

Manufacturing Process Flow Albuterol Sulfate, USP (Cat# AL156)

Manufacturing process description of Albuterol Sulfate:

AD is first dissolved in methanol, adjust the pH of reaction mass 8.0-8.5 with acetic acid, catalyst palladium on carbon added to solution and the solution is hydrogenated at a pressure of 1-5 Kg and at a temperature 12-18°C. A sample of the reaction mass is withdrawn and analyzed for completion of reaction by checking for AD content by TLC (Limit: Bellow 0.5%). If the content of AD is more than 0.5%, hydrogenation is continued further and a sample is again checked for AD content. If the reaction is complete, then the reaction mass is filtered through a Sparkler filter, the filter washed with methanol, the filtrate and washing are combined dilute with methanol and treated with activated charcoal, filtered. The pH of the solution is then adjusted to 3.5-4.0 with Sulphuric acid and maintained at this pH for about 30 min and the product formed is centrifuged, washed with methanol. And spin dried.

The wet product is then dried in a vacuum tray dryer at 70 – 75°C for 8 hours. The dried Salbutamol Sulphate is tested for water content (Limit: NMT 0.3%) and Mill the material through 1 mm # mesh completely than shift the material through 20 mm# mesh after shifting the material blend the material. The Blended material is then unloaded and packed in double antistatic polyethylene (Transparent and Black) in a HDPE drum and analyzed as per the finished product specification.

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