

The results of replicate experiments are as follows:

Uniformity Test results	Replicate 1	Replicate 2
Product stored for 5 months at $\leq 30^\circ \text{C}.$:		
Range of 12 fractions (% label claim)	95-105	98-102
RSD	3.3%	1.8%
Product stored for 4 months at $40^\circ \text{C}.$:		
Range of 12 fractions (% label claim)	99-102	98-102
RSD	1.1%	2.0%

The results indicate that content uniformity is maintained in a test simulating actual use, i.e. shaking only on the first dose, and then no shaking until the content of the bottle is consumed.

EXPERIMENT 10

A commercial rifampicin suspension in the Philippines, Rifamax (Glaxo), containing 200 mg of active per 5 ml was tested. The particle density of rifampicin was determined from a commercially available raw material (Gujarat, India). The liquid density was determined by measuring the density of the liquid phase after centrifugation at $1000 \times g$'s for 2 h to remove the suspended particles (microscopic examination of the liquid phase after centrifugation indicated complete removal of suspended particles). Approximate particle size distribution was determined by microscopy.

The critical parameters of this suspension are:

Particle density @ $25^\circ \text{C}.$, ρ_p	1.2764 g/ml
Liquid density @ $25^\circ \text{C}.$, ρ_L	1.1830 g/ml
Absolute density difference, $ \rho_L - \rho_p $	0.0934 g/ml
<u>Approx. particle size distribution:</u>	
<10 μm	10%
11-40 μm	20%
41-80 μm	30%
81-100 μm	20%
>100 μm	20%
<u>Rheology ($25^\circ \text{C}.$):</u>	
Yield Value, τ	2.3 Pa
Apparent viscosity at 100 sec^{-1}	38 cps

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Centrifugation Test results:	
Range of five fractions (% label claim)	Physical separation
RSD	>200%
Uniformity Test results:	
24 h at Room Temp. $\leq 30^\circ \text{C}.$	Sediments with clear interface

This suspension does not meet the specifications of the present invention, and fails to maintain uniformity 24 hours after shaking.

Accordingly, it is to be understood that the embodiments of the invention herein described are merely illustrative of the application of the principles of the invention. Reference herein to details of the illustrated embodiments is not intended to limit the scope of the claims, which themselves recite those features regarded as essential to the invention.

We claim:

1. An aqueous rifampicin suspension comprising from about 1 to about 5 percent by weight rifampicin with an average particle size less than about 10 μm ; from about 0.1 to about 0.5 percent by weight of xanthan gum; from about 0.01 to about 2 percent by weight of at least one antifoaming agent; from about 0.001 to about 0.5 percent by weight of at least one wetting agent; a liquid phase with an absolute density difference of less than about 0.05 g/ml from the particulate rifampicin; the suspension being further characterized by a relative standard deviation of less than about 6% when tested according to the Centrifugation Test Method.

2. The suspension according to claim 1, wherein the antifoaming agent is present at about 0.02 to about 0.2 percent by weight.

3. The suspension according to claim 1, wherein the wetting agent is present at about 0.005 to about 0.2 percent by weight.

4. The suspension according to claim 1, further comprising one or more additives selected from the group consisting of sweetening agents, flavors, colorants, antioxidants, chelating agents, viscosity-building agents, surfactants, pH modifiers, acidifiers, preservatives, cosolvents, and mixtures thereof.

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