BIOGENOMICS
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COMPARATIVE BIOASSAY OF BIPHASIC INSULIN ASPART MIX 30 OF BIOGENOMICS WITH NOVOMIX® 30 OF NOVO NORDISK

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BACKGROUND:

Insulin is a life saving medicine which regulates blood glucose metabolism. It exerts its key physiological effects such as glucose uptake, glycogenesis & lipogenesis by binding to insulin receptors present on adipocytes & hepatocytes (Fig 1.). Biphasic Insulin aspart mix 30 (IAM) is a suspension of 30% soluble aspart and 70% protaminated aspart.

OBJECTIVE:

To establish the biosimilarity of biphasic Insulin Aspart Mix 30 from BioGenomics Ltd (BGL-IAM) to its innovator, NovoMix® 30 from Novo Nordisk by relevant *in-vitro* bioassays.

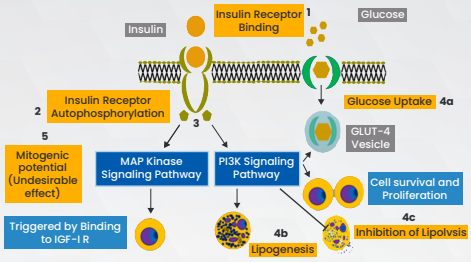
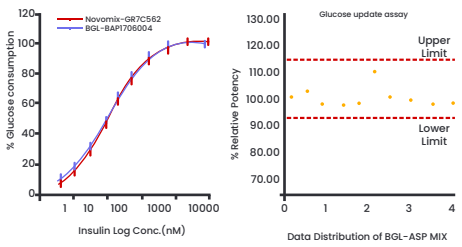


Fig. 1 Mechanism of Insulin action at cellular level

1. Insulin binds to the insulin receptor present on target cells such as adipocytes & skeletal muscle cells.
2. Binding of insulin to its receptor leads to autophosphorylation of the receptor.
3. Insulin receptor autophosphorylation activates Phosphoinositide 3 kinase (PI3K) & Mitogen Activated Protein Kinase (MAPK) pathway.
4. Activation of PI3K pathway leads to glucose uptake, lipogenesis & inhibition of lipolysis in the target cells.
5. Activation of MAPK pathway leads to cell survival & proliferation, often mediated by off-target (IGF-1R)

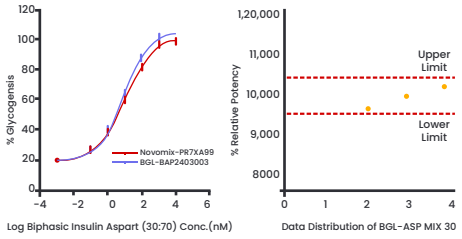
METHODS:

The bioassays were done to establish the biosimilarity of BGL-IAM to its innovator by *In-vitro* assays like receptor autophosphorylation, glucose uptake, glycogenesis, lipogenesis & mitogenic potential. The relative potency of BGL-IAM was determined based on insulin receptor autophosphorylation, cellular uptake of glucose, glycogen formation & lipid droplet accumulation in hepatocytes & adipocytes respectively. The mitogenic potential of BGL-IAM was determined by a cell proliferation assay with MCF-7 cells.



- The mean percentage relative potencies of RMP and BGL-IAM were 101.04 and 102.47, respectively.
- The sigmoidal overlay plot along with the graphical representation shows the apparent similarity between the potencies of BGL-IAM with RMP

Fig. 3 Sigmoidal overlay plot of BGL-IAM & RMP with graphical representation of relative potencies of BGL-IAM from Glucose uptake assay.



- The mean percentage relative potencies of RMP and BGL-IAM were 100.67 and 99.60, respectively.
- The sigmoidal overlay plot along with the graphical representation shows the apparent similarity between the potencies of BGL-IAM with RMP

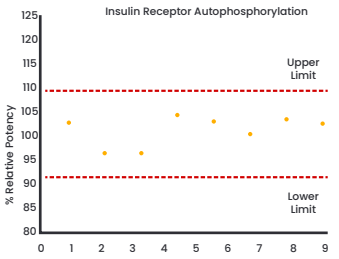
Fig. 4 Sigmoidal overlay plot of BGL-IAM & RMP with graphical representation of relative potencies of BGL-IAM from Glycogenesis assay.

RESULTS:

The *in-vitro* bioassays were done with BGL-IAM & NovoMix® 30 (RMP) for assessing the biosimilarity based on relative potencies. The relative potencies of BGL-IAM determined from *in-vitro* bioassays were within upper & lower biosimilarity limits set at 90% confidence interval & thereby demonstrated high similarity & comparability to RMP (figs. 2 to 5). The mitogenicity assay with BGL-IAM did not show any proliferative effect and was comparable to RMP (fig. 6). The *in-vitro* biological characterization data of BGL-IAM and NovoMix® 30 were found to be highly similar & comparable to each other

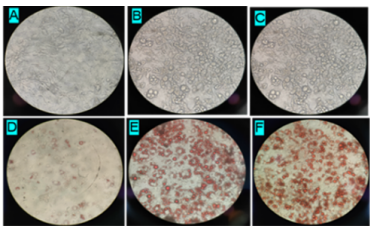
CONCLUSION:

The biological characterization studies conducted with BGL-IAM demonstrated high similarity & comparability to its innovator product, NovoMix®30.



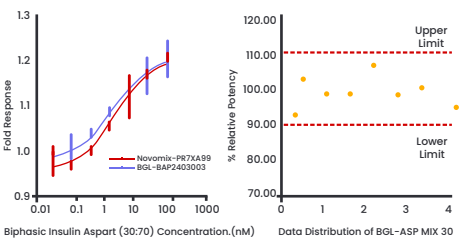
- The mean percentage relative potencies of RMP and BGL-IAM were 100.15 and 99.85, respectively.
- The graphical representation shows that the relative potencies of BGL-IAM batches lies within the upper & lower limit set with RMP

Fig. 2 Graphical representation of relative potencies of BGL-IAM from Insulin receptor autophosphorylation assay.



- The mean percentage relative potencies of RMP and BGL-IAM were 100.56 and 100.57, respectively.
- The microscopic images of lipid droplet formation & the graphical representation shows that the potencies of BGL-IAM & RMP are highly similar & comparable for lipogenesis.

Fig. 5 Microscopic images of BGL-IAM & RMP treated adipocytes with Oil Red O-stained lipid droplets & graphical representation with relative potencies of BGL-IAM from Lipogenesis assay.



- The sigmoidal overlay of BGL-IAM & RMP is highly similar with no proliferative activity.
- The graphical representation shows the potencies of BGL -IAM well within the biosimilarity limits set with RMP.

Fig. 6 Sigmoidal overlay plot of BGL-IAM & RMP with graphical representation showing relative potencies of BGL-IAM from Mitogenicity assay.

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