

Residual Solvent Statement


In the following we state, if according to our knowledge any substance(s) classified as 'Residual Solvent(s)' is/are used in the manufacture and/or purification of:

Product: Lambroxine

- 1 None of the solvents classified 'Residual Solvents' in the Current USP <467> and the ICH Q3C guideline are used. The absence of such solvents as impurities in the above mentioned product is confirmed.
- 2 One or more of the solvents classified as '**Class 1 Residual Solvents**' in the Current USP <467> and the ICH Q3C guideline are used. The compliance of limited values of such solvents as impurities in the above mentioned product in accordance with the Current USP <467> and the ICH Q3C guideline is confirmed.
- 3 One or more of the solvents classified as '**Class 2 Residual Solvents**' in the Current USP <467> and the ICH Q3C guideline are used. The compliance of limited values of such solvents as impurities in the above mentioned product in accordance with the Current USP <467> and the ICH Q3C guideline is confirmed.
- 4 One or more of the solvents classified as '**Class 3 Residual Solvents**' in the Current USP <467> and the ICH Q3C guideline are used. The compliance of limited values of such solvents as impurities in the above mentioned product in accordance with the Current USP <467> and the ICH Q3C guideline is confirmed.
- 5 One or more of the solvents listed under **Table 4** in the Current USP <467> and the ICH Q3C guideline are used.

If 2, 3, 4 or 5 are applicable, please find the details in the table below:

Solvent	Class	USP <467> and the ICH Q3C Specification Limit (ppm)	Please fill this column Amount present in materials (ppm)
n.a	n.a	n.a	n.a



Title: Manager of Compliance and Regulatory Affairs Department

Date: Dec 9, 2023