



MHRA has recently been made aware that some batches of Gentamicin Sulphate Active Pharmaceutical Ingredient (API) used to manufacture the above finished products may contain higher than expected levels of histamine, which is a residual from the manufacturing process” MHRA (2017).

MHRA report “MHRA has recently been made aware that some batches of Gentamicin Sulphate Active Pharmaceutical Ingredient (API) used to manufacture the above finished products may contain higher than expected levels of histamine, which is a residual from the manufacturing process. Batches of API produced between the second half of 2014 and June 2017 are potentially affected. A recall is not considered appropriate at this stage...

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...Healthcare Professionals are advised to be cautious when using the above products. In particular, caution should be taken when using gentamicin concomitantly with drugs known to cause histamine release (for example opioids and muscle relaxants).”

More Information

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