

## CERTIFICATE OF ANALYSIS

<b>PRODUCT NAME</b>		<b>OXYBUTYNIN HCL USP</b>	
<b>BATCH NO.</b>		<b>OBT-17002</b>	
<b>DATE OF MFG.</b>		<b>FEB – 2017</b>	
<b>RE TEST DATE</b>		<b>JAN – 2022</b>	
<b>CERTIFICATE NO.</b>		<b>4408</b>	
<b>SR. NO.</b>	<b>TEST</b>	<b>SPECIFICATIONS</b>	<b>OBSERVATION</b>
01	Description	White crystalline practically odorless powder	White crystalline powder
02	Solubility	Freely soluble in water and in alcohol, very soluble in methanol and in chloroform. Soluble in acetone, slightly soluble in ether, very slightly soluble in hexane.	Complies
03	Residue on ignition	NMT 0.1 % w/w	0.02 %
04	Identification a) M.P b) IR	124° – 129° C The infrared spectrum of the sample should be concordant with the spectrum obtained for the USP Oxybutynin Chloride	128° – 129° C Complies
05	Heavy Metals	NMT 0.002 %	< 0.002 %
06	Related compounds by HPLC 1.Oxybutynin related compound A 2.Diphenyl analog of Oxybutinin chloride 3. Oxybutynin related compound B 4. Oxybutynin related compound C 5.Cyclohexenyl analog of Oxybutynin chloride 6. Ethylpropyl analog of Oxybutynin chloride 7. Any other single impurity 8. Total impurities	NMT 0.5 %  NMT 0.1 % NMT 1.0 % NMT 1.0 % NMT 1.0 %  NMT 0.1 %  NMT 0.1 % NMT 1.0 %	Not detected  Not detected Not detected Not detected Not detected  Not detected  0.08 % 0.19 %
07	Chloride Content	8 to 10 %	8.90 %
08	Loss on drying	NMT 3.0 %	0.65 %
09	Residual Solvents by GC	Methanol - NMT 3000 ppm Ethyl acetate- NMT 5000 ppm Toluene – NMT 890 ppm IPA – NMT 5000 ppm n- Hexane – NMT 290 ppm THF – NMT 720 ppm	Not Detected 273 ppm Not Detected Not Detected Not Detected Not Detected
10	Assay (ODB) By HPLC	97.0 % to 102 %	99.96 %

**Remark: - The above material complies with the USP specification.**

**The main peak retention time of the solution corresponds to that of the standard solution, as obtained in the Assay.**



**Prepared By:**



**Checked By:**



**Approved By:**