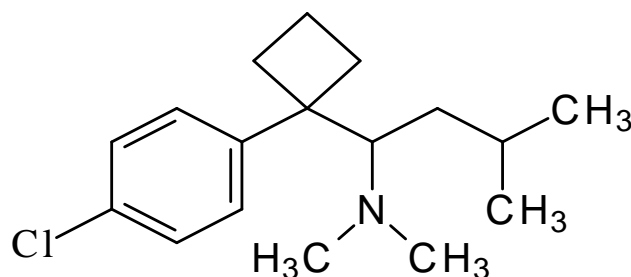


# SIBUTRAMINE HYDROCHLORIDE MONOHYDRATED

## Globe Specification



### Globe Reference: CIPA 5010140

<b>Formula</b>	C <sub>17</sub> H <sub>26</sub> ClN.HCl.H <sub>2</sub> O Mr = 334,33
<b>Action and use</b>	Anorexic Amphetamine Class. Anti-obesity agent.
<b>Characteristics</b>	White or almost white cristaline powder.
<b>Solubility</b>	Soluble in Dimethylformamide and Methanol.
<b>IDENTIFICATION</b>	
. Infrared Spectrum	Conform
<b>ESSAYS</b>	
. Melting point	192°C to 196°C.
. rotation specifics (20°C)	Entre - 0,5° a + 0,5°
. pH (1% w/v in water)	4,0 to 6,0
. Assay in Water	5,0 to 7,0 per cent
. Sulphated ash	Not more than 0,2 per cent
. Formaldehyde	Not more than 20 ppm
. Heavy Metals	Not more than 20 ppm
<b>Related Substances by HPLC:</b>	Conform
. N-di-desmethyl Sibutramine	Not more than 0.5 per cent
. N-mono-desmethyl Sibutramine	Not more than 0.5 per cent
. Total impurities	Not more than 1.0 per cent
<b>ASSAY</b>	
. Potenciometric assay in Sibutramine Hydrochloride Monohydrated in g per 100g calculated in relation to dried substance.	
- Titration	99,0 to 101,0 per cent.
- HPLC	98,0 to 102,0 per cent.
<b>Storage</b>	In well-closed containers.
<b>Packaging</b>	25 Kg fiber drum with double polyethylene bags.



**GLOBE QUÍMICA**  
TECHNOLOGICAL EXPERTISE

SYSTEM OF MANAGEMENT QUALITY **ISO-9001/2000**  
CERTIFICATE COMPANY IN GOOD MANUFACTURING  
PRACTICES – **GMP**

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