



Harman Finochem Ltd.

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CERTIFICATE OF ANALYSIS			
PRODUCT	OXYBUTYNIN HYDROCHLORIDE Ph.Eur		
MANUFACTURER	M/s. HARMAN FINOCHEM LTD.		
BATCH NUMBER	OH/044/2020-2021	A. R. NUMBER	HFC/OH/2020-2021/044
DATE OF MANUFACTURING	OCTOBER 2020	DATE OF EXPIRY	SEPTEMBER 2025
DISPATCH QUANTITY	5.00 Kg	DRUG LIC. NUMBER	849
DATE OF RELEASE	20.10.2020		
TESTS	RESULTS	SPECIFICATIONS / LIMITS	
Characters/Appearance	White crystalline powder	A white or almost white, crystalline, practically odourless powder.	
Solubility	Complies	Freely soluble in water and in ethanol (96%) , soluble in acetone, practically insoluble in cyclohexane.	
Identification	Complies	B. The IR spectrum of sample is concordant with Spectrum of oxybutynin chloride working standard.	
Appearance of solution	Complies	D. It gives reaction (a) of chlorides.	
Loss on drying	1.9%	Solution S is clear and not more intensely coloured than reference solution BY ₅ .	
Sulphated ash	0.07%	Maximum 3.0 % (determined on 1.000 g by drying in an oven at 105°C)	
Related substances (by HPLC).	Below LOQ	Maximum 0.1% (determined on 1.0 g)	
	Below disregard limit	Impurity A: NMT 0.10% (in-house limit) (EP limit : NMT 1.5%)	
	Below disregard limit	In-house impurity [MPGA] NMT 0.15% (in-house limit)	
	Below disregard limit	Any Other Single Impurity NMT 0.10% (in-house limit)	
	Below disregard limit	Impurity B : NMT 0.10% (in-house limit)	
	Below disregard limit	Impurity C : NMT 0.15% (in-house limit)	
	Below disregard limit	Impurity D : NMT 0.15% (in-house limit)	
	Below disregard limit	Impurity E : NMT 0.10% (in-house limit)	
Optical rotation	+0.0059°	Total Impurities NMT 0.5% (in-house limit)	
Assay by titration (ODB)	99.8%	Between - 0.10° and + 0.10° (determined on solution S)	
Residual solvents (by GC)		Not less than 99.0% and Not more than 102.0%	
Heptane	Below LOQ	ICH Limit	In-house limit
Particle size (by Malvern particle size analyzer)	D(90%) - 14 µm D(50%) - 5.0 µm D(10%) - 1.7 µm	NMT 5000 ppm.	NMT 1000 ppm
Remarks : The Batch Complies as per Ph.Eur. and In-house Specifications.			
Prepared by	Checked by	Approved and Released by	
(Mr. B.R. Darkonde) (Sr. Officer Q. A.) Date : 20/10/20	(Mr. R. A. Kale) (Sr. Manager Q. C.) Date : 20/10/20	(Mr. S.C. Kulkarni) (Manager Q. A.) Date : 20/10/20	