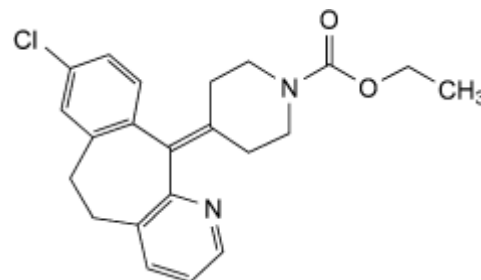


# Product Specification

## PRODUCT Loratadine EP/BP (API)

CAS no. [79794-75-5]

C<sub>22</sub>H<sub>23</sub>ClN<sub>2</sub>O<sub>2</sub>



CHARACTERISTICS White or almost white, crystalline powder.  
Practically insoluble in water, freely soluble in acetone and in methanol.

TEST	SPECIFICATION								
Content	98.5% - 101.5% of (anhydrous substance)								
Identification	Complies with EP/BP tests								
Appearance of solution	The solution is clear and not more intensely coloured than reference solution BY <sub>5</sub>								
Related substances	<table border="0"> <tr> <td>Impurity A,B,C,D,E</td> <td>Maximum 0.1% (each)</td> </tr> <tr> <td>Impurity H</td> <td>Maximum 0.1%</td> </tr> <tr> <td>Unspecified impurities</td> <td>Maximum 0.10% (each)</td> </tr> <tr> <td>Total impurities</td> <td>Maximum 0.5%</td> </tr> </table>	Impurity A,B,C,D,E	Maximum 0.1% (each)	Impurity H	Maximum 0.1%	Unspecified impurities	Maximum 0.10% (each)	Total impurities	Maximum 0.5%
Impurity A,B,C,D,E	Maximum 0.1% (each)								
Impurity H	Maximum 0.1%								
Unspecified impurities	Maximum 0.10% (each)								
Total impurities	Maximum 0.5%								
Sulphates	Maximum 150 ppm								
Loss on drying	Maximum 0.5%								
Sulphated ash	Maximum 0.1%								

STORAGE Should be stored in an airtight container in a cool, dry place and protected from light.

PRODUCT NAMED ABOVE COMPLIES WITH THE SPECIFICATION OF THE EP/BP.



Loratadine EP/BP (API)