CLAIMS

What is claimed is:

1. A method of evaluating the quality and potential *in vivo* activity of a test batch of an herbal composition, the method comprising subjecting the test batch of the herbal composition to one or more biological analysis methods selected from:

(a) a signaling transduction activity response assay; and

(b) a gene expression assay;

and then comparing the test batch results of the biological analysis method with results derived from a known batch of an herbal composition which has a known level of *in vivo* activity;

wherein a measurement of the difference between the test batch results and the known batch results provides an evaluation of the quality and potential *in vivo* activity of the test batch herbal composition.

2. The method of claim 1, wherein the herbal composition comprises one or more compositions selected from the group consisting of herbal extracts of *Scutellaria baicalensis* (S), *Glycyrrhiza uralensis* (G), *Paeonia lactiflora* (P), and *Ziziphus jujuba* (Z), any fractions thereof and any active chemicals present in the herbal extracts or fractions thereof.

3. The method of claim 2, wherein the herbal composition is PHY906, wherein PHY906 comprises herbal extracts of *Scutellaria baicalensis* (S), *Glycyrrhiza uralensis* (G), *Paeonia lactiflora* (P), and *Ziziphus jujuba* (Z) in a 3 : 2 : 2 : 2 (S : G : P : Z) ratio.

4. The method of claim 1, wherein the signal transduction activity response assay comprises one or more assays selected from the group consisting of luciferase reporter assays and enzymatic assays.

5. The method of claim 1, wherein the signal transduction activity response assay comprises measurement of signal transduction activity response against one or more

enzymes selected from inflammation enzymes, cell growth and differentiation enzymes and endocrine and hormone enzymes.

6. The method of claim 5, wherein the one or more enzymes are selected from the group consisting of TNFa-NFkB, TLR2-NFkB, TLR4-NFkB, IL6-stat3, IFNg-stat1/1, INFa-state1/2, DEX-GR, COX-2, iNOS, NRF2, TGFb-Smad2/3, TPA-AP1, CREB, wnt3a-Lef/b-cat, VD3-VDR, ER-alpha, ER-beta, DHT-AR and aldosterone-MR.

7. The method of claim 1, wherein the gene expression assay comprises: treating HepG2 cells with the herbal composition for 24 h, extracting the mRNA produced and quantifying the mRNA through qRT-PCR analysis.

8. The method of claim 1, wherein the gene expression assay comprises measurement of one or more genes encoding proteins having a function selected from inflammation, anti-oxidation, growth and differentiation, metabolism, and cell-cell interaction.

9. The method of claim 8, wherein the one or more genes are selected from the group consisting of ICAM, IRF5, AKR1C1, HO1, GCLC, GCLM, Axin2, GDF15, IGFBP3, OKL38, PIM1, SERTAD, SOS1, BHMT2, CPT1A, SLC7A11, CD24, EMP2 and KRT23.

10. The method of claim 1, wherein the one or more biological analysis methods differentiate between active batches of the herbal composition and inactive batches of the herbal composition better than chemical composition analysis methods.

11. The method of claim 10, wherein the chemical composition analysis methods include LC-MS (liquid chromatography – mass spectrometry).

12. The method of claim 1, wherein if the test batch results are between about 90% and about 110% of the known batch results then the test batch is determined to have sufficiently similar quality as the known batch and potential *in vivo* activity.

13. The method of claim 1, wherein the quality of the test batch of the herbal composition is further analyzed by LC-MS.

14. A method of evaluating the quality and potential *in vivo* efficacy of a test batch of PHY906 by subjecting the herbal composition to one or more biological analysis methods selected from:

(a) a signaling transduction activity response assay; and

(b) a gene expression assay;

comparing the results of the biological analysis method with results derived from a known batch of PHY906 which has a known level of *in vivo* activity;

wherein a measurement of the difference between the test batch results and the known batch results provides an evaluation of the quality and potential *in vivo* activity of the test batch herbal composition.

15. Use of a test batch of PHY906 which shows similar activity in one or more biological analysis methods compared to a known batch of PHY906 which has a known level of *in vivo* activity, in the manufacture of a medicament for the treatment of cancer, wherein the one or more biological analysis methods are selected from:

(a) a signaling transduction activity response assay; and

(b) a gene expression assay.