

**Original Article**

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# HIV Nosode: The Homeopathic Pathogenetic Trial

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**Appendix I. Blood investigations, X-ray, ECG reports, pre-post drug proving, n = 22**

Volunteer Initials/Screening number	GAJ/AS001	GAJ/AR001	PAD/AS0 02	PAD/AR 002	ANP/AS003	ANP/AR003
Date	22-Jun-11	4-Aug-11	22-Jun-11	30-Jul-11	1-Jul-11	8-Aug-11
Investigation	Pre	Post	Pre	Post	Pre	Post
Erythrocyte count (4.7 to 6.0 mill/c.mm)	4.35	4.33	5.32	5.38	4.84	4.90
Haemoglobin (13.5 to 18 gm/dl)	<u>12.4</u>	12.6	14.3	14.8	14.1	14.3
PCV (42 to 52%)	38.2	37.8	43.9	44.00	42.3	43.0
MCV (78 to 100 fl.)	87.8	87.3	82.5	81.8	87.3	87.7
MCH (27 to 31 pg)	28.5	29.2	<u>26.9</u>	27.5	29.1	29.1
MCHC (32 to 36 g/dl)	32.4	33.4	32.6	33.6	33.3	33.2
RDW (11.5 to 14.0 %)	13.7	13.9	14.0	12.9	13.2	13.2
Total Leucocyte count (4,000 to 10,500/c.mm)	<u>10,800</u>	9,900	4,400	4,300	7,500	6,400
Neutrophils (40 to 80%)	70.0	73.0	53.0	54.0	61.0	68.0
Lymphocytes (20 to 40%)	24.0	25.0	37.3	36.0	30.0	22.0
Monocytes (2 to 10 %)	5.0	<u>1.0</u>	8.0	8.0	8.0	9.0
Eosinophils (1 to 6 %)	1.0	1.0	2.0	2.0	1.0	1.0
Basophils (1 to 6 %)	0.0	0.0	0.0	0.0	0.0	0.0
Platelet Count (150 to 450* 1000/c.mm)	290	269	164	162	288	299
MPV (6 to 905 cum)	8.80	9.30	<u>9.80</u>	<u>9.80</u>	7.70	7.30
PCT (0.2 to 0.5%)	0.25	0.25	<u>0.16</u>	<u>0.16</u>	0.22	0.22
PDW (9 to 17%)	15.80	15.60	16.60	17.00	16.20	16.60
Creatinine (0.8 to 1.3 mg/dl)	0.68	0.73	<u>0.70</u>	<u>0.79</u>	<u>0.53</u>	0.60
Plasma glucose (Normal: <140 mg/dl)	123.0	81.0	67.0	84.0	56.0	<u>47.0</u>
Bilirubin-Total (0.2 to 1.0 mg/dl)	0.64	0.58	0.59	0.38	0.46	0.44
Bilirubin-Direct (0.0 to 0.2 mg/dl)	0.13	0.12	0.11	0.07	0.09	0.10
Bilirubin- Indirect (0.1 to 1.0 mg/dl)	0.51	0.46	0.48	0.31	0.37	0.34
SGOT (16-19 years: 10-41 U/l, Adults: 15 to 37 U/l)	15.00	19.00	20.00	19.00	21.00	19.00
SGPT (16-19 years: 24-59 U/l, Adults: 30-65 U/l)	<u>25.00</u>	<u>24.00</u>	31.00	34.00	19.00	24.00
Alkaline Phosphatase (16-19 years: 98-317 U/l, Adults: 50-136 U/l)	100.00	100.00	95.00	97.00	98.00	96.00
ESR (0 to 15 mm/hr)	7	7	2	7	7	7
HIV (Non Reactive)	Non Reactive (0.16)	Non Reactive (0.28)	Non Reactive (0.27)	Non Reactive (0.26)	Non Reactive (0.26)	Non Reactive (0.24)
Volume (ml)	10	13	12	13	5	12
Colour (pale yellow)	Pale Yellow	Pale Yellow	<u>Yellow</u>	Pale Yellow	Pale Yellow	Yellow

Volunteer Initials/Screening number	GAJ/AS001	GAJ/AR001	PAD/AS002	PAD/AR002	ANP/AS003	ANP/AR003
Transparency (clear)	Clear	Clear	Clear	Clear	Clear	Clear
Deposit (absent)	Absent	Absent	Absent	Absent	Absent	Absent
Reaction (4.5 to 8.0)	6.00	8.00	6.00	6.50	6.00	5.00
Specific Gravity (1.01 to 1.03)	1.01	1.01	1.02	1.01	1.02	1.01
Urine protein (Absent)	Absent	Absent	Absent	Absent	Absent	Absent
Urine glucose (Absent)	Absent	Absent	Absent	Absent	Absent	Absent
Urine Ketones (Absent)	Absent	Absent	Absent	Absent	Absent	Absent
Bile pigments (Absent)	Absent	Absent	Absent	Absent	Absent	Absent
Bile Salts (Absent)	Absent	Absent	Absent	Absent	Absent	Absent
Urobilinogen (Normal)	Normal	Normal	Normal	Normal	Normal	Normal
Nitrite (Negative)	Negative	Negative	Negative	Negative	Negative	Negative
RBCs (Absent)	Absent	4--5	Absent	Absent	Absent	Absent
WBCs (0-5/hpf)	<u>5--6</u>	1--2	1--2	1--2	1--2	4--5
Epithelial Cells (0-4/hpf)	<u>6--8</u>	1--2	1--2	1--2	1--2	2--3
Crystals (Absent)	Absent	Absent	Absent	Absent	Absent	Absent
Cast (Absent)	Absent	Absent	Absent	Absent	Absent	Absent
Amorphous deposits (Absent)	Absent	Absent	Absent	Absent	Absent	Absent
Bacteria (Absent)	Absent	Absent	Absent	Absent	Absent	Absent
Trichomonas vaginalis (Absent)	Absent	Absent	Absent	Absent	Absent	Absent
Yeast cells (Absent)	<u>Present</u>	Absent	Absent	Absent	Absent	Absent
Urine pregnancy test	Negative	Negative	Not applicable	Not applicable	Negative	Negative
X ray	No significant abnormality is noted.	No significant abnormality is noted.	Cardiomegaly	Cardiomegaly	No significant abnormality is noted.	No significant abnormality is noted.
ECG	Within normal limits except sinus tachycardia	Within normal limits except sinus tachycardia.	Within normal limits	Within normal limits at rest		Within normal limits at rest
Volunteer Initials/Screening number	DNT/AS004	DNT/AR004	ABK/AS005	ABK/AR005	AHK/AS006	AHK/AR006
Date	1-Jul-11	8-Aug-11	1-Jul-11	13-Aug-11	1-Jul-11	8-Aug-11
Investigation	Pre	Post	Pre	Post	Pre	Post
Erythrocyte count (4.7 to 6.0 mill/c.mm)	5.11	5.18	<u>4.47</u>	<u>4.43</u>	5.63	5.39
Haemoglobin (13.5 to 18 gm/dl)	13.7	14.2	14.1	14.0	15.3	14.7
PCV (42 to 52%)	42.3	42.7	<u>41.5</u>	<u>40.8</u>	47.7	45.7
MCV (78 to 100 fl.)	82.7	82.4	92.8	92.1	84.6	84.7
MCH (27 to 31 pg)	<u>26.8</u>	27.4	<u>31.5</u>	<u>31.6</u>	27.2	27.2
MCHC (32 to 36 g/dl)	32.4	33.2	33.9	34.3	32.1	32.2
RDW (11.5 to 14.0 %)	<u>15.3</u>	<u>19.5</u>	12.7	12.9	<u>14.4</u>	<u>15.0</u>
Total Leucocyte count (4,000 to 10,500/c.mm)	<u>11,600</u>	9,600	7,400	6,900	6,700	6,200
Neutrophils (40 to 80%)	56.0	49.0	<u>37.0</u>	40.0	64.0	55.0
Lymphocytes (20 to 40%)	32.0	38.0	<u>49.0</u>	46.0	24.0	32.0

Volunteer Initials/Screening number	GAJ/AS001	GAJ/AR001	PAD/AS002	PAD/AR002	ANP/AS003	ANP/AR003
Monocytes (2 to 10 %)	7.0	6.0	9.0	8.0	10.0	7.0
Eosinophils (1 to 6 %)	5.0	<u>7.0</u>	5.0	6.0	2.0	6.0
Basophils (1 to 6 %)	0.0	0.0	0.0	0.0	0.0	0.0
Platelet Count (150 to 450* 1000/c.mm)	273	257	222	250	320	210
MPV (6 to 905 cum)	<u>2.80</u>	9.20	7.70	8.10	7.90	8.10
PCT (0.2 to 0.5%)	0.27	0.24	<u>0.17</u>	0.20	0.25	<u>0.17</u>
PDW (9 to 17%)	<u>17.30</u>	16.70	16.00	16.60	16.30	16.60
Creatinine (0.8 to 1.3 mg/dl)	0.94	1.03	0.90	1.08	0.83	0.86
Plasma glucose (Normal: <140 mg/dl)	<u>49.0</u>	68.0	<u>46.0</u>	55.0	<u>42.0</u>	113.0
Bilirubin- Total (0.2 to 1.0 mg/dl)	0.81	0.55	<u>1.31</u>	0.68	<u>1.04</u>	<u>1.12</u>
Bilirubin-Direct (0.0 to 0.2 mg/dl)	0.12	0.12	<u>0.21</u>	0.12	0.13	0.17
Bilirubin- Indirect (0.1 to 1.0 mg/dl)	0.69	0.43	<u>1.10</u>	0.56	0.91	0.95
SGOT (16-19 years: 10-41 U/l, Adults: 15 to 37 U/l)	24.00	25.00	24.00	28.00	30.00	27.00
SGPT (16-19 years: 24-59 U/l, Adults: 30-65 U/l)	30.00	28.00	31.00	<u>25.00</u>	44.00	49.00
Alkaline Phosphatase (16-19 years: 98-317 U/l, Adults: 50-136 U/l)	87.00	94.00	105.00	106.00	<u>163.00</u>	135.00
ESR (0 to 15 mm/hr)	6	7	6	7	2	1
HIV (Non Reactive)	Non Reactive (0.21)	Non Reactive (0.28)	Non Reactive (0.55)	Non Reactive (0.24)	Non Reactive (0.3)	Non Reactive (0.42)
Volume (ml)	14	12	14	10	14	12
Colour (pale yellow)	Pale Yellow	Pale Yellow	Pale Yellow	Pale Yellow	Pale Yellow	Pale Yellow
Transparency (clear)	Clear	Clear	Clear	Clear	Clear	Clear
Deposit (absent)	Absent	Absent	Absent	Absent	Absent	Absent
Reaction (4.5 to 8.0)	5.00	5.00	5.00	5.00	6.00	5.00
Specific Gravity (1.01 to 1.03)	1.02	1.01	1.02	1.02	1.01	1.01
Urine protein (Absent)	Absent	Absent	Absent	Absent	Absent	Absent
Urine glucose (Absent)	Absent	Absent	Absent	Absent	Absent	Absent
Urine Ketones (Absent)	Absent	Absent	Absent	Absent	Absent	Absent
Bile pigments (Absent)	Absent	Absent	Absent	Absent	Absent	Absent
Bile Salts (Absent)	Absent	Absent	Absent	Absent	Absent	Absent
Urobilinogen (Normal)	Normal	Normal	Normal	Normal	Normal	Normal
Nitrite (Negative)	Negative	Negative	Negative	Negative	Negative	Negative
RBCs (Absent)	<u>4-5</u>	Absent	Absent	Absent	Absent	Absent
WBCs (0-5/hpf)	1--2	1--2	1--2	1--2	1--2	1--2
Epithelial Cells (0-4/hpf)	1--2	1--2	1--2	1--2	1--2	1--2
Crystals (Absent)	Absent	Absent	Absent	Absent	Absent	Absent
Cast (Absent)	Absent	Absent	Absent	Absent	Absent	Absent

<b>Volunteer Initials/Screening number</b>	<b>GAJ/AS001</b>	<b>GAJ/AR001</b>	<b>PAD/AS0 02</b>	<b>PAD/AR 002</b>	<b>ANP/AS003</b>	<b>ANP/AR003</b>
<b>Bacteria (Absent)</b>	Absent	Absent	Absent	Absent	Absent	Absent
<b>Trichomonas vaginalis (Absent)</b>	Absent	Absent	Absent	Absent	Absent	Absent
<b>Yeast cells (Absent)</b>	Absent	Absent	Absent	Absent	Absent	Absent
<b>Urine pregnancy test</b>	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
<b>X ray</b>	No significant abnormality is noted.		No significant abnormalit y is noted.	No significant abnormali ty is noted.	No significant abnormality is noted.	No significant abnormality is noted
<b>ECG</b>	Within normal limits at rest		Within normal limits at rest	Within normal limits at rest	Bilateral apical pleural thickening is seen, suggests clinical correlation.	Within normal limits at rest

Volunteer Initials/ Screening number	KND/AS007	KND/AR007	SBM/AS008	SBM/AR008	RRY/AR009	RRY/AR 009
Date	1-Jul-11	8-Aug-11	1-Jul-11	8-Aug-11	1-Jul-11	8-Aug-11
Investigation	Pre	Post	Pre	Post	Pre	Post
Erythrocyte count (4.7 to 6.0 mill/c.mm)	<u>3.90</u>	4.06	4.78	4.91	5.29	5.20
Haemoglobin (13.5 to 18 gm/dl)	13.8	14.1	14.5	15.1	15.5	15.1
PCV (42 to 52%)	<u>41.8</u>	42.6	43.3	44.8	47.0	45.1
MCV (78 to 100 fl.)	<u>107.1</u>	<u>104.9</u>	90.6	91.3	88.9	86.7
MCH (27 to 31 pg)	<u>35.3</u>	34.9	30.4	30.8	29.3	29.1
MCHC (32 to 36 g/dl)	33.0	<u>33.2</u>	33.6	33.8	32.9	33.5
RDW (11.5 to 14.0 %)	<u>14.9</u>	<u>14.4</u>	13.2	13.5	<u>14.1</u>	13.8
Total Leucocyte count (4,000 to 10,500/c.mm)	7,100	7,100	7,400	6,000	10,100	7,700
Neutrophils (40 to 80%)	58.0	58.0	55.0	53.0	60.0	56.0
Lymphocytes (20 to 40%)	34.0	35.0	34.0	36.0	24.0	28.0
Monocytes (2 to 10 %)	6.0	5.0	8.0	7.0	7.0	7.0
Eosinophils (1 to 6 %)	2.0	2.0	3.0	4.0	<u>9.0</u>	<u>9.0</u>
Basophils (1 to 6 %)	0.0	0.0	0.0	0.0	0.0	0.0
Platelet Count (150 to 450* 1000/c.mm)	209	210	290	275	227	206
MPV (6 to 905 cum)	7.30	7.80	9.20	9.10	<u>10.80</u>	<u>11.30</u>
PCT (0.2 to 0.5%)	<u>0.15</u>	<u>0.16</u>	0.27	0.25	0.24	0.23
PDW (9 to 17%)	<u>17.40</u>	<u>17.30</u>	16.40	16.10	16.30	16.70
Creatinine (0.8 to 1.3 mg/dl)	0.88	1.06	0.86	0.89	<u>0.63</u>	<u>0.63</u>
Plasma glucose (Normal: <140 mg/dl)	74.0	71.0	72.0	81.0	80.0	73.0
Bilirubin-Total (0.2 to 1.0 mg/dl)	0.59	0.44	0.53	0.32	0.48	0.38
Bilirubin-Direct (0.0 to 0.2 mg/dl)	0.10	0.11	0.07	0.07	0.07	0.09
Bilirubin- Indirect (0.1 to 1.0 mg/dl)	0.49	0.33	0.46	0.25	0.41	0.29
SGOT (16-19 years: 10-41 U/l, Adults: 15 to 37 U/l)	17.00	16.00	17.00	16.00	32.00	33.00
SGPT (16-19 years: 24-59 U/l, Adults: 30-65 U/l)	32.00	32.00	27.00	<u>28.00</u>	57.00	63.00
Alkaline Phosphatase (16-19 years: 98-317 U/l, Adults: 50-136 U/l)	85.00	103.00	72.00	83.00	98.00	104.00
ESR (0 to 15 mm/hr)	6	13	6	3	7	9
HIV (Non Reactive)	Non Reactive (0.39)	Non Reactive (0.28)	Non Reactive (0.26)	Non Reactive (0.34)	Non Reactive (0.7)	Non Reactive (0.23)
Volume (ml)	14	12	14	13	15	13
Colour (pale yellow)	Pale Yellow	Yellow	Pale Yellow	Pale Yellow	Pale Yellow	Pale Yellow
Transparency (clear)	Clear	Clear	Clear	Clear	Clear	Clear
Deposit (absent)	Absent	Absent	Absent	Absent	Absent	Absent
Reaction (4.5 to 8.0)	6.00	5.00	5.00	6.00	5.00	6.00

Volunteer Initials/ Screening number	KND/AS007	KND/AR007	SBM/AS008	SBM/AR008	RRY/AR009	RRY/AR 009
Urine protein (Absent)	Absent	Absent	Absent	Absent	Absent	Absent
Urine glucose (Absent)	Absent	Absent	Absent	Absent	Absent	Absent
Urine Ketones (Absent)	Absent	Absent	Absent	Absent	Absent	Absent
Bile pigments (Absent)	Absent	Absent	Absent	Absent	Absent	Absent
Bile Salts (Absent)	Absent	Absent	Absent	Absent	Absent	Absent
Urobilinogen (Normal)	Normal	Normal	Normal	Normal	Normal	Normal
Nitrite (Negative)	Negative	Negative	Negative	Negative	Negative	Negative
RBCs (Absent)	Absent	Absent	Absent	Absent	Absent	Absent
WBCs (0-5/hpf)	1--2	1--2	1--2	1--2	1--2	1--2
Epithelial Cells (0- 4/hpf)	1--2	1--2	1--2	1--2	1--2	1--2
Crystals (Absent)	Absent	Absent	Absent	Absent	Absent	Absent
Cast (Absent)	Absent	Absent	Absent	Absent	Absent	Absent
Amorphous deposits (Absent)	Absent	Absent	Absent	Absent	Absent	Absent
Bacteria (Absent)	Absent	Absent	Absent	Absent	Absent	Absent
Trichomonas vaginalis (Absent)	Absent	Absent	Absent	Absent	Absent	Absent
Yeast cells (Absent)	Absent	Absent	Absent	Absent	Absent	Absent
Urine pregnancy test	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
X ray	No significant abnormality is noted.	No significant abnormality is noted.	No significant abnormality is noted.		No significant abnormality is noted.	No significan t abnormali ty is noted.
ECG		Within normal limits at rest correlate clinically	Within normal limits at rest correlate clinically	Within normal limits at rest correlate clinically		Left axis deviation rest within normal limits correlate clinically

Volunteer Initials/ Screening number	LMK/AS010	LMK/AR010	GSJ/AS011	GSJ/AR015	JPN/AS012	JPN/ AR011
Date	1-Jul-11	8-Sep-11	2-Jul-11	11-Aug-11	2-Jul-11	17-Aug-11
Investigation	Pre	Post	Pre	Post	Pre	Post
Erythrocyte count (4.7 to 6.0 mill/c.mm)	5.86	5.42	5.43	5.14	<u>4.55</u>	<u>4.63</u>
Haemoglobin (13.5 to 18 gm/dl)	14.7	13.9	15.4	14.5	13.7	14.1
PCV (42 to 52%)	45.2	<u>41.6</u>	46.5	42.7	<u>41.2</u>	<u>41.2</u>
MCV (78 to 100 fl.)	<u>77.1</u>	<u>76.7</u>	85.6	83.2	90.6	89.1
MCH (27 to 31 pg)	<u>25.1</u>	<u>25.6</u>	28.4	28.3	30.0	30.5
MCHC (32 to 36 g/dl)	32.6	33.4	33.1	34.0	33.2	34.3
RDW (11.5 to 14.0 %)	14.5	<u>15.0</u>	<u>15.0</u>	<u>15.1</u>	<u>14.2</u>	12.7
Total Leucocyte count (4,000 to 10,500/c.mm)	6,300	6,700	7,900	6,800	5,900	6,700
Neutrophils (40 to 80%)	56.0	61.0	61.0	51.0	59.0	63.0
Lymphocytes (20 to 40%)	35.0	30.0	30.0	38.0	31.0	28.0
Monocytes (2 to 10 %)	5.0	6.0	6.0	10.0	8.0	8.0
Eosinophils (1 to 6 %)	4.0	3.0	3.0	1.0	2.0	1.0
Basophils (1 to 6 %)	0.0	0.0	0.0	0.0	0.0	0.0
Platelet Count (150 to 450* 1000/c.mm)	292	253	274	252	<u>142</u>	<u>112</u>
MPV (6 to 905 cum)	8.80	8.70	8.10	8.60	<u>12.90</u>	<u>12.70</u>
PCT (0.2 to 0.5%)	0.26	0.22	0.22	0.22	<u>0.18</u>	<u>0.14</u>
PDW (9 to 17%)	16.3	16.50	16.20	16.20	<u>17.30</u>	<u>17.70</u>
Creatinine (0.8 to 1.3 mg/dl)	<u>0.76</u>	<u>0.72</u>	<u>0.70</u>	<u>0.78</u>	<u>0.77</u>	<u>0.8</u>
Plasma glucose (Normal: <140 mg/dl)	58.0	65.0	90.0	71.0	67.0	53.0
Bilirubin-Total (0.2 to 1.0 mg/dl)	0.47	0.23	<u>1.44</u>	<u>6.43</u>	0.42	0.26
Bilirubin-Direct (0.0 to 0.2 mg/dl)	0.08	0.07	<u>0.25</u>	<u>4.22</u>	0.09	0.08
Bilirubin- Indirect (0.1 to 1.0 mg/dl)	0.39	0.16	<u>1.19</u>	<u>2.21</u>	0.33	0.18
SGOT (16-19 years: 10-41 U/l, Adults: 15 to 37 U/l)	23.00	25.00	27.00	<u>456.00</u>	27.00	26.00
SGPT (16-19 years: 24-59 U/l, Adults: 30-65 U/l)	29.00	32.00	34.00	<u>1,161.00</u>	35.00	37.00
Alkaline Phosphatase (16-19 years: 98-317 U/l, Adults: 50-136 U/l)	93.00	83.00	95.00	230.00	132.00	136.00
ESR (0 to 15 mm/hr)	6	3	7	4	7	7
HIV (Non Reactive)	Non Reactive (0.23)	Non Reactive (0.21)	Non Reactive (0.61)	Non reactive	Non Reactive (0.15)	Non Reactive (0.23)
Volume (ml)	13	10	12	12	12	12
Colour (pale yellow)	Pale Yellow	Pale Yellow	Pale Yellow	<u>Yellow</u>	Pale Yellow	Pale Yellow
Transparency (clear)	Clear	Clear	Clear	Clear	Clear	Clear
Deposit (absent)	Absent	Absent	Absent	Absent	Absent	Absent
Reaction (4.5 to 8.0)	6.50	6.00	5.00	6.00	5.00	6.00



Volunteer Initials/ Screening number	LMK/AS010	LMK/AR010	GSJ/AS011	GSJ/AR015	JPN/AS012	JPN/ AR011
Urine protein (Absent)	Absent	Absent	Absent	Absent	Absent	Absent
Urine glucose (Absent)	Absent	Absent	Absent	Absent	Absent	Absent
Urine Ketones (Absent)	Absent	Absent	Absent	Absent	Absent	Absent
Bile pigments (Absent)	Absent	Absent	Absent	<u>Present</u>	Absent	Absent
Bile Salts (Absent)	Absent	Absent	Absent	<u>Present</u>	Absent	Absent
Urobilinogen (Normal)	Normal	Normal	Normal	<u>Increase</u>	Normal	Normal
Nitrite (Negative)	Negative	Negative	Negative	Negative	Negative	Negative
RBCs (Absent)	Absent	Absent	Absent	Absent	Absent	Absent
WBCs (0-5/hpf)	1--2	1--2	1--2	1--2	1--2	1--2
Epithelial Cells (0-4/hpf)	1--2	1--2	1--2	1--2	1--2	1--2
Crystals (Absent)	Absent	Absent	Absent	Absent	Absent	Absent
Cast (Absent)	Absent	Absent	Absent	Absent	Absent	Absent
Amorphous deposits (Absent)	Absent	Absent	Absent	Absent	Absent	Absent
Bacteria (Absent)	Absent	Absent	Absent	Absent	Absent	Absent
Trichomonas vaginalis (Absent)	Absent	Absent	Absent	Absent	Absent	Absent
Yeast cells (Absent)	Absent	Absent	Absent	Absent	Absent	Absent
Urine pregnancy test	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
X ray	No significant abnormality is noted.	No significant abnormality is noted.	No significant abnormality is noted.	No significant abnormality is noted.	No significant abnormality is noted.	No significant abnormality is noted.
ECG		Within normal limits at rest Correlate Clinically		Within normal limits at rest Correlate Clinically	Within normal limits at rest Correlate Clinically	Within normal limits

Volunteer Initials/ Screening number	SSK/AS013	SSK/AR012	PNG/AS014	PNG/AR013	LSK/AS0 15	LSK/AR01 4
Date	2-Jul-11	8-Aug-11	2-Jul-11	8-Aug-11	2-Jul-11	8-Aug-11
Investigation	Pre	Post	Pre	Post	Pre	Post
Erythrocyte count (4.7 to 6.0 mill/c.mm)	4.83	4.83	5.08	5.19	4.75	4.65
Haemoglobin (13.5 to 18 gm/dl)	14.6	14.9	15.8	16.4	<u>12.0</u>	<u>12.0</u>
PCV (42 to 52%)	44.0	43.3	47.8	49.0	37.5	<u>36.7</u>
MCV (78 to 100 fl.)	91.1	89.7	94.0	94.4	78.8	78.9
MCH (27 to 31 pg)	30.1	30.8	<u>31.1</u>	<u>31.7</u>	<u>25.2</u>	<u>25.8</u>
MCHC (32 to 36 g/dl)	33.0	34.3	33.1	33.5	25.2	32.8
RDW (11.5 to 14.0 %)	13.3	13.8	<u>15.3</u>	<u>16.5</u>	32.0	<u>14.2</u>
Total Leucocyte count (4,000 to 10,500/c.mm)	7,400	6,700	5,800	5,700	7,800	5,700
Neutrophils (40 to 80%)	50.0	58.0	58.0	63.0	60.0	45.0
Lymphocytes (20 to 40%)	<u>41.0</u>	33.0	30.0	26.0	29.0	<u>43.0</u>
Monocytes (2 to 10 %)	7.0	7.0	8.0	7.0	7.0	7.0
Eosinophils (1 to 6 %)	2.0	2.0	4.0	4.0	4.0	5.0
Basophils (1 to 6 %)	0.0	0.0	0.0	0.0	0.0	0.0
Platelet Count (150 to 450* 1000/c.mm)	230	237	172	214	269	281
MPV (6 to 905 cum)	8.00	8.00	<u>12.50</u>	<u>10.40</u>	8.60	8.30
PCT (0.2 to 0.5%)	<u>0.18</u>	<u>0.19</u>	0.22	0.22	0.23	0.23
PDW (9 to 17%)	<u>17.10</u>	<u>17.10</u>	17.20	16.20	15.70	15.50
Creatinine (0.8 to 1.3 mg/dl)	0.94	0.89	0.90	1.09	<u>0.50</u>	<u>0.52</u>
Plasma glucose (Normal: <140 mg/dl)	64.0	63.0	55.0	<u>43.0</u>	107.0	77.0
Bilirubin-Total (0.2 to 1.0 mg/dl)	0.64	0.47	0.79	0.56	0.71	0.40
Bilirubin-Direct (0.0 to 0.2 mg/dl)	0.12	0.09	0.17	0.15	0.13	0.09
Bilirubin- Indirect (0.1 to 1.0 mg/dl)	0.52	0.38	0.62	0.41	0.58	0.31
SGOT (16-19 years: 10-41 U/l, Adults: 15 to 37 U/l)	15.00	<u>14.00</u>	31.00	27.00	16.00	16.00
SGPT (16-19 years: 24-59 U/l, Adults: 30-65 U/l)	27.00	<u>25.00</u>	36.00	39.00	<u>22.00</u>	<u>23.00</u>
Alkaline Phosphatase (16-19 years: 98-317 U/l, Adults: 50-136 U/l)	97.00	109.00	127.00	126.00	130.00	122.00
ESR (0 to 15 mm/hr)	6	10	3	2	9	11
HIV (Non Reactive)	Non Reactive (0.31)	Non Reactive (0.26)	Non Reactive (0.29)	Non Reactive (0.3)	Non Reactive (0.4)	Non Reactive (0.31)
Volume (ml)	13	13	12	12	12	13
Colour (pale yellow)	Pale Yellow	Pale Yellow	Pale Yellow	Pale Yellow	Pale Yellow	Pale Yellow
Transparency (clear)	Clear	Clear	Clear	Clear	Clear	Clear
Deposit (absent)	Absent	Absent	Absent	Absent	Absent	Absent
Reaction (4.5 to 8.0)	6.00	6.50	6.00	6.00	6.50	5.00

Volunteer Initials/ Screening number	SSK/AS013	SSK/AR012	PNG/AS014	PNG/AR013	LSK/AS015	LSK/AR014
Specific Gravity (1.01 to 1.03)	1.01	1.01	1.01	1.01	1.01	1.02
Urine protein (Absent)	Absent	Absent	Absent	Absent	Absent	Absent
Urine glucose (Absent)	Absent	Absent	Absent	Absent	Absent	Absent
Urine Ketones (Absent)	Absent	Absent	Absent	Absent	Present (Rechecked)	Absent
Bile pigments (Absent)	Absent	Absent	Absent	Absent	Absent	Absent
Bile Salts (Absent)	Absent	Absent	Absent	Absent	Absent	Absent
Urobilinogen (Normal)	Normal	Normal	Normal	Normal	Normal	Normal
Nitrite (Negative)	Negative	Negative	Negative	Negative	Negative	Negative
RBCs (Absent)	Absent	Absent	Absent	Absent	Absent	Absent
WBCs (0-5/hpf)	1--2	1--2	1--2	1--2	1--2	1--2
Epithelial Cells (0-4/hpf)	1--2	1--2	1--2	1--2	1--2	1--2
Crystals (Absent)	Absent	Absent	Absent	Absent	Absent	Absent
Cast (Absent)	Absent	Absent	Absent	Absent	Absent	Absent
Amorphous deposits (Absent)	Absent	Absent	Absent	Absent	Absent	Absent
Bacteria (Absent)	Absent	Absent	Absent	Absent	Absent	Absent
Trichomonas vaginalis (Absent)	Absent	Absent	Absent	Absent	Absent	Absent
Yeast cells (Absent)	Absent	Absent	Absent	Absent	Absent	Absent
Urine pregnancy test	Not applicable	Not applicable	Not applicable	Not applicable	Negative	Negative
X ray	No significant abnormality is noted.	Left axis deviation rest within normal limits correlate clinically	Above findings is s/o Granulomatous infection to rule out Koch's.	Above findings are s/o granulomatous infection to rule out kochs.	No significant abnormality is noted.	Sinus bradycardia T-wave inversion in anterior leads rest within normal limits correlate clinically
ECG		Within normal limits Correlate Clinically		Within normal limits at rest correlate clinically		

Volunteer Initials/ Screening number	KSJ/AS016	KSJ/AR016	SPK/AS017	SPK/AR017	GOY/AS018	WC
Date	5-Jul-11	12-Aug-11	5-Jul-11	12-Aug-11	12-Jul-11	
Investigation	Pre	Post	Pre	Post	Pre	Post
Erythrocyte count (4.7 to 6.0 mill/c.mm)	5.02	4.99	4.88	<u>4.34</u>	4.71	
Haemoglobin (13.5 to 18 gm/dl)	15.1	15.3	13.6	<u>12.4</u>	<u>12.4</u>	
PCV (42 to 52%)	45.9	45.5	<u>41.5</u>	<u>36.4</u>	38.4	
MCV (78 to 100 fl.)	91.4	91.1	85.0	83.9	81.5	
MCH (27 to 31 pg)	30.2	30.6	28.0	28.6	<u>26.2</u>	
MCHC (32 to 36 g/dl)	33.0	33.6	32.9	34.0	32.2	
RDW (11.5 to 14.0 %)	<u>15.2</u>	<u>14.6</u>	13.8	13.8	<u>16.0</u>	
Total Leucocyte count (4,000 to 10,500/c.mm)	7,600	5,400	8,100	6,500	8,400	
Neutrophils (40 to 80%)	63.0	47.0	56.0	52.0	69.0	
Lymphocytes (20 to 40%)	<u>17.0</u>	29.0	34.0	31.0	24.0	
Monocytes (2 to 10 %)	10.0	10.0	5.0	5.0	6.0	
Eosinophils (1 to 6 %)	<u>10.0</u>	<u>14.0</u>	5.0	12.0	1.0	
Basophils (1 to 6 %)	0.0	0.0	0.0	0.0	0.0	
Platelet Count (150 to 450* 1000/c.mm)	211	265	274	232	214	
MPV (6 to 905 cum)	8.20	7.80	7.90	8.30	<u>10.10</u>	
PCT (0.2 to 0.5%)	<u>0.17</u>	0.21	0.22	<u>0.19</u>	0.22	-
PDW (9 to 17%)	16.30	16.10	15.90	15.60	16.00	
Creatinine (0.8 to 1.3 mg/dl)	<u>0.78</u>	0.82	0.98	0.94	0.84	
Plasma glucose (Normal: <140 mg/dl )	56.0	75.0	55.0	73.0	<u>45.0</u>	
Bilirubin-Total (0.2 to 1.0 mg/dl)	0.36		0.74	0.44	0.21	
Bilirubin-Direct (0.0 to 0.2 mg/dl)	0.08		0.13	0.10	0.06	
Bilirubin- Indirect (0.1 to 1.0 mg/dl)	0.28		0.61	0.34	0.15	-
SGOT (16-19 years: 10-41 U/l, Adults: 15 to 37 U/l)	123.00	31.00	26.00	25.00	18.00	-
SGPT (16-19 years: 24-59 U/l, Adults: 30-65 U/l)	23.00	32.00	<u>27.00</u>	30.00	<u>29.00</u>	
Alkaline Phosphatase (16-19 years: 98-317 U/l, Adults: 50-136 U/l)	<u>29.00</u>	113.00	88.00	85.00	64.00	-
ESR (0 to 15 mm/hr)	7	2	6	6	9	
HIV (Non Reactive)	Non Reactive (0.38)	Non Reactive (0.22)	Non Reactive (0.69)	Non Reactive (0.22)	Non Reactive (0.12)	
Volume (ml)	12	40	13	14	30	
Colour (pale yellow)	Yellow	Pale Yellow	Pale Yellow	Pale Yellow	Pale Yellow	
Transparency (clear)	Clear	Clear	Clear	Clear	Clear	
Deposit (absent)	Absent	Absent	Absent	Absent	Absent	
Reaction (4.5 to 8.0)	6.00	6.00	5.00	5.00	5.00	

Volunteer Initials/ Screening number	KSJ/AS016	KSJ/AR016	SPK/AS017	SPK/AR017	GOY/AS018	WC
Specific Gravity (1.01 to 1.03)	1.03	1.02	1.02	1.02	1.02	
Urine protein (Absent)	Absent	Absent	Absent	Absent	Absent	
Urine glucose (Absent)	Absent	Absent	Absent	Absent	Absent	
Urine Ketones (Absent)	Absent	Absent	Absent	Absent	Absent	-
Bile pigments (Absent)	Absent	Absent	Absent	Absent	Absent	
Bile Salts (Absent)	Absent	Absent	Absent	Absent	Absent	
Urobilinogen (Normal)	Normal	Normal	Normal	Normal	Normal	
Nitrite (Negative)	Negative	Negative	Negative	Negative	Negative	
RBCs (Absent)	Absent	Absent	Absent	Absent	Absent	
WBCs (0-5/hpf)	1--2	1--2	1--2	1--2	1--2	
Epithelial Cells (0-4/hpf)	1--2	1--2	1--2	1--2	2--3	
Crystals (Absent)	Absent	Absent	Absent	Absent	Absent	
Cast (Absent)	Absent	Absent	Absent	Absent	Absent	
Amorphous deposits (Absent)	Absent	Absent	Absent	Absent	Absent	
Bacteria (Absent)	Absent	Absent	Absent	Absent	Absent	
Trichomonas vaginalis (Absent)	Absent	Absent	Absent	Absent	Absent	
Yeast cells (Absent)	Absent	Absent	Absent	Absent	Absent	
Urine pregnancy test	Not applicable	Not applicable	Not applicable	Not applicable	Negative	
X ray	No significant abnormality is noted.		No significant abnormality is noted.	Heterogenous opacity is seen in right lower zone s/o early consolidation.	No significant abnormality is noted.	Not done
ECG	No significant abnormality is noted.	No significant abnormality is noted.	Within normal limits Correlate Clinically	Within normal limits at rest correlate clinically	Not done	Not done

Volunteer Initials/ Screening number	RGC/AS019	RGC/AR018	GHG/AS020	GHG/AR019	JVT/AS021	JVT/A R020
Date	27-Jul-11	5-Oct-11	27-Jul-11	5-Oct-11	4-Aug-11	12-Sep-11
Investigation	Pre	Post	Pre	Post	Pre	Post
Erythrocyte count (4.7 to 6.0 mill/c.mm)	4.75	4.55	5.32	5.2	<u>4.61</u>	<u>4.43</u>
Haemoglobin (13.5 to 18 gm/dl)	14.3	13.7	14.7	14.5	<u>13.4</u>	<u>12.8</u>
PCV (42 to 52%)	43.0	40.6	44.2	43.4	<u>40.6</u>	<u>38.1</u>
MCV (78 to 100 fl.)	90.4	89.2	83.0	83.5	88.0	86.2
MCH (27 to 31 pg)	30.1	30.1	27.7	27.8	29.1	29.0
MCHC (32 to 36 g/dl)	33.3	33.8	33.3	33.3	33.1	33.7
RDW (11.5 to 14.0 %)	13.6	13.8	12.6	13.5	13.0	13.2
Total Leucocyte count (4,000 to 10,500/c.mm)	8,400	8,700	6,200	7,900	8,400	7,600
Neutrophils (40 to 80%)	64.0	59.0	59.0	61.0	53.0	43.0
Lymphocytes (20 to 40%)	26.0	31.0	30.0	32	34.0	<u>43.0</u>
Monocytes (2 to 10 %)	9.0	5.0	4.0	2.0	7.0	8.0
Eosinophils (1 to 6 %)	1.0	5.0	<u>7.0</u>	5	6.0	6.0
Basophils (1 to 6 %)	0.0	0.0	0.0	0.0	0.0	0.0
Platelet Count (150 to 450* 1000/c.mm)	245	186	256	251	341	342
MPV (6 to 905 cum)	<u>9.70</u>	<u>10.6</u>	8.70	9.5	7.50	7.50
PCT (0.2 to 0.5%)	0.24	0.2	0.22	0.24	0.26	0.26
PDW (9 to 17%)	<u>17.40</u>	17.00	16.3	16.30	15.9	15.40
Creatinine (0.8 to 1.3 mg/dl)	0.86	0.88	1.03	0.91	0.98	0.91
Plasma glucose (Normal: <140 mg/dl )	73.0	<u>Below 40</u>	66.0	<u>Below 40</u>	60.0	57.0
Bilirubin-Total (0.2 to 1.0 mg/dl)	<u>1.05</u>		0.62		0.74	<u>1.04</u>
Bilirubin-Direct (0.0 to 0.2 mg/dl)	0.15		0.16		0.17	0.20
Bilirubin- Indirect (0.1 to 1.0 mg/dl)	0.90		0.46		0.57	0.84
SGOT (16-19 years: 10-41 U/l, Adults: 15 to 37 U/l)	22.00	21.00	20.00	21.00	25.00	19.00

Volunteer Initials/ Screening number	RGC/AS019	RGC/AR018	GHG/AS020	GHG/AR019	JVT/AS021	JVT/A R020
<b>SGPT (16-19 years: 24-59 U/l, Adults: 30-65 U/l)</b>	39.00	25	<u>28.00</u>	22	31.00	27.00
<b>Alkaline Phosphatase (16-19 years: 98-317 U/l, Adults: 50-136 U/l)</b>	73.00	85.00	53.00	58.00	104.00	107.00
<b>ESR (0 to 15 mm/hr)</b>	5	5	8	4	7	7
<b>HIV (Non Reactive)</b>	Non Reactive (0.34)	Non Reactive (0.22)	Non Reactive (0.31)	Non Reactive (0.22)	Non Reactive (0.35)	Non Reactive (0.19)
<b>Volume (ml)</b>	13	13	13	14	14	13
<b>Colour (pale yellow)</b>	Pale Yellow	Pale yellow	Pale Yellow	Pale Yellow	Pale Yellow	Pale Yellow
<b>Transparency (clear)</b>	Clear	Hazy	Clear	Hazy	Clear	Clear
<b>Deposit (absent)</b>	Absent	Absent	Absent	Absent	Absent	Absent
<b>Reaction (4.5 to 8.0)</b>	8.00	5.00	5.00	6.00	6.00	5.00
<b>Specific Gravity (1.01 to 1.03)</b>	1.01	1.02	1.02	1.02	1.02	1.02
<b>Urine protein (Absent)</b>	Absent	Absent	Absent	Absent	Absent	Absent
<b>Urine glucose (Absent)</b>	Absent	Absent	Absent	Absent	Absent	Absent
<b>Urine Ketones (Absent)</b>	Absent	Absent	Absent	Absent	Absent	Absent
<b>Bile pigments (Absent)</b>	Absent	Absent	Absent	Absent	Absent	Absent
<b>Bile Salts (Absent)</b>	Absent	Absent	Absent	Absent	Absent	Absent
<b>Urobilinogen (Normal)</b>	Normal	Normal	Normal	Normal	Normal	Normal
<b>Nitrite (Negative)</b>	Negative	Negative	Negative	Negative	Negative	Negative
<b>RBCs (Absent)</b>	Absent	Absent	Absent	Absent	Absent	Absent
<b>WBCs (0-5/hpf)</b>	0--1	0-1	1--2	0-1	1--2	0--1
<b>Epithelial Cells (0- 4/hpf)</b>	1--2	0-1	1--2	0-1	1--2	0--1
<b>Crystals (Absent)</b>	Absent	Absent	Absent	Absent	Absent	Absent
<b>Cast (Absent)</b>	Absent	Absent	Absent	Absent	Absent	Absent
<b>Amorphous deposits (Absent)</b>	Absent	Present	Absent	<u>Present</u>	Absent	Absent
<b>Bacteria (Absent)</b>	Absent	Absent	Absent	Absent	Absent	Absent
<b>Trichomonas vaginalis (Absent)</b>	Absent	Absent	Absent	Absent	Absent	Absent
<b>Yeast cells (Absent)</b>	Absent	Absent	Absent	Absent	Absent	Absent

<b>Volunteer Initials/ Screening number</b>	<b>RGC/AS019</b>	<b>RGC/AR018</b>	<b>GHG/AS020</b>	<b>GHG/AR019</b>	<b>JVT/AS021</b>	<b>JVT/A R020</b>
<b>Urine pregnancy test</b>	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Not applicabl e
<b>X ray</b>	No significant abnormality is noted.				No abnormality is detected	
<b>ECG</b>	Within normal limits at rest correlate clinically				Within normal limits	Within normal limits at rest correlate clinically



Volunteer Initials/ Screening number	KNG/AS022	KNG/AR021	KDK/AS023	KDK/AR022
Date	4-Aug-11	12-Sep-11	4-Aug-11	12-Sep-11
Investigation	Pre	Post	Pre	Post
Erythrocyte count (4.7 to 6.0 mill/c.mm)	<u>4.43</u>	<u>4.52</u>	5.37	5.09
Haemoglobin (13.5 to 18 gm/dl)	14.7	15.2	16.5	15.8
PCV (42 to 52%)	43.6	44.4	48.0	45.1
MCV (78 to 100 fl.)	98.5	98.2	89.3	88.6
MCH (27 to 31 pg)	<u>33.2</u>	<u>33.5</u>	30.7	30.9
MCHC (32 to 36 g/dl)	33.7	34.2	34.4	34.9
RDW (11.5 to 14.0 %)	<u>15.7</u>	<u>14.7</u>	13.3	13.4
Total Leucocyte count (4,000 to 10,500/c.mm)	7,400	5,100	8,600	9,700
Neutrophils (40 to 80%)	44.0	<u>33.0</u>	66.0	70.0
Lymphocytes (20 to 40%)	<u>46.0</u>	<u>53.0</u>	26.0	22.0
Monocytes (2 to 10 %)	6.0	9.0	7.0	7.0
Eosinophils (1 to 6 %)	4.0	5.0	1.0	1.0
Basophils (1 to 6 %)	0.0	0.0	0.0	0.0
Platelet Count (150 to 450* 1000/c.mm)	207	285	267	260
MPV (6 to 905 cum)	7.90	7.70	7.90	8.00
PCT (0.2 to 0.5%)	<u>0.16</u>	0.22	0.21	0.21
PDW (9 to 17%)	17.00	16.70	16.10	16.00
Creatinine (0.8 to 1.3 mg/dl)	0.84	<u>0.75</u>	1.03	0.99
Plasma glucose (Normal: <140 mg/dl )	71.0	63.0	<u>49.0</u>	<u>1.09</u>
Bilirubin- Total (0.2 to 1.0 mg/dl)	0.57	0.80	<u>1.40</u>	0.19
Bilirubin-Direct (0.0 to 0.2 mg/dl)	0.15	0.16	<u>0.22</u>	0.90
Bilirubin- Indirect (0.1 to 1.0 mg/dl)	0.42	0.64	<u>1.18</u>	<u>45.0</u>
SGOT (16-19years: 10-41 U/l, Adults: 15 to 37 U/l)	48.00	37.00	33.00	30.00
SGPT (16-19years: 24-59 U/l, Adults: 30-65 U/l)	44.00	42.00	<u>24.00</u>	<u>26.00</u>
Alkaline Phosphatase (16-19 years: 98-317 U/l, Adults: 50-136 U/l)	104.00	101.00	122.00	118.00
ESR (0 to 15 mm/hr)	8	3	1	4
HIV (Non Reactive)	Non Reactive (0.3)	Non Reactive (0.47)	Non Reactive (0.26)	Non Reactive (0.43)
Volume (ml)	14	13	14	13
Colour (pale yellow)	Pale Yellow	Yellow	Pale Yellow	Pale Yellow
Transparency (clear)	Clear	Clear	Clear	Clear
Deposit (absent)	Absent	Absent	Absent	Absent
Reaction (4.5 to 8.0)	5.00	7.00	5.00	5.00
Specific Gravity (1.01 to 1.03)	1.02	1.01	1.02	1.02
Urine protein (Absent)	Absent	Absent	Absent	Absent
Urine glucose (Absent)	Absent	Absent	Absent	Absent
Urine Ketones (Absent)	Absent	Absent	Absent	Absent
Bile pigments (Absent)	Absent	Absent	Absent	Absent
Bile Salts (Absent)	Absent	Absent	Absent	Absent
Urobilinogen (Normal)	Normal	Normal	Normal	Normal
Nitrite (Negative)	Negative	Negative	Negative	Negative

<b>Volunteer Initials/ Screening number</b>	<b>KNG/AS022</b>	<b>KNG/AR021</b>	<b>KDK/AS023</b>	<b>KDK/AR022</b>
<b>WBCs (0-5/hpf)</b>	1--2	1--2	0--1	0--1
<b>Epithelial Cells (0-4/hpf)</b>	1--2	0--1	1--2	0--1
<b>Crystals (Absent)</b>	Absent	Absent	Absent	Absent
<b>Cast (Absent)</b>	Absent	Absent	Absent	Absent
<b>Amorphous deposits (Absent)</b>	Absent	Absent	Absent	Absent
<b>Bacteria (Absent)</b>	Absent	Absent	Absent	Absent
<b>Trichomonas vaginalis (Absent)</b>	Absent	Absent	Absent	Absent
<b>Yeast cells (Absent)</b>	Absent	Absent	Absent	Absent
<b>Urine pregnancy test</b>	Not applicable	Not applicable	Not applicable	Not applicable
<b>X ray</b>	No Significant abnormality is detected.		No abnormality is detected.	
<b>ECG</b>				Within normal limits

## Appendix II. Safety report

- **Event Narrative:** The Volunteer AR-015 has completed his all 5 doses of the medication A-007. Post investigations were done and it was observed that above mentioned values are high. Volunteer was referred to the physician and the appropriate lab investigations were done (Hepatitis A IgG and IgM ) The Hepatitis A IgG was found to be reactive (13.47) and Hepatitis A IgM found to be non- reactive (0.49), the rise in the values are due to the infection.
  - The symptoms reported by the volunteers AR015 were not considered as drug related and hence were omitted from the final report.
- (Hepatitis A IgG and IgM ) The Hepatitis A IgG was found to be reactive (13.47) and Hepatitis A IgM found to be non- reactive (0.49), the rise in the values are due to the infection.
  - The symptoms reported by the volunteers AR015 were not considered as drug related and hence were omitted from the final report.

Sr. no	Volunteer Randomization Number	Observation			Remark and Clinical correlation	Action taken
		Parameter	Pre	Post		
1.	AR-015	<b>Creatinine</b>	0.70	0.78	Volunteer is Hepatitis A positive	*Referred to physician and done the lab investigation Hepatitis A IgG and IgM values
		<b>Bilirubin-total</b>	1.44	6.43		
		<b>Bilirubin-Direct</b>	0.25	4.22		
		<b>Bilirubin- Indirect</b>	1.19	2.21		
		<b>SGOT</b>	27.00	456.00		
		<b>SGPT</b>	34.00	1,161.00		
		<b>Alkaline phosphatase</b>	95.00	230.00		
		<b>Bile pigment</b>	Absent	Present		
		<b>Bile Salts</b>	Absent	Present		
		<b>Urobilinogen</b>	Absent	Present		

- **Event Narrative:** The Volunteer AR-011 has taken 4 doses of the medication A-007. Volunteer was suffered from fever at the 3<sup>rd</sup> day of 4<sup>th</sup> week. Volunteer send for the blood investigations. The result was found to P.Vivax Trophozoites 0.01 % positive.

After decoding the volunteer AR011 found to be in placebo group, symptoms reported by the volunteer AR011, were not considered as drug related and hence were omitted from the final report.

Sr. no	Volunteer Randomization Number	Observation			Remark and Clinical correlation	Action taken
		Parameter	Pre	Post		
1.	AR-011	Platelet count	142	112	Volunteer was suffered from fever in 4 <sup>th</sup> week duration of drug administration.	*Referred to physician and done the lab. Investigation
		Bilirubin-total	0.42	0.26		
		Bilirubin-Direct	0.09	0.08		
		Bilirubin- Indirect	0.33	0.18		
		SGOT	27.00	26.00		
		SGPT	35.00	37.00		
		Alkaline phosphatase	132.00	136.00		

### Appendix III. Symptoms of verum group and selected symptoms for clinical practice

#### A. Symptoms of Verum group

##### Mind (Number of volunteers: 6) (1<sup>++</sup>, 2<sup>++</sup>, 4<sup>+</sup>, 10<sup>++</sup>, 14<sup>+</sup>, 21<sup>+++</sup>)

1. Mind: Anger: (Number of volunteers: 1) [2<sup>++</sup>]
  - a. Aggressive, short tempered for 2 days [2<sup>++</sup> (day 20, 21 for a day)]
  - b. Anger, trifles at [2<sup>++</sup> (day 8 for a day, day 20 for 10 to 20 minutes)]
2. Confusion of mind, as if drunken [21<sup>++</sup> (day 8 for a day)]
3. Depressed feeling for 5 days [1<sup>++</sup> (day 18, 19, 20, 21, 22)]
4. Dual thoughts of mind [21<sup>++</sup> (day 21 for a day)]
5. Disturbed feeling [10<sup>++</sup> (day 27 morning few hours, day 27 for a day)]
6. Hurried, eating while [21<sup>++</sup> (day 33 for a day)]
7. **Irritability** (Number of volunteers: 5) (1<sup>++</sup>, 2<sup>++</sup>, 4<sup>+</sup>, 14<sup>+</sup>, 21<sup>+++</sup>)
  - a. **Irritability**, small mistakes done by others [21<sup>+++</sup> (day 37 for a day)]
  - b. Irritability, when asked something for 5 days [1<sup>+</sup> (day 18, 19, 20, 21, 22)]
  - c. Irritability, short tempered, situation based [2<sup>++</sup> (day 19)]
  - d. Irritability, <contradiction, trifles from anyone talk between my conversation. [2<sup>++</sup> (day 20 for few minutes)]
  - e. Irritability gets easily offended < when scolded [4<sup>+</sup> (day 20, 21, 22, 23, 24, 25)]
  - f. Irritability gets angry small matters, < by slight sound [14<sup>+</sup> (day 20 for a day)]
  - g. Irritability < when asked unwanted questions, < while talking [14<sup>+</sup> (day 31 for a day)]
8. Lonely feeling [1<sup>+</sup> (day 20)]
9. **Restlessness**, cannot sit in one place even when tired, < lying on the floor, > by stretching for 2 days [21<sup>+++</sup> (day 23, 24, 25 for a day)]
10. Sense of frustration for 3 days. [2<sup>++</sup> (day 20 for 10 to 20 minutes, day 21,22 a day)]
11. Weeping [14<sup>+</sup> (day 20 for 1 hour)][18]

**Dreams (Number of volunteers: 3) (1+, 10++, 21++++)**

12. **Dreams as if someone snatched my gadget and I am applying my full force to resist it** [21++++ (day 21)]
13. Dream, death of his father [10++ (day 27)]
14. Dreams as if going somewhere, but could not reach [1+ (day 17)]
15. Dreams as if lost somewhere [1+ (day 26)]
16. Dreams of travelling [1+ (day 30)]
17. Dreams of accident and blood [1+ (day 32)][24]

**Head (Number of volunteers: 7) (1+, 5+++ , 6+, 7+++ , 9+, 10++, 18++)**

18. **Dull headache** (Number of volunteers: 3)[(5+++ , 9+, 10++)]
  - a. Dull headache < overwork 7-8 pm [10++ (day 29 for one hour)]
  - b. Dull headache with heaviness of head all over the head < 1-4 pm associated with sleepiness [9+ (day 22 for 2-3 hours)]
  - c. **Dull, temporal headache** with eye pain [5+++ (day 22 for 2 to 3 hours)]
19. Headache, frontal, region < afternoon, on 2 days [18++ (day 28 for 2 hours, 29 for 3 hours)]
20. **Headache, right sided temporal region**; pricking sensation remained for 10 minutes (2 episodes) [7+++ (day 15)]
21. **Heaviness of head** (Number of volunteers: 2) [1+, 6+ (day 15)]
  - a. Heaviness of head [6+ (day 15)]
  - b. Heaviness of head along with dull pain in whole head with feverish feeling and irritability, < 2 pm to 5 pm [1+ (day 20, for 2 to 3 hours)]
22. **Headache, bursting in temples** < as the day progress [5+++ (day 29 for 2 to 3 hours)]
23. **Pulsating pain in temporal region with redness of eyes** [5+++ (day 35)][33]

**Eyes (Number of volunteers: 2) (5+, 21++++)**

24. **Burning, heaviness, irritation in eyes, < exposure to light rays, reading, > closing eyes** [21++++ (day 9)]
25. **Burning, in eyes, blurred vision with lacrimation while reading for 2 days** [21++++ (day 8, 9 and repeated on 12)]
26. **Burning, sensation as if something present in eye (sand) < morning, for 2 days** [21++++ (day 16, 17 for 2 days)]
27. **Lacrimation, irritation, burning in eyes < yawning > by closing eyes** [21++++ (day 15 for a day)]
28. Pain in eye [5+ (day 22 for 1 hour)][38]

**Nose (Number of volunteers: 5) (6<sup>+</sup>, 9<sup>+</sup>, 12<sup>+</sup>, 18<sup>++</sup>, 21<sup>++++</sup>)**

**29. Nose, watery discharge** (Number of volunteers: 3)[6<sup>+</sup>, 9<sup>+</sup>, 21<sup>++++</sup>]

- a. **Nose, watery, discharge, running nose, obstruction, < 3.47 am, > taking hot vapors** [21<sup>++++</sup> (day 30 for one hour)]
- b. **Irritation in nose with watery discharge for a day and repeated for two days with a day's gap** [21<sup>++++</sup> (day 31,33,34 for entire day)]
- c. Running nose, watery coryza all the day from morning till night. [9<sup>+</sup> (day 10, 16)]
- d. Cold, watery discharge from nose [6<sup>+</sup> (day 16)]

**30. Running nose alternate with nose block** [9<sup>+</sup> (day 10)]

**31. Sneezing** (Number of volunteers: 2) (6<sup>+</sup>, 18<sup>++</sup>) [6<sup>+</sup> (6 - 8 times in morning, day 16, 17),

18<sup>++</sup> (Sneezing < afternoon, day 9 for 3 to 4 hours)]

**32. Watery coryza, with sneezing at morning 4 to 8 times and feverish feeling for 2 days** [12<sup>+</sup> (day 16, 17)][45]

**Throat (Number of volunteers: 2) (2<sup>++</sup>, 21<sup>++++</sup>)**

**33. Throat pain** (Number of volunteers: 2) [2<sup>++</sup>, 21<sup>++++</sup>]

- a. **Throat, sore pain, dryness, rawness feeling irritation and plug like sensation**

< Evening [21<sup>++++</sup> (day 22, 23 for a day)]

- b. Throat pain [2<sup>++</sup> (day 26)]

**34. Irritation of throat** (Number of volunteers: 1) [21<sup>++++</sup>]

- a. **Difficult in expectoration < morning after getting from bed.** [21<sup>++++</sup> (day 14 for a day)]
- b. Irritation of throat <exposure to cold and > warmth. [21<sup>+++</sup> (day 9 for a day)]

**35. Mucus in throat, difficult expectoration, continuous hawking and clearing throat < talking, laughing for 4 days** [2<sup>++</sup> (day 25, 26, 27, 28)]

**36. Pulling sensation in throat.** [21<sup>+</sup> (day 10 for a day)][51]

**Mouth (Number of volunteers: 3) (14<sup>++++</sup>, 18<sup>++</sup>, 21<sup>++</sup>)**

**37. Mouth ulcers** (Number of volunteers: 2) [(14<sup>++++</sup>, 21<sup>++</sup>)]

- a. **Ulceration in whole mouth, and on tongue** [14<sup>++++</sup> (day 35, 36)]
- b. Ulcerated outgrowth on the tip of the tongue for 2 days [21<sup>++</sup> (day 16, 17 for entire day)]
- c. **Ulcer over left lower side of tongue** < pain while talking, brushing teeth, while eating, for 4 days [14<sup>++++</sup> (day 31, 32, 33, 34)]

**38. Inflamed upper palate** [21<sup>++</sup> (day 24 for entire day)]

**39. Bleeding gums for 4 days while brushing teeth** [18<sup>++</sup> (day 20, 21, 22, 23)][56]

**Stomach (Number of volunteers: 5) (1<sup>+</sup>, 5<sup>++</sup>, 10<sup>++</sup>, 12<sup>++</sup>, 21<sup>++++</sup>)**

40. **Reduced appetite** (Number of volunteers: 2)[1<sup>+</sup> (day 16, 17, 18, 19, 20), 12<sup>++</sup> (day 28 for a day)]
41. **Nausea** (Number of volunteers: 2) [5<sup>++</sup> (day 29), 21<sup>++++</sup> (day 22 for one day)]
- Bilious vomiting with nausea [5<sup>++</sup> (day 29)]
  - Stomach sour eructation < empty stomach with nausea and vomiting [21<sup>++++</sup> (day 22 for one day)]
42. Retrosternal burning < morning, taking oily things [10<sup>++</sup> (day 8 for 2 to 3 hours)]
43. Thirst increased with bitter taste in mouth [21<sup>++++</sup> (day 17 for 3 to 4 hours)]
44. **Ravenous appetite, wants to eat everything in hurry** [21<sup>++++</sup> (day 33 for a day)]
45. Feeling hungry but continuous nausea<sup>++</sup> and vomiting [5<sup>++</sup> (day 35, for 4-5 hours)][63]

**Abdomen (Number of volunteers: 3) (1<sup>+</sup>, 14<sup>+</sup>, 21<sup>++++</sup>)**

46. **Pain in abdomen** (Number of volunteers: 3) [(1<sup>+</sup>, 14<sup>+</sup>, 21<sup>++++</sup>)]
- Pain in abdomen extending to pelvic/rectal region** [21<sup>++++</sup> (day 23 for 3 hours, 24 for one hour)]
  - Dull pain in right hypochondrium < walking, laughing [1<sup>+</sup> (day 16, for 2 hours)]
  - Dull pain and heaviness in epigastric and umbilical region < after eating, after afternoon. [1<sup>+</sup> (day 9, for 5 to 6 hours)]
  - Pain in epigastric region with fullness feeling [1<sup>+</sup> (day 25, for a day)]
  - Crampy pain in lower abdomen, ineffectual urging to stool [14<sup>+</sup> (day 26)]
47. Acidity and burning in epigastric region < 12 - 2 pm, > after eating [1<sup>+</sup> (day 16 for 2 hours)][69]

**Rectum (Number of volunteers: 3) (2<sup>++</sup>, 6<sup>+</sup>, 21<sup>++</sup>)**

48. Constipated, unsatisfied stool after taking outside food [6<sup>+</sup> (day 9)]
49. Burning in anus, after defecation on 3 days [2<sup>++</sup> (day 15, 16, 17 for 10 min)]
50. Itching around anus [21<sup>++</sup> (day 24 for a day)][73]

**Stool (Number of volunteers: 2) (14<sup>+</sup>, 21<sup>++++</sup>)**

51. **Urge to stool < after hot drinks (tea or coffee)** [21<sup>++++</sup> (day 16)]
52. **Stool, loose** [Number of volunteers: 2] [14<sup>+</sup>, 21<sup>++++</sup>]
- Loose offensive<sup>++++</sup>, sour in odor, burning > after passage of stool** [21<sup>++++</sup> (day 15)]
  - Watery stool, twice a day on 3 days [14<sup>+</sup> (day 18, 19, 20)][75]

**Urinary organs (Number of volunteers: 2) (5<sup>+</sup>, 21<sup>++++</sup>)**

53. **Burning micturition** with pricking pain and burning after urination, < night [21<sup>++++</sup> (day 29 for few minutes)]
54. Bladder, swollen, tightness, just after passage of urine associated with back pain. [21<sup>++</sup> (day 28 for few minutes)]
55. Burning micturition (5<sup>+</sup>)(day 35)[78]



**Male sexual organs (Number of volunteers: 1) (17<sup>+</sup>)**

56. Premature ejaculation for 2 days [17<sup>+</sup> (day 11,12)][79]

**Cough (Number of volunteers: 1) (4<sup>++</sup>)**

57. Dry cough < drinking outside water, <morning, <cold weather. [4<sup>++</sup> (day 40, 41, 42)][80]

**Neck (Number of volunteers: 4) (1<sup>+</sup>, 10<sup>++</sup>, 17<sup>+++</sup>, 21<sup>++++</sup>)**

58. **Twitching of the muscles of shoulder lining** < **Sitting relaxed by keeping shoulders down for 4 days** [21<sup>+++</sup> (day 33, 34, 35, 36 for entire day)]

59. Pain in right side of neck < evening for 2 days (17<sup>+++</sup> (day 35, 36 for entire day))

60. Dull continuous pain in cervical region, < sitting for long time, > pressure, sleep [1<sup>+</sup> (day 18, for 5 to 6 hours)]

61. Pain in neck due to sprain < morning, after waking up [10<sup>++</sup> (day 26)][84]

**Back (Number of volunteers: 4) (1<sup>+</sup>, 14<sup>++</sup>, 18<sup>+++</sup>, 21<sup>++++</sup>)**

62. **Pricking, needles, as if number of needles are pricked at the time over the back only** < **evening, sweating > scratching, for 2 days** [21<sup>+++</sup> (day 33, 34 for entire day)]

63. **Muscles of back and trunk get stiffened** < **moving body, > stretching, complete rest.** [21<sup>+++</sup> (28, 29, 30 day for a day)]

64. **Pain in the lower back** (Number of volunteers: 3) [1<sup>+</sup>, 14<sup>++</sup>, 18<sup>+++</sup>]

- a. Dull, continuous pain in lumbar region, < sitting for long time, movement > pressure [1<sup>+</sup> (day 18, for 5 to 6 hours)]
- b. Pain in lower back < night, rising from sleep > by continued motion for 5 days. [14<sup>++</sup> (day 12, 13, 14, 15, 16)]
- c. Pain in lower back < 3-4 pm [18<sup>++</sup> (day 37 for one hour)]
- d. **Pain in the lower back** < 12 - 1 pm > stretching backwards. [18<sup>+++</sup> (day 15, for one hour)][90]

**Extremities (Number of volunteers 4) (1<sup>+</sup>, 2<sup>++</sup>, 14<sup>++</sup>, 21<sup>++++</sup>)**

65. **Pain knee joint** [Number of volunteers: 2] (1<sup>+</sup>, 21<sup>+++</sup>)

- a. Pain in left knee joint, < walking, standing for long time, > sleep [1<sup>+</sup> (day 19, for 1 to 2 hours, day 22, for 3 to 4 hours)]
- b. **Pain in left knee joint** < when stop walking, > by dancing, complete rest and pressure. [21<sup>+++</sup> (day 30 for entire day)]

66. **Severe pain in both soles** [Number of volunteers: 2] [14<sup>++</sup>, 21<sup>++</sup>]

- a. Unable to keep legs down > elevating legs up, for 5 days [14<sup>++</sup> (day 12, 13, 14, 15, 16)]
- b. Pain in both soles, < pressure [21<sup>++</sup> (day 9 for a day)]

**67. Pain in leg** [Number of volunteers: 3] [1<sup>+</sup>, 2<sup>++</sup>, 21<sup>++++</sup>]

- a. **Pain in left leg < early morning** [21<sup>++++</sup> (day 21 for a day)]
- b. Pain in left leg, more in knee joint, < walking, standing for long time, > sleep [1<sup>+</sup> (day 19, for 1 to 2 hours, day 22, for 3to4 hours)]
- c. Pain, along first 1/3<sup>rd</sup> course of sciatic nerve < by touch, motion, changing position, > warmth, for 4 days (Number of volunteers: 1) [2<sup>++</sup> (day 17,18,19,20)]
- d. Sciatica, electric shock-like pain in 1/3<sup>rd</sup> upper part of femur [2<sup>++</sup> (day 19)][**98**]

**Fever (Number of volunteers: 3) (1<sup>+</sup>, 5<sup>+++</sup>, 21<sup>+</sup>)**

**68. Fever with chill** [Number of volunteers: 2] [5<sup>+++</sup>, 21<sup>+</sup>]

- a. Fever with chill < 11 am < outdoors > by rest [5<sup>+++</sup> (day 36, for 4-5 hours)]
- b. Fever with chill has to cover by blanket early morning < morning, > by warmth, as the day passes [21<sup>+</sup> (day 19 for 2-3 hours)]

**69. Feverish** [Number of volunteers: 1] [1<sup>+</sup>]

- a. Feverish feeling followed by perspiration over palms and soles, with heaviness of head, 11 am to 5 pm [1<sup>+</sup> (day 25, for 5 to 6 hours)]
- b. Feverish along with lethargic feeling [1<sup>+</sup> (day 17, for 2 to 3 hours)][**102**]

**Sleep (Number of volunteers: 4) (1<sup>+</sup>, 6<sup>+</sup>, 14<sup>++</sup>, 21<sup>+++</sup>)**

**70. Sleepiness** [Number of volunteers: 2] [14<sup>++</sup>, 21<sup>+++</sup>]

- a. Sleepiness with tiredness, does not feel to do anything, for 2 days [14<sup>++</sup> (day 15, 16 for entire day)]
- b. Sleepy whole day, un-refreshing sleep. [21<sup>++</sup> (day 28 for a day)]
- c. **Sleepiness** < after least exertion > by continued motion [21<sup>+++</sup> (day 27 for entire day)]

**71. Drowsy feeling.** (Number of volunteers: 2) [1<sup>+</sup>, 21<sup>+++</sup>]

- a. **Drowsy feeling** [21<sup>+++</sup> (day 27 for entire day)]
- b. Drowsy feeling in the evening < 7-10 pm associated with heaviness of eyelids. [1<sup>+</sup> (day 15, for 2 to 3 hours)]

**72. Sleeplessness, unable to sleep till 3 am, un-refreshing sleep** [6<sup>+</sup> (day 19)]

**73. Disturbed sleep, waking up frequently** [1<sup>+</sup> (day 21)]

**74. Un-refreshing sleep, full of dreams** [1<sup>+</sup> (day 19)][**110**]

**Perspiration (Number of volunteers: 1) (7<sup>+</sup>)**

**75. Perspiration, all over body < afternoon, followed by shivering.** [7<sup>+</sup> (day 9)][**111**]

**Skin (Number of volunteers: 3) (1<sup>++</sup>, 14<sup>++</sup>, 21<sup>+++</sup>)**

**76. Acne over right cheek, itching, painful < by touch, for 2 days** [21<sup>+++</sup> (day 18,19 for entire day)]

**77. Skin rash papular eruption**

- a. Papular eruption on left side of neck, itching ++ with redness for 3 days; [1++ (day 19, 20, 21)]
- b. Erythematous papular eruption on left arm with itching for 5 days [14++ (day 28,29,30,31,32)]

**78. Itching**

- a. Itching of scalp, > by scratching [21+++ (day 22 for entire day, repeated on day 24 for a day)]
- b. Itching over both the palms [1+ (day 21, for 10-15 minutes)][116]

**Generalities (Number of volunteers: 6) (1+, 2++, 5++, 10++, 12++++, 21+++)**

**79. Exhaustion and tiredness (Number of volunteers: 3) [1+, 2++, 21+++]**

- a. **Exhaustion and tiredness < slight exertion** [21+++ (day 26 for entire day)]
- b. Lethargic feeling with increased sensitivity to cold [1+ (day 17 for a day)]
- c. Exhausted < less motion > by continued motion [21+ (day 19 for a day)]
- d. Tired feeling, easy fatigue < evening 8-10 pm [1+ (day 16, for 3 to 4 hours)]
- e. Weak and exhausted feeling for 2 days [2++ (day 15,16)]

**80. Body ache (Number of volunteers: 4) (5++, 7++, 10++, 21+++)**

- a. Body ache for 2 days [10++ (day 26, since evening, day 27 for a day)]
- b. Body pain including knee pain [7++ (day 9, 2 to 3 hours)]
- c. Pain all over body [21+++ (day 33,34 for entire day)]
- d. Body pain [5++ (day 35, for 4-5 hours)]

**81. Lethargy feeling with increased sensitivity to cold. [1+ (day 17, for 2 to 3 hours)]**

**82. Weakness (Number of volunteers: 2) [(2++, 12++++)]**

- a. Weak and exhausted feeling [2++ (day 15,16)]
- b. **Weakness** [12++++ (day 28 for a day, 29 for 4-5 hours)]

**83. Increased sensitivity to heat, wants more fan and air conditioner [1+ (day 11 for a day)]**

**84. Pain, rheumatic type pain in all joints < morning, before getting from bed > as the day passes, associated with mild fever, for 5 days, and again after two weeks [21<sup>++++</sup> (day 16, 17,18,19,20 for entire day, and repeated on day 34 for 5 to 6 hours)]**[130]

B. Selected symptoms for clinical practice

List of the clinically significant symptoms of the HIV nosode on the basis of frequency of appearance (in volunteers), with intensity and duration arrived at from the HPT, which can be applied in clinical practice.

1. Mind: **Irritability, anger**, short-tempered (5 volunteers). Irritability at trifles; when scolded, disturbed. *Depressed, lonely, frustrated*, confusion. Restlessness, cannot sit at once place. Hurried eating
2. Generalities: **Exhaustion, tiredness. Lethargic, weakness, easy fatigue < slight exertion** (4 volunteers).
3. Sleep: **Sleepiness, drowsiness** (3 volunteers). Sleepless till 3 a.m., *refreshing*, dreamy
4. Dreams: Someone snatched my gadget and I am applying my full force to resist it; father's death; traveling; accident and blood; lost somewhere; going somewhere but could not reach (all dreams, except the first one, from the single volunteer)
5. Head: **Dull headache** (5 volunteers), **heaviness** in head, **< afternoon**, frontal, *temporal*, right-sided, entire head, *pulsating, bursting*.
6. Eyes: **Burning, irritation, lachrymation** (one volunteer, but intense and repeatedly observed)
7. Ear, Nose, Throat: **Watery coryza, irritation in nose** (5 volunteers), **sneezing**, nose block, (*watering of eyes*). *Soreness, dryness, rawness, irritation like plug sensation, pulling in throat. Mucus in throat, with difficult expectoration. < Cold, > heat.*
8. Mouth: **Ulcers in mouth** (2 volunteers), *tongue, tip of the tongue, whole mouth*, and palate. Bleeding gums.
9. Stomach: *Ravenous appetite*, reduced appetite. Bilious vomiting with nausea. *Retrosternal burning*. Sour eructation. Feeling hungry but continuous nausea and vomiting.
10. Abdomen: **Pain in abdomen** extending to pelvis and rectum. Pain in right hypochondrium <walking, laughing. *Acidity, burning in epigastric < 12 – 2 p.m., > eating. Cramps in lower abdomen.*
11. Rectum and stools: Constipation, burning in anus after stool. *Urge to stool < hot drinks. Loose, offensive, sour smelling stool.*
12. Urinary organs: *Burning, before and after urination < night. With back pain.*
13. Male sexual organs: Premature ejaculation
14. Cough: Dry cough
15. Neck and back: **Twitching of the muscles of shoulder lining muscles. < Sitting relaxed by keeping shoulders down. Neck pain** (4 volunteers), right side, < morning, on waking up. **Pricking, needles, as if number of needles are pricked at the time over the back only < evening, sweating, > scratching.** *Stiffness in the muscles of back and neck. Pain in lower back. <12 – 1 p.m., < 3 – 4 p.m., > pressure.*
16. Extremities: *Pain in all joints, < morning, <on waking up, > as day passes, < walking, < standing for long time. Pain in joints with fever. Pain in knee, left. Body pain. Severe pain in soles, > elevating legs. Pain in left knee, left thigh, left leg. Pain in left knee < when stop walking, > dancing, > pressure. Pain in left thigh, as if scrapped with any metal sheet > pressure, rest. Pain, along first 1/3<sup>rd</sup> course of sciatic nerve < by touch, motion, changing position, > warmth. Electric shock-like pain similar to sciatica, in 1/3<sup>rd</sup> upper part of femur. Pain all over body. Weakness of legs with want of power.*

17. Fever: **Fever** (3 volunteers). *Fever with chills.* < Morning, > warmth. Feverish feeling followed by perspiration, with heavy head, 11 a.m. to 5 p.m. Feverish and lethargic.
18. Perspiration: Perspiration, all over body < afternoon, followed by shivering.
19. Skin: **Papular, erythematous eruptions** on neck, **left arm**, with itching. **Acne.** Acne over right cheek, arm, itching, painful < by touch. Itching over both the palms

**Appendix IV.** Symptoms experienced by volunteers in the first week (run-in period) when on placebo

**Head (Number of volunteers: 9) (1+, 4+, 7+, 9+, 10+, 12+, 14+++, 18++, 21+++)**

1. **Headache, frontal region (Number of volunteers: 4) (9+, 10+, 12+, 21+++)**
  - a. Headache, right sided, frontal region < exertion, workload [10+ (day 6 for 5-6 hours)]
  - b. Heaviness, frontal region > by closing eyes [21+++ (day 3 for 10 minutes)]
  - c. Headache, frontal region (Number of volunteers: 1)[12+ (day 1 for 3 – 4 hours)]
  - d. Heaviness, of forehead, temples, immediately after intake of medicine [9++ (day 1 for 15 minutes)]
  - e. Headache, frontal region with vertigo< on seeing bright object > absolute rest [21+++ (day 4 for 1 hour, day 2 for 2-3 hours, day 3 for 10minutes, day 4 for 1 hour, day 5 for 5 minutes)]
2. Giddiness, mild headache [7+ (day 1 for 30 minutes)]
3. **Throbbing headache (Number of volunteers: 4) (1+, 18++)**
  - a. Throbbing headache In frontal region < noise, movement, 2 -5 pm [1+ (day 3 for 2 – 3 hours, day 6 for 3 hours)]
  - b. Throbbing pain, in head (Number of volunteers: 1) [18++ (day 4 for 10 minutes)]
4. Headache, temporal region < anger from [4+ (day 2 for 1day)]
5. Headache, vertex region heaviness of head< morning & under Air conditioner, associated with running nose, cough, throat pain, fever with chilliness [14+++ (day 1, 2, 3 for 3 days)][10]

**Eye (Number of volunteers: 1) (21++)**

6. Irritation, of eyes, dryness > blinking & rubbing eyes [21++ (day 5 for 1 day)][11]

**Nose (Number of volunteers: 1) (17+)**

7. Coryza, watery [17+ (day 3, 4, 5, 6 for 4 days)]
8. Sneezing [17+ (day 3, 4, 5, 6 for 4 days)][13]

**Teeth (Number of volunteers: 1) (21+++)**

9. Numbness, pricking pain in caries teeth [21+++ (day 3 for 3 hours, day 4 for 1 hour)][14]

**Throat (Number of volunteers: 1) (20+++)**

10. Shifting pain from right to left throat, lump like sensation in throat with itching < drinking water > warm drinks, difficulty in swallowing. [20+++ (day 2, 3 for 2 days, 4, 5, 6 for 5-10 minutes)][15]

**Rectum Number of volunteers: 1) (21++)**

11. Hard, unsatisfactory stool [21++ (day 5 for 1day)]
12. Burning, pain rectum [21++ (day 5 for 1 day)][17]

**Stool (Number of volunteers: 1) (21++)**

13. Fatty stool, loose greasy stool [21++ (day 2 for 1 day)][18]

**Neck (Number of volunteers: 1) (20++)**

14. Right sided scapular region, muscular spasm < exertion from > hard pressure, absolute rest [20++ (day 2, 3, 4, 5, 6, 7 for 6 days)][19]

**Back (Number of volunteers: 1) (21<sup>++++</sup>)**

15. Lower back, radiating pain in > by rest, by massage & by warmth [21<sup>++++</sup> (day 2 for 1 hour)]
16. Pain in all joints & back region < morning after rising [21<sup>++++</sup> (day 5 for 1 day)][21]

**Chest (Number of volunteers: 1) (21<sup>+++</sup>)**

17. Stretching pain in intercostal muscles < by pressure, deep breathing [21<sup>+++</sup> (day 7 for 1-2 hours)][22]

**Cough (Number of volunteers: 1) (14<sup>++</sup>)**

18. Dry cough [14<sup>++</sup> (day 4, 5, 6 for 3 days)][23]

**Sleep (Number of volunteers: 1) (9<sup>++++</sup>)**

19. Extreme, sleepiness, eyes closing [9<sup>++++</sup> (day 4 for 8 hours)] [24]

**Fever (Number of volunteers: 1) (21<sup>+</sup>)**

20. Cold with a mild fever in morning [21<sup>+</sup> (day 2 for 1hour)][25]

**Extremities (Number of volunteers: 2) (7<sup>+</sup>, 21<sup>+++</sup>)**

21. Pain in medial & lateral thigh of left leg, sensation as if scraped by a metal object > by pressure & rest [21<sup>+++</sup> (day 4 for 1 day)]
22. Weakness, in legs with want of power [7<sup>+</sup> (day 1, 2 for 2 days)]
23. Leg pain, pulling sensation < morning while waking from bed [7<sup>+</sup> (day 2 for 1 day)][28]

**Skin (Number of volunteers: 1) (21<sup>+++</sup>)**

24. Eruption, vesicular, itching, face & neck [21<sup>+++</sup> (day 7, 8 for 2 days)][29]

**Generalities (Number of volunteers: 2) (14<sup>+++</sup>, 21<sup>++++</sup>)**

25. Body ache, unable to get up from bed [14<sup>+++</sup> (day 2, 3 for 2days)]
26. Exhaustion & tiredness < slight exertion [21<sup>++++</sup> (day 1, for a day)][31]

## Appendix V. Symptoms experienced by volunteers during 5 weeks when on placebo

### Mind (Number of volunteers: 4) (3<sup>+++</sup>, 13<sup>++</sup>, 16<sup>+</sup>, 19<sup>+++</sup>)

1. Anger (Number of volunteers: 2) (3<sup>+++</sup>, 13<sup>+</sup>)
  - a. Aggressive < while talking with others [3<sup>+++</sup> (day 15 for 2 hours)]
  - b. Anger, when opposite person does not listen to him, associated with heaviness of head (Number of volunteers: 1) [13<sup>++</sup> (day 10 for 1 hour, 11 for a day)]
2. Anxious thoughts about future [19<sup>+++</sup> (day 8, 9, 10, 11, 12, 13 for 6 days)]
3. Irritability (Number of volunteers: 2) (3<sup>+</sup>, 13<sup>+</sup>)
  - a. Irritability < morning < while talking with others [3<sup>+</sup> (day 15, for 2 hours, 16 for 30 minutes)]
  - b. Irritability, does not talk to anyone avoids getting angered.(Number of volunteers: 1) [13<sup>+</sup> (day 20, 23 for whole day)]
4. Losing patience, easily [13<sup>++</sup> (day 10, for 1 hour, day 11,12 for 2 days)]
5. Low spirited, feeling [3<sup>++</sup> (day 26 for a day)]
6. Work, aversion to [16<sup>+</sup> (day 13 for a day)] [8]

### Head Number of volunteers: 5) (3<sup>++</sup>, 13<sup>++</sup>, 16<sup>+++</sup>, 19<sup>++</sup>, 22<sup>+++</sup>)

7. Headache, frontal region (Number of volunteers: 3) (3<sup>++</sup>, 16<sup>+++</sup>, 19<sup>++</sup>)
  - a. Headache, frontal region with heaviness <working under computer. (Number of volunteers: 1) [3<sup>++</sup> (day 15, 16 for 1 hour)]
  - b. Headache, frontal feeling of heaviness < 7 - 8 pm, < 2 - 4 pm, < 6 - 7 pm > morning.(Number of volunteers: 1) (16<sup>+++</sup>)
  - c. Severe frontal headache feeling as if I will collapse < 3 - 6 pm > by rest (Number of volunteers: 1) [16<sup>+++</sup> (day 18 for 3 hours)]
  - d. Headache < talking from > closing eyes (Number of volunteers: 1) [19<sup>++</sup> (day 8, for 10 minutes, day 9, 10, 11, 12, 13 for 5 - 10 minutes)]
8. Headache, left temporal region (Number of volunteers: 1) (22<sup>+++</sup>)
  - a. Left, temple, pricking with needle sensation < morning, mental exertion > by sleep (Number of volunteers: 1) [22<sup>+++</sup> (day 15 for 10 - 15 minutes)]
  - b. Headache, left temporal region, as if pressed by some hard object & extend to left side of face < morning 10-11 am, mental exertion after > hard pressure. (Number of volunteers: 1) [22<sup>+++</sup> (day 22, 25 for 4 - 5 minutes, 32 for 10 minutes)]
9. Pulling sensation in vertex region [13<sup>++</sup> (day 42 for 3 - 4 hours)][15]

### Eye: (Number of volunteers: 1) (22<sup>+++</sup>)

10. Right lower eyelid twitching < night [22<sup>+++</sup> (day 1, 2, 17, 33 for 1 - 2 minutes, day 26, 29 for 2 - 3 minutes, day 30 for 4 - 5 minutes)][16]

### Nose (Number of volunteers: 2) (16<sup>+</sup>, 22<sup>+++</sup>)

11. Thin watery discharge from left nostril < open air, < night [22<sup>+++</sup> (day 30 for a day)]
12. Coryza with thick whitish discharge< morning, night, > Vicks (Number of volunteers: 1)[22<sup>+++</sup> (day 31 for a day)]
13. Sneezing, since morning [16<sup>+</sup> (day 18 for 5 - 6 hours)][19]



**Teeth (Number of volunteers: 1) (22<sup>++++</sup>)**

14. Toothache
  - a. Pricking pain, left, lower molar & premolar tooth as if tooth has been broken into pieces. < evening, drinking water (Number of volunteers: 1) [22<sup>++++</sup> (day 22 for 3 to 5 minutes, 28 for 4 -5 minutes, day 31 for 1 hour)]
  - b. **Left sided, lower molar tooth, pain, as if pricking in needles < drinking, eating** [22<sup>++++</sup> (day 33 for a day)][21]

**Mouth (Number of volunteers: 1) (13<sup>++</sup>)**

15. Ulcer over left side of tongue tip, pain, redness< eating chilly food. [13<sup>++</sup> (day 34, 35, 36 for a day)][22]

**Throat (Number of volunteers: 2) (13<sup>+</sup>, 22<sup>+</sup>)**

16. Pain in throat with irritation [13<sup>+</sup> (day 1 for 2 - 3 hours, 29 for 1 hour)]
17. Throat, obstruction < swallowing while [22<sup>+</sup> (day 29 for 1 hour)][24]

**Stomach (Number of volunteers: 1) (22<sup>++</sup>)**

18. Stomach sour eructation < empty stomach [22<sup>++</sup> (day 23 for 1 day)][25]

**Abdomen (Number of volunteers: 2) (3<sup>++</sup>, 22<sup>++++</sup>)**

19. **Spasmodic pain, pricking sensation, in needles in left lumbar and umbilical region < after eating < afternoon 2-3 pm**< evening, lying down [22<sup>++++</sup> (day 35 for 1 hour day 33 for 2 - 3 minutes)]
20. Pain in iliac fossa (Number of volunteers: 1) (3<sup>++</sup>)
  - a. Pain in iliac fossa radiates to back < 6 - 9 pm, motion [3<sup>++</sup> (day 16 for 1 hour, 17, 18, for 3 hours day 25 for 2 hours)]
  - b. Pain in left iliac fossa [3<sup>+</sup> (day 9, 10 for 15 minutes)]
21. Pain in epigastric region fullness feeling < after eating, afternoon (22<sup>+</sup>)
22. Burning sensation in umbilical and left iliac fossa, < after eating [22<sup>+++</sup> (day 1 for 4 - 5 minutes)][30]

**Rectum (Number of volunteers: 2) (19<sup>+++</sup>, 22<sup>+++</sup>)**

23. Burning, twitching in rectum< morning [22<sup>+++</sup> (day 2, 30 for an hour)]
24. Constipation [19<sup>+++</sup> (day 37, 38, 39, 40 for 4 days)] [32]

**Stool (Number of volunteers: 1) (22<sup>++</sup>)**

25. Diarrhea, 4 - 5 times watery slimy stool, mucus of small pieces of undigested food particles like gunshot < morning [22<sup>++</sup> (day 16, 17 for a day)]
26. Stool, clay like [22<sup>++</sup> (day 2 for 1 day)][34]

**Urinary Organs (Number of volunteers: 1) (22<sup>+++</sup>)**

- a. Burning micturition pricking sensation of urethra < night. [22<sup>++</sup> (day 3 for 30 minutes)]
- b. Burning micturition < after passing stool [22<sup>+++</sup> (day 15 for 10 minutes, 16 for 1day)][36]

**Male Sexual Organs (Number of volunteers: 1) (22<sup>+++</sup>)**

27. Twitching sensation in testis < sitting. [22<sup>+++</sup> (day 2, 3, 4 for 4 - 5 minutes)][37]

**Female Sexual Organs (Number of volunteers: 1) (3<sup>++</sup>)**

28. Menses, flow heavier than usual, flow < at noon. [3<sup>++</sup> (day 27, for 2 hours)][38]

**Cough Number of volunteers: 1) (22<sup>++++</sup>)**

29. Violent coughing with profuse expectoration < eating, night [22<sup>++++</sup> (day 32, 33, 34, 35, 36 for 1 hour)]
30. Rattling of mucus in chest without expectoration < morning, night [22<sup>+++</sup> (day 31 for 1 day)][40]

**Back (Number of volunteers: 1) (13<sup>++</sup>)**

31. Back pain sprain < evening, before going to sleep, < 9 pm- 10.30 pm, < lying on back [13<sup>++</sup> (day 24 for a day 25 for 1<sup>1/2</sup> an hour)][41]

**Extremities (Number of volunteers: 2) (22<sup>+++</sup>, 13<sup>++</sup>)**

32. Twitching of left arm and thigh < sitting [22<sup>+++</sup> (day 28 29 for 2 days)]
33. Left hand, tip of elbow joint pain < extension, evening > flexion [22<sup>++</sup> (day 35 for 1 day)]
34. Muscular pain & pulling sensation in upper and lower extremities [13<sup>++</sup> (day 42 for 3 - 4 hours)]
35. Tingling & numbness of left leg < by sitting > by rubbing great toe & rubbing thumb [22<sup>++</sup> (day 35 for 1 day)][45]

**Fever (Number of volunteers: 2) (16<sup>+</sup>, 19<sup>+</sup>)**

36. Chilly feeling all over body > by covering [19<sup>+++</sup> (day 8 for a day, day 10 for 2 hours)]
37. Feverish feeling (Number of volunteers: 2)(16<sup>+</sup>, 19<sup>+</sup>)
  - a. Feeling of heat with intense chilliness < 2 – 3 pm to 7 - 8 pm (Number of volunteers: 1) [16<sup>+</sup> (day 11, 12, 13, 14, 15, 16, for 1 hour in afternoon & 1 hour in evening lasted for 6 days)]
  - b. Feverish feeling > by covering (Number of volunteers: 1) [19<sup>++</sup> (11, 12, 13 for 3 days)][48]

**Sleep (Number of volunteers: 5) (3<sup>++</sup>, 8<sup>+</sup>, 13<sup>++</sup>, 16<sup>++</sup>, 19<sup>++</sup>)**

38. Sleepiness & drowsiness persist for 12 - 12.30 pm after taking the dose of medicine. [3<sup>++</sup> (day 8, 9, 10 for ½ an hour)]
39. Drowsiness (Number of volunteers: 2) (3<sup>++</sup>, 16<sup>++</sup>)
  - a. Drowsiness feeling, unable to sleep, < 4 pm- 1.30 am < 4 - 9 pm < evening (Number of volunteers: 1) [16<sup>++</sup> (day 1, 3 for 5 hours day 4 for 9 hours)]
  - b. Sleepiness, drowsy feeling, un-refreshed feeling [3<sup>++</sup> (day 1, 2, 3 evening hours)]
40. Sleeplessness until 2 am associated with restlessness [16<sup>++</sup> (day 9, 10, 11, 12, 13 for 2 hours)]
41. Disturbed sleep [13<sup>++</sup> (day 17 for 1 hour)]
42. Increased sleep, morning refreshing sleep [8<sup>+</sup> (day 19 for 1 hour, day 20 for ½ an hour)]
43. Uneasy feeling due to lack of sleep [19<sup>++</sup> (day 15, 16, 17, 18 for 4 days)] [55]

**Skin (Number of volunteers: 1) (13<sup>++</sup>)**

44. Wheals with itching on both hands < night [13<sup>++</sup> (day 11 for 1 hour, day 12 for 1 hour)][56]

**Generalities (Number of volunteers: 3) (13<sup>++</sup>, 16<sup>+</sup>, 19<sup>++</sup>)**

45. Restlessness [16<sup>+</sup> (day 9, 10, 11, 12, 13, 14, 16, for whole day)]
46. Weakness (Number of volunteers: 2) (13<sup>++</sup>, 19<sup>++</sup>)
  - a. Weakness < exertion [19<sup>++</sup> (day 9 for a day)]
  - b. Weakness < loss of sleep from > drinking tea [19<sup>++</sup> (day 28, 29, 30, 31, 32, 33 for 6 days)]
  - c. Weakness [13<sup>++</sup> (day 2, 3 for a day)][60]

**Appendix VI. Volunteer randomization details (A-007)**

Sr.No.	Volunteer Screening No.	Volunteer's Initial	Date of Screening	Gender	Date of randomization	Randomization number
1.	AS001	GAJ	21-Jun-11	Female	27-Jun-11	AR001
2.	AS002	PAD	21-Jun-11	Male	23-Jun-11	AR002
3.	AS003	ANP	30-Jun-11	Female	02-Jul-11	AR003
4.	AS004	DNT	30-Jun-11	Male	02-Jul-11	AR004
5.	AS005	ABK	30-Jun-11	Male	02-Jul-11	AR005
6.	AS006	AHK	30-Jun-11	Male	02-Jul-11	AR006
7.	AS007	KND	30-Jun-11	Male	02-Jul-11	AR007
8.	AS008	SBM	30-Jun-11	Male	02-Jul-11	AR008
9.	AS009	RRY	30-Jun-11	Male	02-Jul-11	AR009
10.	AS010	LMK	30-Jun-11	Male	02-Jul-11	AR010
11.	AS011	GSJ	30-Jun-11	Male	06-Jul-11	AR015
12.	AS012	JPN	01-Jul-11	Male	02-Jul-11	AR011
13.	AS013	SSK	01-Jul-11	Male	02-Jul-11	AR012
14.	AS014	PNG	01-Jul-11	Male	02-Jul-11	AR013
15.	AS015	LSK	01-Jul-11	Female	02-Jul-11	AR014
16.	AS016	KSJ	01-Jul-11	Male	07-Jul-11	AR016
17.	AS017	SPK	01-Jul-11	Male	07-Jul-11	AR017
18.	AS019	RGK	26-Jul-11	Male	27-Jul-11	AR018

Sr.No.	Volunteer Screening No.	Volunteer's Initial	Date of Screening	Gender	Date of randomization	Randomization number
19.	AS020	GHG	26-Jul-11	Male	27-Jul-11	AR019
20.	AS021	JVT	03-Aug-11	Male	03-Aug-11	AR020
21.	AS022	KNG	03-Aug-11	Male	03-Aug-11	AR021
22.	AS023	KDK	03-Aug-11	Male	03-Aug-11	AR022

**Appendix VII. Comparative analysis of symptoms in pathogenetic index (PI), placebo, and run-in phase**

No	Organ	IP group (N=15) (Duration=5 weeks)(Chart 1)					Run- in period (N=15) (Duration=1 week)(Chart 3)					Placebo group (N=7) (Duration=6 weeks) (Chart 2)				
		Main symptoms	Sub symptoms	Total number of symptoms	Volunteers	Volunteers with intensity	Main symptoms	Sub symptoms	Total number of symptoms	Volunteers	Volunteers with intensity	Main symptoms	Sub symptoms	Total number	Volunteers	Volunteers with intensity
1	Mind	11	9	18	6	1+, 2+, 4+, 10+, 14+, 21+++	0	0	0	0	0	6	4	8	4	3+, 13+, 16+, 19+++
2	Dreams	6	0	6	3	1+, 10+, 21++++	0	0	0	0	0	0	0	0	0	0
3	Head	6	5	9	7	1+, 5+, 6+, 7+, 9+, 10+, 18++	5	7	10	9	1+, 4+, 7+, 9+, 10+, 12+, 14+, 18+, 21+++	3	6	7	5	3+, 13+, 16+, 19+, 22+++
4	Eyes	5	0	5	2	5+, 21++++	1	0	1	1	21++	1	0	1	1	22+++
5	Nose	4	4	7	5	6+, 9+, 12+, 18+, 21+++	2	0	2	1	17+	3	0	3	2	16+, 22++
6	Throat	4	4	6	2	2+, 21++++	1	0	1	1	20+++	2	0	2	2	13+, 22+
7	Mouth	3	3	5	3	14+, 18+, 21+++	0	0	0	0	0	1	0	1	1	13++
8	Teeth	0	0	0	0	0	1	0	1	1	21+++	1	2	2	1	22+++
9	Larynx, cough, exp.	1	0	1	1	4++	1	0	1	1	14++	2	0	2	1	22+++
10	Chest	0	0	0	0	0	1	0	1	1	21+++	0	0	0	0	0
11	Stomach	6	2	7	5	1+, 5+, 10+, 12+, 21+++	0	0	0	0	0	1	0	1	1	22++
12	Abdomen	2	5	6	3	1+, 14+, 21++++	0	0	0	0	0	4	2	5	2	3+, 22+++
13	Rectum	3	0	3	3	2+, 6+, 21++	2	0	2	1	21++	2	0	2	2	19+, 22+++
14	Stool	2	2	3	3	14+, 21++++	1	0	1	1	21++	2	0	2	1	22++
15	Urinary Organs	3	0	3	2	5+, 21+++	0	0	0	0	0	1	2	2	1	22++
16	Male sexual organs	1	0	1	1	17+	0	0	0	0	0	1	0	1	1	22+++
17	Female sexual organs	0	0	0	0	0	0	0	0	0	0	1	0	1	1	3++
18	Neck	4	0	4	4	1+, 10+, 17+, 21+++	1	0	1	1	20++	0	0	0	0	0
19	Back	3	4	6	4	1+, 14+, 18+, 21+++	2	0	2	1	21++++	1	0	1	1	13++
20	Extremitie	3	8	8	4	1+, 2+,	3	0	3	2	7+,	4	0	4	2	22+++

	s					14 <sup>++</sup> , 21 <sup>++++</sup>					21 <sup>+++</sup>					13 <sup>++</sup>
21	Sleep	5	5	8	4	1 <sup>+</sup> , 6 <sup>+</sup> , 14 <sup>++</sup> , 21 <sup>+++</sup>	1	0	1	1	9 <sup>++++</sup>	6	2	7	5	3 <sup>++</sup> , 8 <sup>+</sup> , 13 <sup>++</sup> , 16 <sup>++</sup> , 19 <sup>++</sup>
22	Fever	2	4	4	3	1 <sup>+</sup> , 5 <sup>+++</sup> , 21 <sup>+</sup>	1	0	1	1	21 <sup>+</sup>	2	2	3	2	16 <sup>+</sup> , 19 <sup>+</sup>
23	Skin	3	4	5	3	1 <sup>++</sup> , 14 <sup>++</sup> , 21 <sup>+++</sup>	1			1	21 <sup>+++</sup>	1	0	1	1	13 <sup>++</sup>
24	Generalities	6	11	14	6	1 <sup>+</sup> , 2 <sup>++</sup> , 5 <sup>++</sup> , 10 <sup>++</sup> , 12 <sup>++++</sup> , 21 <sup>+++</sup>	2	0	2	2	14 <sup>+++</sup> , 21 <sup>++++</sup>	2	3	4	3	13 <sup>++</sup> , 16 <sup>+</sup> , 19 <sup>++</sup>
25	Perspiration	1	0	1	1	7 <sup>+</sup>	0	0	0	0	0	0	0	0	0	0
<b>Total symptoms</b>		<b>84</b>	<b>70</b>	<b>130</b>	<b>13</b>		<b>26</b>	<b>7</b>	<b>30</b>	<b>13</b>		<b>47</b>	<b>23</b>	<b>60</b>	<b>6</b>	
(PE) Incidence of Pathogenetic Effect (per volunteer)		10					2.307					10				
(Quantitative PI) Quantitative Pathogenetic Index (per volunteer, per day)		(Quantitative PI = PE / Number of days) = 10 / 35 (days) = 0.285					2.307 / 7 (days) = 0.329					10 / 42 (days) = 0.238				

**Appendix VIII.** Qualitative study of symptoms in pathogenetic index (PI), run-in, and placebo groups

Location	Group I (IP)						Group II (RUN-IN)						Group III (PLACEBO)				Total
	+	++	+++	++++	Total		+	++	+++	++++	Total		+	++	+++	++++	
Mind	6	10	2	0	18		0	0	0	0	0		3	3	2	0	8
Dreams	4	1	0	1	6		0	0	0	0	0		0	0	0	0	0
Head	3	2	4	0	9		5	2	3	0	10		0	3	4	0	7
Eyes	1	0	0	4	5		0	1	0	0	1		0	0	1	0	1
Ears	0	0	0	0	0		0	0	0	0	0		0	0	0	0	0
Nose	5	1	0	2	8		2	0	0	0	2		1	0	2	0	3
Face	0	0	0	0	0		0	0	0	0	0		0	0	0	0	0
Mouth	0	3	0	2	5		0	0	0	0	0		0	1	0	0	1
Teeth	0	0	0	0	0		0	0	1	0	1		0	0	1	1	2
Throat	1	2	1	2	6		0	1	0	0	1		2	0	0	0	2
Stomach	1	4	2	1	8		0	0	0	0	0		0	1	0	0	1
Abdomen	5	0	0	1	6		0	0	0	0	0		2	1	1	1	5
Rectum & stool	2	2	0	2	6		0	3	0	0	3		0	2	2	0	4
Female sexual organs	0	0	0	0	0		0	0	0	0	0		0	1	0	0	1
Male sexual organs	1	0	0	0	1		0	0	0	0	0		0	0	1	0	1
Urinary organ	1	1	1	0	3		0	0	0	0	0		0	1	1	0	2
Neck	1	1	2	0	4		0	1	0	0	1		0	0	0	0	0
Back	1	2	3	0	6		0	0	0	2	2		0	1	0	0	1
Extremities	2	4	1	1	8		2	0	1	0	3		0	3	1	0	4
Sleep	4	2	2	0	8		0	0	0	1	1		1	6	0	0	7
Fever	3	0	1	0	4		1	0	0	0	1		1	1	1	0	3
Perspiration	1	0	0	0	1		0	0	0	0	0		0	0	0	0	0
Skin	1	2	2	0	5		0	0	1	0	1		0	1	0	0	1
Generalities	5	5	2	2	14		0	0	1	1	2		1	3	0	0	4
Larynx, cough, exp. (L,C,E)	0	1	0	0	1		0	1	0	0	1		0	0	1	1	2
Chest	0	0	0	0	0		0	0	1	0	1		0	0	0	0	0
Total	48	43	23	18	132		10	9	8	4	31		11	28	18	3	60
No. of volunteers	10	10	5	3	13		7	5	2	2	13		5	5	4	1	6
Qualitative Pathogenetic Index = No of symptoms (particular intensity) /No of volunteers/no of days	0.137	0.123	0.131	0.171	0.1405 (Average)		0.204	0.257	0.571	0.286	0.3295 (Average)		0.052	0.133	0.107	0.071	0.0907 (Average)

**Appendix IX.** Qualitative symptoms study (intensity)

Total Symptom in Group I (IP) (13 volunteers, 35 days)				Total Symptom in Group II (Run-in)(13 volunteers, 7 days)				Total Symptom in Group III (Placebo)(6 volunteers, 42 days)			
+	++	+++	++++	+	++	+++	++++	+	++	+++	++++
48	43	23	18	10	9	8	4	11	28	18	3