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Govind et al.

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(54) **COMPOSITION FOR INHALATION**
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A01N 45/00 (2006.01)
A61K 31/335 (2006.01)
(52) **U.S. Cl.** **514/167; 514/463**
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424/46, 489, 48
See application file for complete search history.

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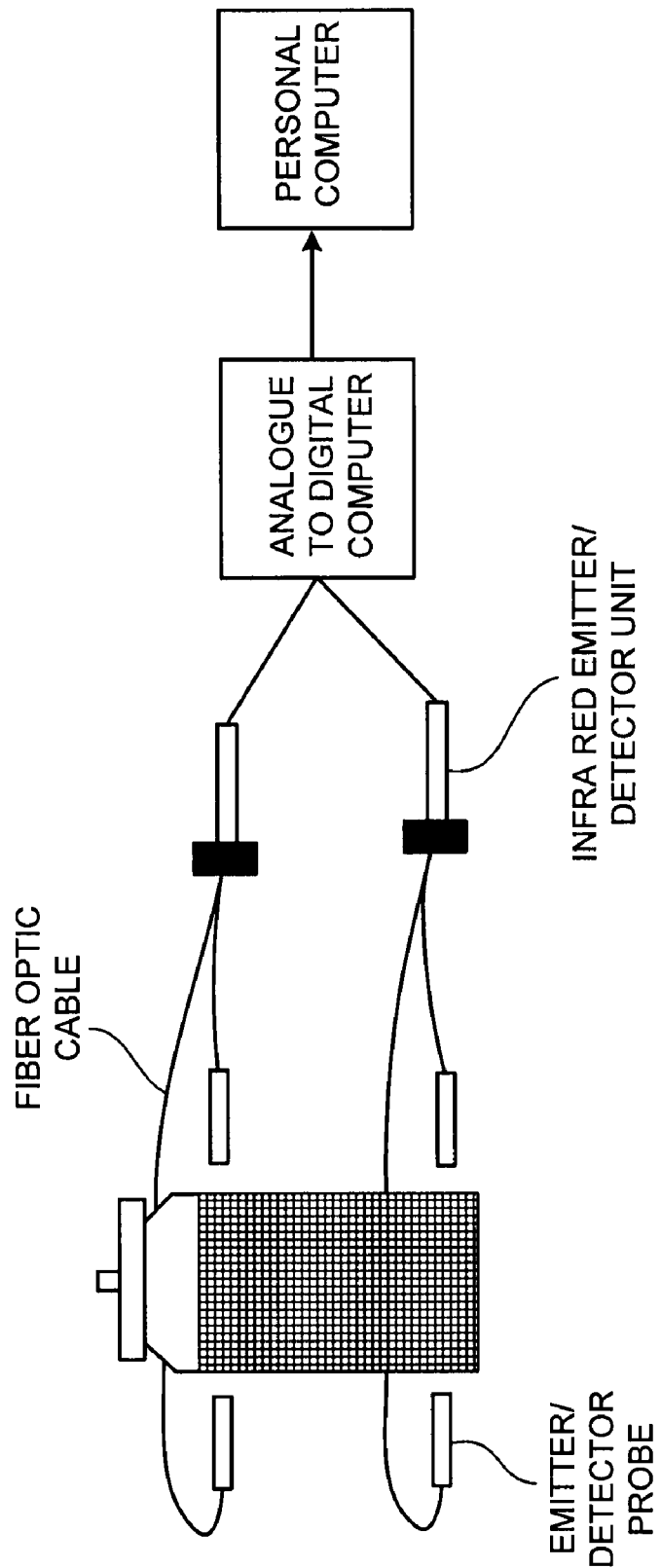
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(57) **ABSTRACT**

The invention relates to a formulation comprising formoterol and budesonide for use in the treatment of respiratory diseases. The composition further contains HFA 227, PVP and PEG, preferably PVP K25 and PEG 1000.

15 Claims, 16 Drawing Sheets



SCHEMATIC FOR OSCAR SET-UP

FIG. 1

Averages of OSCAR data (lower sensor) for formulation containing 160/4.5ug Budesonide/Formoterol.
0.3% w/w PEG 1000. 0.0001% - 0.05% w/w PVP K25.

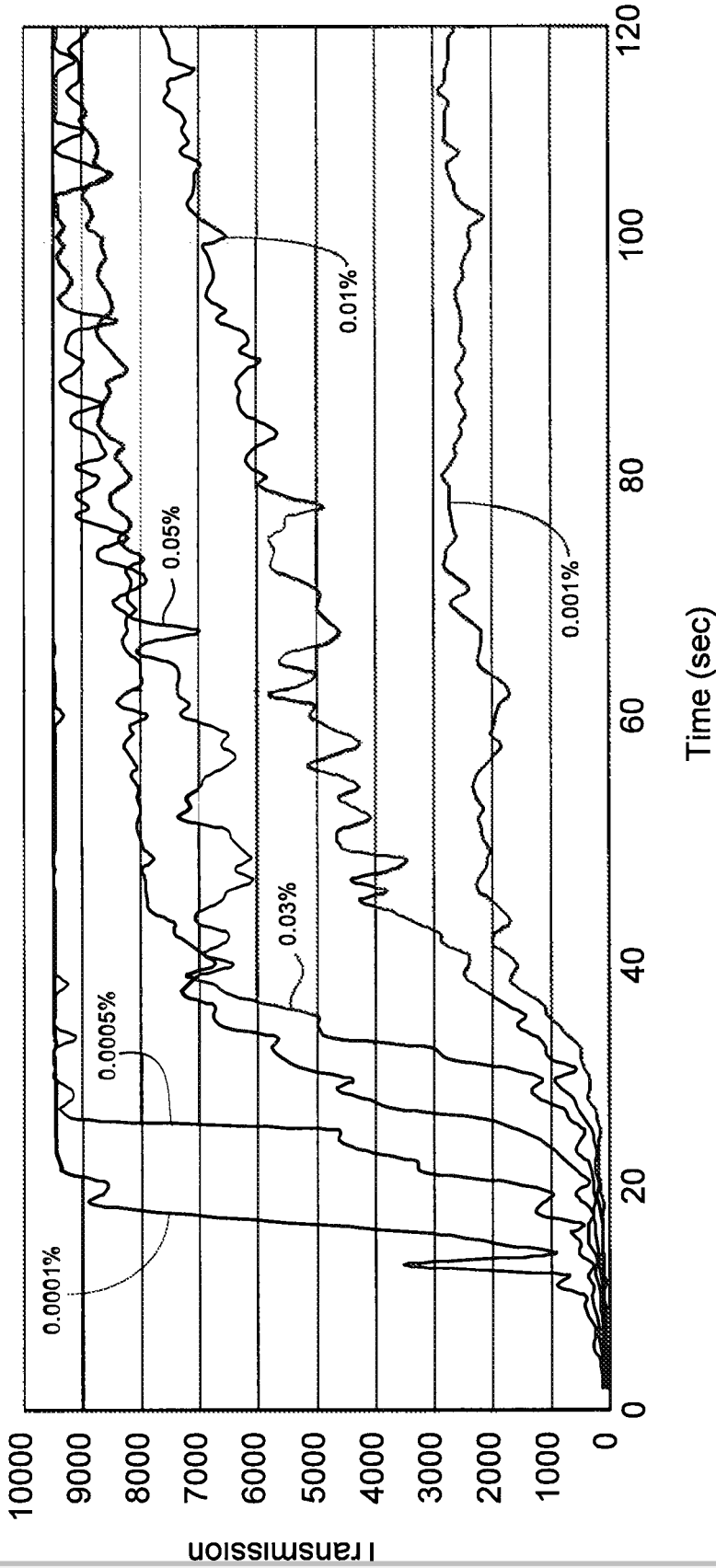


FIG. 2

Averages of OSCAR data (lower sensor) for formulation containing 80/4.5ug Budesonide/Formoterol. 0.3% w/w PEG 1000. 0.0001% - 0.05% w/w PVP K25, in HFA 227.

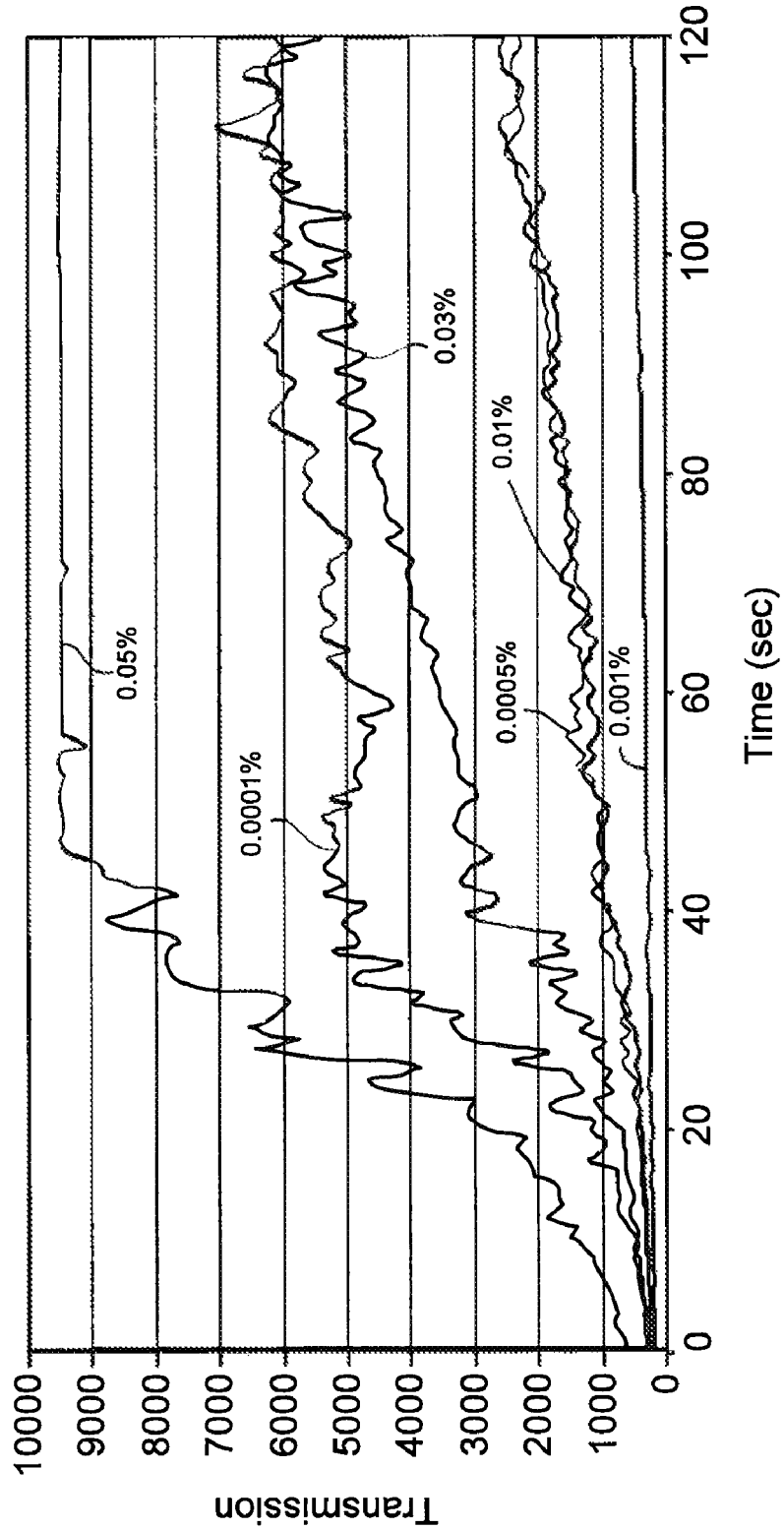
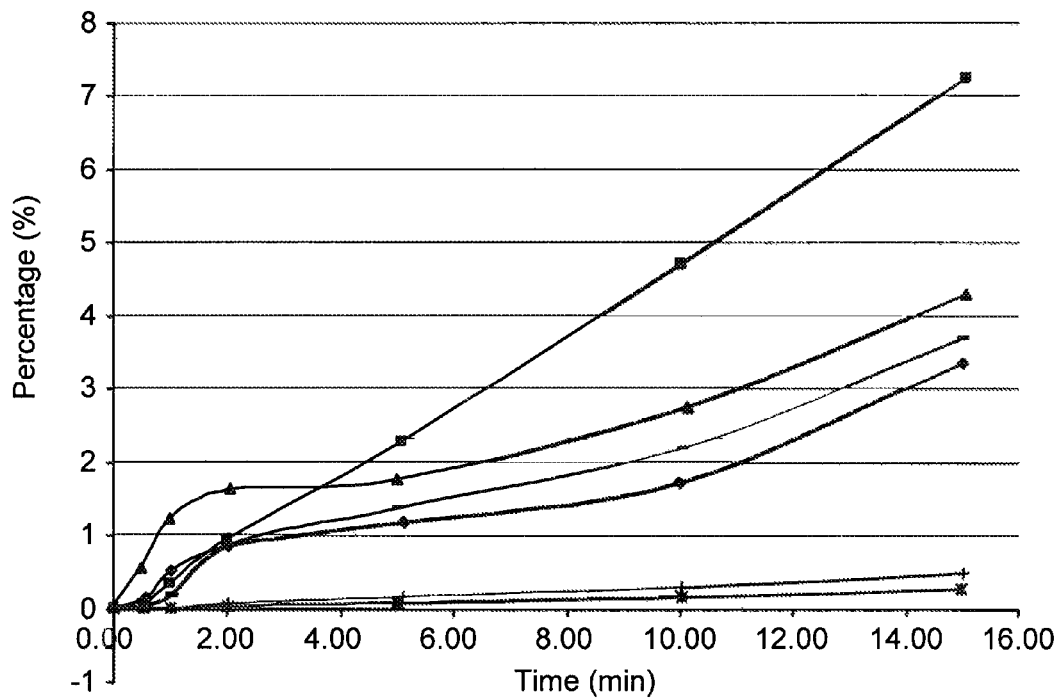


FIG. 3

Averages of Turbiscan data for formulation containing 160/4.5ug
Budesonide/Formoterol. 0.3% w/w PEG 1000.
0.0001% - 0.05% w/w PVP K25, in HFA 227.



- ◆ 160/4.5ug. 0.0001%. (Trans)
- + 160/4.5ug. 0.01% (Trans)
- ▲ 160/4.5ug. 0.0005%. (Trans)"
- 160/4.5ug. 0.03% (Trans)
- * 160/4.5ug. 0.001% (Trans)
- 160/4.5ug. 0.05% (Trans)

FIG. 4

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