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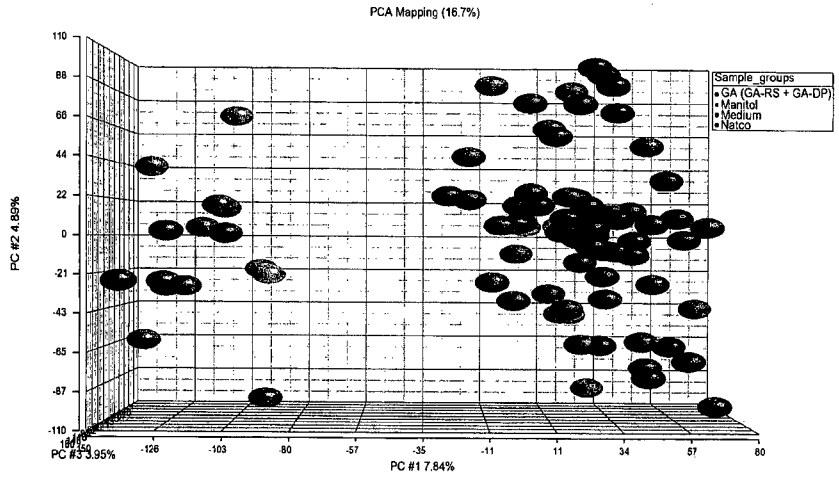


FIGURE 1

(57) Abstract: The present invention provides a process for characterizing a glatiramer acetate related drug substance or drug product comprising the steps of: a) obtaining a batch of the glatiramer acetate related drug substance or drug product; b) immunizing a mammal with a predetermined amount of a glatiramer acetate related drug substance or drug product; c) preparing a culture of cells from the mammal of step b) at a predetermined time after immunization; d) incubating cells from the culture of step c) with a predetermined amount of the glatiramer acetate drug related substance or drug product of step a); and e) determining the level of expression of at least one gene disclosed herein or determining the level of biological activity of the cells of step c) as disclosed herein, thereby characterizing the glatiramer acetate related drug substance or drug product of step a).

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