Macsen Laboratories

Manufacturer of Fine Chemicals & Pharmaceuticals

Name of product : Allopurinol Ph.Eur/BP

CAS No. : 315-30-0

Molecular weight : 136.11 g/mol

SR.NO	CRITERIA	SPECIFICATION
1.	**APPEARANCE**	White or almost white powder
2.	**SOLUBILITY**	Very slightly soluble in water and in ethanol (96 per cent). It dissolves in dilute solutions of alkali hydroxides
3.	**IDENTIFICATION**	
	Test – A **UV-Vis Spectrophotometry**	Absorbance maximum 250 nm Absorbance minimum 231 nm Absorbance ratio A_{231}/A_{250} = 0.52 to 0.62
	Test – B **IR**	The infrared spectrum of test sample should match with working standard / reference standard
	Test - C **Identification Test**	A white precipitate is formed which does not dissolve on the addition of 5 mL of ammonia solution.
	Test – D **TLC**	The principal spot in the chromatogram obtained with the test solution is similar in position and size to the principal spot in the chromatogram obtained with the reference solution.
4.	**LOSS ON DRYING**	NMT 0.50%
5.	**Sulfated ash**	NMT 0.1%
6.	**ASSAY BY HPLC (On dried basis)**	NLT 97.00% to NMT 102.00%
7.	**ORAGNIC IMPURITIES BY HPLC**	**Name** / **Acceptance Criteria, NMT (%)** Allopurinol Impurity A / 0.2

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		<table><tr><td>Allopurinol Impurity B</td><td>0.1</td></tr><tr><td>Allopurinol Impurity C</td><td>0.1</td></tr><tr><td>Allopurinol Impurity D</td><td>0.1</td></tr><tr><td>Allopurinol Impurity E</td><td>0.1</td></tr><tr><td>Unspecified Impurity</td><td>0.1</td></tr><tr><td>Sum of impurities other than A, B and C</td><td>1.0</td></tr></table>
8.	**Allopurinol Impurity F**	10 ppm of hydrazine sulfate equivalent to 2.5 ppm of hydrazine.