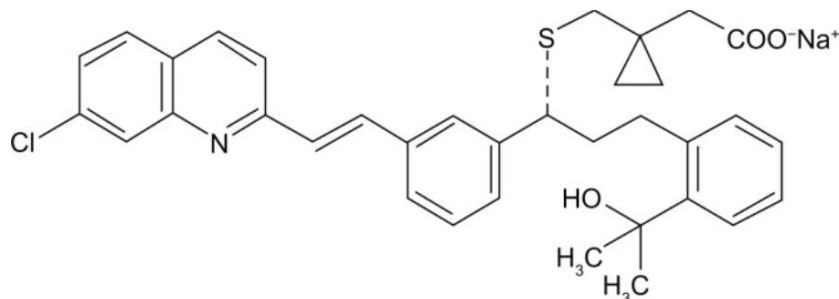


PRODUCT Montelukast Sodium Ph. Eur.

CAS no. 151767-02-1



CHARACTERISTICS White or almost white, hygroscopic powder. Freely soluble in water and in methylene chloride, freely soluble to very soluble in ethanol (96%).

TEST	SPECIFICATION												
Content (Assay)	98.0% to 102.0% (anhydrous basis)												
Identification	Conforms to Ph. Eur. tests												
Enantiomeric purity	Maximum 0.2% of Impurity A*												
Related substances	<table border="0"> <tr> <td>Impurity B*</td> <td>Maximum 0.3%</td> </tr> <tr> <td>Impurity C*</td> <td>Maximum 0.2%</td> </tr> <tr> <td>Impurity F, G*</td> <td>Maximum 0.15% (each)</td> </tr> <tr> <td>Impurity D+E*</td> <td>Maximum 0.15%</td> </tr> <tr> <td>Unspecified impurities</td> <td>Maximum 0.10% (each)</td> </tr> <tr> <td>Total impurities</td> <td>Maximum 0.6%</td> </tr> </table>	Impurity B*	Maximum 0.3%	Impurity C*	Maximum 0.2%	Impurity F, G*	Maximum 0.15% (each)	Impurity D+E*	Maximum 0.15%	Unspecified impurities	Maximum 0.10% (each)	Total impurities	Maximum 0.6%
Impurity B*	Maximum 0.3%												
Impurity C*	Maximum 0.2%												
Impurity F, G*	Maximum 0.15% (each)												
Impurity D+E*	Maximum 0.15%												
Unspecified impurities	Maximum 0.10% (each)												
Total impurities	Maximum 0.6%												
Water	Maximum 4.0%												

Impurity A	[1-[[[(1S)-1-[3-[(E)-2-(7-chloroquinolin-2-yl)ethenyl]-phenyl]-3-[2-(1-hydroxy-1-methylethyl)phenyl]propyl]-sulfanyl]methyl]cyclopropyl]acetic acid
Impurity B	[1-[[[(1R)-1-[3-[(E)-2-(7-chloroquinolin-2-yl)ethenyl]-phenyl]-3-[2-(1-methylethenyl)phenyl]propyl]sulfanyl]-methyl]cyclopropyl]acetic acid
Impurity C	[1-[[[1-[3-[(E)-2-(7-chloroquinolin-2-yl)ethenyl]-phenyl]-3-[2-(1-hydroxy-1-methylethyl)phenyl]propyl]-sulfanyl]methyl]cyclopropyl]acetic acid,
Impurity D	1-[[[(1R)-1-[3-[(1R)-1-[[[1-(carboxymethyl)cyclopropyl]-methyl]sulfanyl]-2-(7-chloroquinolin-2-yl)ethyl]phenyl]-3-[2-(1-hydroxy-1-methylethyl)phenyl]propyl]sulfanyl]-methyl]cyclopropyl]acetic acid,
Impurity E	1-[[[(1R)-1-[3-[(1S)-1-[[[1-(carboxymethyl)cyclopropyl]-methyl]sulfanyl]-2-(7-chloroquinolin-2-yl)ethyl]phenyl]-3-[2-(1-hydroxy-1-methylethyl)phenyl]propyl]sulfanyl]-methyl]cyclopropyl]acetic acid,
Impurity F	[1-[[[(1R)-3-(2-acetylphenyl)-1-[3-[(E)-2-(7-chloroquinolin-2-yl)ethenyl]phenyl]propyl]sulfanyl]methyl]-cyclopropyl]acetic acid,
Impurity G	[1-[[[(1R)-1-[3-[(Z)-2-(7-chloroquinolin-2-yl)ethenyl]-phenyl]-3-[2-(1-hydroxy-1-methylethyl)phenyl]propyl]-sulfanyl]methyl]cyclopropyl]acetic acid,

ENQUIRY