



DELTA SYNTHETIC CO., LTD.

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立大化成工業股份有限公司

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June 25, 2018

Declaration: Guaifenesin

1. Delta Guaifenesin is manufactured at the Delta manufacturing plant located at 15 Minsheng St., Tucheng Dist., New Taipei City 23679, Taiwan, R.O.C., in a dedicated facility using dedicated equipment.
2. Delta Guaifenesin is a pure substance which satisfies all USP, Ph. Eur., and JP requirements.
3. EDQM granted a Certificate of Suitability for Delta Guaifenesin since January 26, 2011.
4. Delta Guaifenesin is manufactured from Guaiacol and α -monochlorohydrin. Water is used in the manufacture and purification of Guaifenesin. Therefore, there is no potential for Delta Guaifenesin to contain any Class 1, Class 2, Class 3, or other solvents. No solvents are produced during the manufacture of Guaifenesin.
5. Delta Guaifenesin is not listed in Annex I of the Dangerous Substance Directive (67/548/EEC) or in the current California Proposition 65.
6. Delta Guaifenesin is in compliance with the EMEA/410/01, CHMP/QWP/251344/2006, and CPMP/SWP/5199/02 guidelines. No raw materials are derived from animal or plant sources.
7. Delta Guaifenesin is in compliance with the EMEA/CHMP/SWP/4446/2000 and ICH Q3D guidelines. No metal catalysts or metal reagents are used in the manufacture or purification of Delta Guaifenesin. Therefore, there is no potential for Delta Guaifenesin USP/EP to contain any Class 1, Class 2, Class 3, or other metals. Delta has conducted studies on selected lots of Guaifenesin, and the results show that Delta Guaifenesin meets ICH Q3D requirements.
8. Delta routinely tests selected lots of Guaifenesin, and all test results show that Delta Guaifenesin meets the requirements of USP General Chapter <1111> MICROBIOLOGICAL EXAMINATION OF NONSTERILE PRODUCTS: ACCEPTANCE CRITERIA FOR PHARMACEUTICAL PREPARATIONS AND SUBSTANCES FOR PHARMACEUTICAL USE.
9. Delta manufactured Guaifenesin is monomorphic and only one polymorph exists. In addition, Delta Guaifenesin is a non-hygroscopic substance.
10. Delta Guaifenesin is free from alcohol, aspartame, asbestos, aflatoxins, allergens, calcium, dioxins, irradiation, iron, genetically modified organisms (GMO), gluten, glycerin/diethylene glycol, lactose, latex, magnesium, melamine, pesticides, bis-phenylalanine (BPA), potassium, phthalates, polycyclic aromatic hydrocarbons (PAH), sulfa/sulfonamides/sulfite, and TSE/BSE contamination.
11. Delta does not add any additives, preservatives, antioxidants, colorants, or perfumes to its Guaifenesin.
12. All primary packaging materials of Delta Guaifenesin are in compliance with CPMP/QWP/4359/03 and EMEA/CVMP/205/04 guidelines.
13. Delta Guaifenesin is stable for 5 years and 12 months, respectively, under ICH guideline Q1A for long-term stability conditions (25 ± 2 °C and $60 \pm 5\%$ RH) and accelerated stability conditions (40 ± 2 °C and $75 \pm 5\%$ RH).
14. Delta is committed to notifying customers of any possibility that a non-kosher or non-halal substance could exist in Delta Guaifenesin.
15. Delta is committed to notifying customers of any unsatisfactory animal testing results related to the safety of Delta Guaifenesin.
16. Delta is committed to notifying customers of any changes in the Guaifenesin manufacturing process which could potentially affect API quality according to Annex I of Directive 2001/83/EC; e.g., changes in Delta's manufacturing site, DMF/COS/Methods, etc.
17. Delta uses wooden, plywood/veneer, and corrugated fiberboard pallets for shipment which are compliant with ISPM 15 regulations.

Delta Synthetic Co., Ltd.

Spencer Chu

Director, QA & QC