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Stability Indicating HPTLC Method for Determination of Terbutaline Sulfate in Bulk and from Submicronized Dry Powder Inhalers

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A stability-indicating high-performance thin-layer chromatographic (HPTLC) method has been developed for the determination of terbutaline sulfate (TBS) as a bulk drug and in pharmaceutical formulations (submicronized dry powder inhalers). The separation was achieved on TLC aluminum plates precoated with silica gel 60F-254 using chloroform-methanol (9.0:1.0 v/v) as mobile phase. The densitometric analysis was carried out at 366 nm wavelength. Compact spots appeared at R_f = 0.34 ± 0.02. For the proposed procedure, linearity (r^2 = 0.9956 ± 0.0015), limit of quantification (28.35 ng spot^{-1}), limit of detection (9.41 ng spot^{-1}), recovery (97.06 – 99.56%), and precision (≤1.86) were found to be satisfactory. TBS was subjected to acid and alkali hydrolyses, oxidation and photodegradation treatments. The degraded products were well separated from the pure drug. Statistical analysis reveals that the developed method has potential for routine analysis and stability testing of terbutaline sulfate in pharmaceutical drug delivery systems.

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