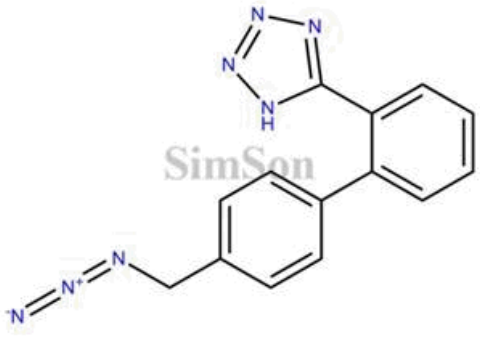
Absence of AZBT

Product group: Lactose, Inhalation, MCC, Starch, Biopharma and Superdisintegrants

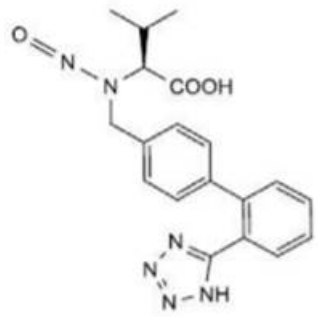
Dear Customer,

Herewith we would like to inform about our approach to AZBT topic.

(5-(4'-(azidomethyl)-[1,1'-biphenyl]-2yl)-1H-tetrazole) has the following structural formula:



It is related to the nitroso-components identified in Angiotensin Receptor Blocking substances (see: https://www.ema.europa.eu/en/documents/variation-report/angiotensin-ii-receptor-antagonists-sartans-article-31-referral-chmp-assessment-report_en.pdf).



The majority of DFE Pharma products are extracted from natural sources without the involvement of any chemistry. In addition no reactive nitrogen containing substances or solvents are used. The formation of (5-(4'-(azidomethyl)-[1,1'-biphenyl]-2yl)-1H-tetrazole) is thus very unlikely. The raw materials in question are lactose monohydrate, lactose (anhydrous), trehalose, sucrose and starches.
In case of microcrystalline cellulose a mild hydrolysis is performed in the process and ammonia is used to neutralize the hydrochloric acid used in the process. As ammonia is very stable also here the formation of (5-(4'-(azidomethyl)-[1,1'-biphenyl]-2yl)-1H-tetrazole) is very unlikely.

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In case of sodium starch glycolate and croscarmellose sodium both cross linking and carboxymethylation of starch/cellulose is done. Also here no nitrogen containing substances are used in the production and the formation of (5-(4'-(azidomethyl)-[1,1'-biphenyl]-2yl)-1H-tetrazole) is very unlikely.

This statement substitutes all previous versions issued for the brand names mentioned above.
We trust this information, which is made up to the best of our knowledge, will be helpful to you.

With kindest regards,

Name : Armand M. Janssen
Job title : QA Regulatory Affairs Officer
Signature :

This document is controlled by a validated, electronic system and is valid without signature.
The above facsimile signature is only for display.

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