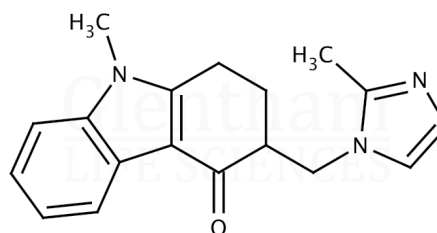


Product Specification

Product Name	Ondansetron hydrochloride dihydrate, EP grade
Glentham Code	GP6185
CAS Number	103639-04-9
MDL-Nummer	MFCD00374371
Zusätzliche CAS	99614-02-5
Zusätzliche CAS	99614-01-4
Zusätzliche CAS	116002-70-1 (base)
MDL-Nummer	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 % ($C_{18}H_{19}N_3O \cdot HCl$, 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 or contact us using the details above for the current version of this document.

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