

ALLERGEN DECLARATION

PRODUCT NAME:

DILTIAZEM HYDROCHLORIDE, USP

1. The starting material (source) is:

All-natural

Synthetic

Mineral-based:

Animal-based:
Vegetable-based:
Other:

Please note that there may be several steps before the raw material is produced and access to data on manufacturing raw materials is not easily obtained for the starting materials and intermediates used in the production process.

No raw material sourced or derived from animals are used in the manufacturing. Hence, the materials used in the production of have demonstrated compliance with the note for the guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products.

The following items are not used in the manufacturing process of the product, and although manufacturer does not specifically assay for the presence of the items below, it is unlikely that any traces of these items are present in the starting materials or in the end product –

2. The product is unlikely to contain the following -		
Cereals containing gluten (i.e. wheat, rye, barley, oats, spelt, kamut or their hybridised strains) and products thereof		
Crustaceans and products thereof		
🖾 Corn		
Celery and products thereof		
Soybeans and products thereof		
🔀 Yeast		
Fish and products thereof,		
Eggs and products thereof		
Dairy Products(Milk, Lactose, Caseinates, Whey)		
🖾 Sugar		
Sodium/ Salt		
Peanuts and products thereof		
⊠ Tree nuts (oils) or derivatives		
Mustard and products thereof		
🔀 Sesame Oil		
Sunflower Oil		
Sulfites/Bisulfites		
Artificial Colours and Flavours		
Genetically-modified organisms (GMOs)		
Beef/Chicken/Pork derivatives		
Seafood derivatives		

3. The product is made via:

Chemical Synthesis

Chemical Extraction

Other:

n/a

Please be advised that Medisca has not tested for the presence of the above stated allergens. Therefore, this statement is provided for **informational purposes** only, as instructed to Medisca by the manufacturer, and is not meant to be a guarantee of absence of the above stated allergens.

Prepared by: Linda Trang

Title: Jr. QC Document Assistant

Version: 01 Issued Date: 01/22/2019 Supersedes Date: Not applicable

Signature: Linpry