16/33	0.15/36	0.12/48	0.11/56	0.08/66	0.07/73	0.01	0.01	-0.02	-0.04	-0.06
-0.06	0.16/34	0.15/37	0.12/49	0.11/57	0.08/67	0.07/74	0.01	0	-0.03	-0.05	-0.06
-0.08	0.15/38	0.14/44	0.11/54	0.10/58	0.07/72	0.06/79	0	-0.01	-0.04	-0.06	-0.07
-0.14	0.12/50	0.11/53	0.07/71	0.06/78	0.03	0.02	-0.03	-0.04	-0.07	-0.09	-0.1
-0.16	0.11/51	0.09/60	0.06/76	0.05/80	0.02	0.01	-0.04	-0.05	-0.08	-0.1	
-0.17	0.11/52	0.09/61	0.06/77	0.05/81	0.02	0.01	-0.05	-0.05	-0.08		
-0.22	0.08/68	0.07/70	0.04	0.03	0	-0.02	-0.07	-0.08			
-0.25	0.07/69	0.05/82	0.02	0.01	-0.02	-0.03	-0.09				
-0.35	0.02	0	-0.03	-0.04	-0.07	-0.08					
-0.44	-0.03	-0.05	-0.08	-0.09	-0.12						
-0.46	-0.04	-0.06	-0.09	-0.1							
-0.47	-0.04	-0.06	-0.09								
-0.47	-0.05	-0.06									
-0.72	-0.17										

The median of the difference between RP-PP is between 12th and 13th value: $[(-0.06) + (-0.08)] / 2 = (-0.07)$ The numbers after the values represent ranks.

The mean pairwise differences that do not exceed the median (here -0.07) are computed. The critical values for Wilcoxin's matched-pair signed-ranks test the entry for $n=24$ and a one-sided $P=0.025$ level of significance the critical value is 81. Hence $c = 81 + 1 = 82$. The pairwise differences are sorted in descending order. The 82nd value is 0.05. Hence, the Hodges – Lehmann upper one-sided 97.5% confidence limit for the difference in lgRs between RP and PP is 0.05, which is below the agreed inferiority margin of 0.85.

Therefore, the hypothesis of inferiority of the immediate effect of PP versus RP can be rejected.

Conclusion: as both the immediate and 3 h effects of RP are significantly inferior to those of PP the product fulfilled the requirements of EN 12791.

Appendix 10

Interpretation:

Both, the reference substance and tested product (Chemisept GEL, batch no. 198251017) fulfilled all acceptance criteria in case of number of complete test results, overall means of individual lg pre-values and absolute differences of mean between RP and PP (see appendix 7).

Conclusion:

According to the EVS-EN 12791:2016+A1:2017, the fulfilled validation criteria, test results, lg values and Hodges Lehmann system show that the tested product – Chemisept GEL – is accepted in surgical hand disinfection procedures on the following application: rub 2x3 ml of the product onto the hands within 90 seconds.



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