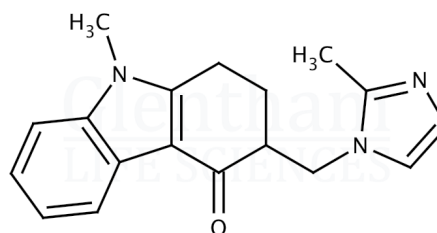


## Product Specification

Product Name	Ondansetron hydrochloride dihydrate, EP grade
Glentham Code	GP6185
CAS Number	103639-04-9
MDL Number	MFCD00374371
Additional CAS	99614-02-5
Additional CAS	99614-01-4
Additional CAS	116002-70-1 (base)
MDL Number	MFCD00764297 (anhy.)
Molecular Weight	365.85
Molecular Formula	$C_{18}H_{19}N_3O \cdot HCl \cdot 2H_2O$
Storage Temp.	+20°C



Property	Specification
Physical Description	White or almost white powder
Solubility	Sparingly soluble in water and in ethanol, soluble in methanol
Identification (IR)	To conform to standard
Identification	To pass test B
Impurity B	≤ 0.4% (TLC)
Related Substances (HPLC)	
Impurity C	≤ 0.20%
Impurity D	≤ 0.15%
Impurities A and G	≤ 0.20%
Impurities E and F	≤ 0.20%
Any Unspecified Impurity	≤ 0.10%
Total Impurities	≤ 0.40%
Water (KF)	9.0 - 10.5 %
Sulphated Ash	≤ 0.1%
Assay (HPLC)	97.5 - 102.0 % (C <sub>18</sub> H <sub>19</sub> N <sub>3</sub> O·HCl, anhydrous basis)
Pharmacopoeia Specification(s)	EP

Specification Version	-	v1.0
Date Created	-	2017-02-16

Glentham Life Sciences confirm that the above referenced product conformed to the information displayed in this document on the quality release date. Please check [www.glentham.com](http://www.glentham.com) or contact us using the details above for the current version of this document.

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