

## Supplementary Material

### **Standardized extract of *Valeriana officinalis* improves overall sleep quality in human subjects with sleep complaints: a randomized, double-blind, placebo-controlled, clinical study**

Harshith Chandra Shekhar<sup>1</sup>, Lincy Joshua<sup>2</sup>, Jestin V Thomas<sup>2,\*</sup>

<sup>1</sup>BGS Global Institute of Medical Sciences, No.67, BGS Health and Education City, Uttarahalli Road, Kengeri, Bengaluru 560060, Karnataka, India

<sup>2</sup>Leads Clinical Research and Bio Services Pvt. Ltd. No.9, 1st Floor Mythri Legacy, Kalyan Nagar, Chelekere Main Road, Bengaluru 560043, Karnataka, India

Corresponding Author: Jestin V Thomas, Leads Clinical Research and Bio Services Pvt. Ltd. No.9, 1st Floor Mythri Legacy, Kalyan Nagar, Chelekere Main Road, Bengaluru 560043, Karnataka, India. Email: [jestin@leadsbio.com](mailto:jestin@leadsbio.com)

Supplementary Table 1 – Mean and mean change from baseline data for PSQI, Sleep latency, Actual sleep time, Sleep efficiency, Beck Anxiety Inventory, Feeling of waking up refreshed using VAS, and Epworth Sleepiness Scale

Test Name	Visit	Placebo (N=35)			VE (N=37)			P-value by independent t-test
		Mean (SE)	Change from Baseline (SE)	P-value by paired t-test	Mean (SE)	Change from Baseline (SE)	P-value by paired t-test	Change from Baseline values Placebo vs. VE
Pittsburgh Sleep Quality Index (PSQI)	Baseline	11.43 (0.22)	-	-	11.89 (0.20)	-	-	-
	Day 14	11.11 (0.20)	-0.31 (0.22)	0.1691	10.59 (0.20)	-1.30 (0.24)	0.0000*	0.0041*
	Day 28	11.43 (0.21)	0.00 (0.27)	1.0000	10.27 (0.19)	-1.62 (0.20)	0.0000*	0.0000*
	Day 56	11.34 (0.19)	-0.09 (0.28)	0.7607	9.84 (0.18)	-2.05 (0.23)	0.0000*	0.0000*
Sleep Latency by Wrist Actigraphy	Baseline	74.26 (5.24)	-	-	89.39 (8.20)	-	-	-
	Day 3	122.34 (9.12)	48.08 (10.27)	0.0000*	73.88 (7.76)	-15.51 (6.79)	0.0283*	0.0000*
	Day 14	81.51 (8.29)	7.25 (9.27)	0.4393	52.72 (8.39)	-36.67 (12.40)	0.0054*	0.0060*
	Day 28	63.90 (9.39)	-10.37 (10.33)	0.3229	46.96 (6.80)	-42.43 (10.48)	0.0003*	0.0328*
	Day 56	62.53 (8.70)	-11.73 (9.31)	0.2164	41.36 (6.38)	-48.03 (9.23)	0.0000*	0.0072*
Actual Sleep Time by Wrist Actigraphy	Baseline	339.80 (6.40)	-	-	306.09 (7.61)	-	-	-
	Day 3	303.21 (7.71)	-36.59 (9.14)	0.0003*	325.89 (8.19)	19.80 (7.37)	0.0108*	0.0000*
	Day 14	329.46 (8.09)	-10.35 (9.31)	0.2744	344.86 (10.08)	38.76 (10.31)	0.0006*	0.0007*
	Day 28	341.46 (8.37)	1.65 (9.61)	0.8645	346.39 (11.10)	40.30 (8.89)	0.0001*	0.0043*
	Day 56	342.13 (9.16)	2.33 (9.84)	0.8144	362.41 (8.22)	56.31 (9.89)	0.0000*	0.0002*
Sleep Efficiency by Wrist Actigraphy	Baseline	72.87 (1.15)	-	-	66.40 (1.67)	-	-	-
	Day 3	63.05 (1.53)	-9.82 (1.80)	0.0000*	69.07 (1.74)	2.66 (1.52)	0.0885#	0.0000*
	Day 14	71.40 (1.78)	-1.46 (1.90)	0.4472	74.21 (1.98)	7.81 (2.17)	0.0010*	0.0020*
	Day 28	73.10 (1.81)	0.23 (1.95)	0.9065	74.00 (2.23)	7.60 (1.82)	0.0002*	0.0073*
	Day 56	73.47 (1.76)	0.61 (1.80)	0.7388	77.73 (1.59)	11.33 (1.85)	0.0000*	0.0001*
Beck Anxiety Inventory	Baseline	11.57 (0.24)	-	-	11.30 (0.22)	-	-	-
	Day 3	11.51 (0.22)	-0.06 (0.07)	0.4221	11.11 (0.20)	-0.19 (0.09)	0.0328*	0.2362
	Day 14	11.46 (0.23)	-0.11 (0.09)	0.2105	10.70 (0.18)	-0.59 (0.13)	0.0001*	0.0036*
	Day 28	11.69 (0.24)	0.11 (0.13)	0.3788	10.38 (0.19)	-0.92 (0.17)	0.0000*	0.0000*
	Day 56	11.60 (0.27)	0.03 (0.14)	0.8448	10.22 (0.20)	-1.08 (0.20)	0.0000*	0.0000*
Feeling of waking up refreshed using VAS	Baseline	7.29 (0.13)	-	-	6.98 (0.15)	-	-	-
	Day 3	7.26 (0.15)	-0.03 (0.11)	0.7749	6.78 (0.14)	-0.20 (0.08)	0.0112*	0.2172
	Day 14	7.16 (0.15)	-0.14 (0.14)	0.3530	6.50 (0.13)	-0.48 (0.11)	0.0001*	0.0646#
	Day 28	7.11 (0.15)	-0.18 (0.13)	0.1733	6.26 (0.11)	-0.72 (0.13)	0.0000*	0.0047*
	Day 56	7.02 (0.15)	-0.27 (0.14)	0.0657#	5.94 (0.07)	-1.04 (0.16)	0.0000*	0.0007*
Epworth Sleepiness Scale	Baseline	8.74 (0.32)	-	-	8.65 (0.25)	-	-	-
	Day 3	8.80 (0.31)	0.06 (0.06)	0.3244	8.57 (0.25)	-0.08 (0.05)	0.0831#	0.0628#

Day 14	8.69 (0.33)	-0.06 (0.09)	0.5349	8.30 (0.24)	-0.35 (0.12)	0.0050*	0.0522#
Day 28	8.77 (0.30)	0.03 (0.12)	0.8124	8.08 (0.21)	-0.57 (0.14)	0.0002*	0.0016*
Day 56	8.71 (0.32)	-0.03 (0.13)	0.8223	7.89 (0.19)	-0.76 (0.16)	0.0000*	0.0007*

\*p<0.05 VE over placebo; # p<0.1 & p>0.05 VE over placebo

N - Number of subjects in the specified treatment; n - number of subjects in the specified category; SE – Standard Error