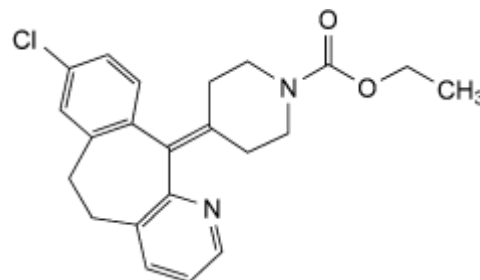


# Product Specification

## 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	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)