CUREWORTH DRUGS & INTERMEDIATES PVT. LTD.

Active Pharmaceutical Ingredients....

ABOUT US

Nature Of Business :

Manufacture Of Active Pharmaceutical Ingredients & Intermediates.

Contact Person :

Ashutosh Gokhale (Director)
cureworth@gmail.com
+91 7738155701

Establishment :

The company was incorporated in 2010 & have started commercial production in September 2012.

Certificates & Licenses:

- Ministry of Environment
  (SEAC 2010/CR 477/ TC. 2 dated 29/03/2011).
- MPCB Consent September 2012.
  (Renewed up to 2022).
- Food and Drug Administration Approval No. KD / 754
- GMP from Food and Drug Administration in December 2015.
- Department of Industrial Safety & Health Factory License in November 2012.

FACILITIES

Plant is Designed as per requirement of cGMP

Plot Area	2400 sq. mtr.
Built up Area	1600 sq. mtr.
Area Under AHU	180 sq. mtr.

Salient features of our Production Plant:

- Two storey reinforced concrete building complying with cGMP norms.
- Clean Rooms with HEPA Filters (Class 100,000)
- UF water system
- Uniflow of men and material
- Built in Safety systems
- Member of common effluent treatment plant
- Full-fledge effluent treatment plant in operations
- Filtered fresh air supply in processing area-comfort zone.

The installed Power is 200 HP. With a backup of Diesel Generator of 200 KVA is also installed as alternate source of power.

Water connection is adequate to carry out the All Plant activities.

Quality Control : Laboratory is separated in three parts like wet analysis, Instrumentation Room, Microbiology Room. The Instrumentation Room is equipped with HPLC, Gas Chromatograph, Karl-Fischer etc.

CUREWORTH DRUGS & INTERMEDIATES PRIVATE LIMITED

PLOT NO. N-49, ADDITIONAL AMBERNATH IND. AREA,
M.I.D.C., AMBERNATH (EAST) 421 506, DIST. THANE, MAHARASHTRA. INDIA.
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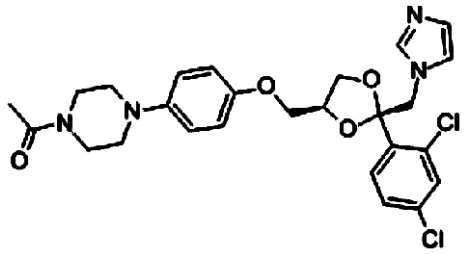
Ph. No. : +91 7738155701 / 7738155708

CUREWORTH DRUGS & INTERMEDIATES PVT. LTD.

KETOCONAZOLE

Structre		
Product Name	KETOCONAZOLE	
Grade	EP / USP	
CAS No.	65277-42-1	
Molecular Weight	531.43	
Molecular Formula	$C_{26}H_{28}CL_2N_4O_4$	
Specifications	**EP**	**USP**
Appearance	A white to almost white powder.	A white to almost white powder.
Identification by IR	Infrared absorption spectrum of sample should be concordant with that of working standard spectrum.	Infrared absorption spectrum of sample should be concordant with that of working standard spectrum.
Melting Point	Between 148°C to 152°C	Between 148°C to 152°C
Specific Rotation	Between -0.10° to + 0.10°	Between -1.0° and +1.0° (T=20°C)
Sulphated Ash	Not More Than 0.1% w/w	Not More Than 0.1% w/w
Related Substances	**By HPLC :** In the chromatogram obtained with the test solution, the sum of areas all peaks, apart from the principal peak, is not greater than the area of principal peak in the chromatogram obtained with reference solution(b) (Not more than : 0.5 per cent)	**By TLC :** The principal spot obtained from the Test solution has about the same size and Rf value as that obtained from the Standard solution and the sum of the intensities of any secondary spots obtained from the test solution does not exceed the intensity of the principal spot obtained from the Diluted standard solution. (NMT : 0.5%)
Loss On Drying	Not More Than 0.5% w/w	Not More Than 0.5% w/w
Assay by Titration	NMT 99.0% and NMT 101.0% w/w on dried basis	Not less than 98.0% & not more than 102.0% w/w

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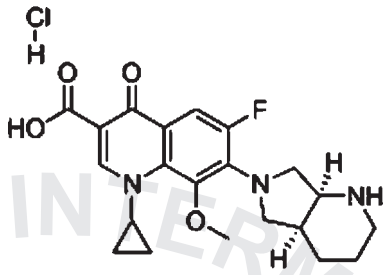
MOXIFLOXACIN HYDROCHLORIDE

Structre		
Product Name	MOXIFLOXACIN HYDROCHLORIDE	
Grade	EP/USP	
CAS No.	186826-86-8	
Molecular Weight	437.89	
Molecular Formula	$C_{21}H_{25}CLFN_3O_4$	
Specifications	**EP**	**USP**
Appearance	Light yellow or yellow powder or crystals, slightly hygroscopic.	Slight yellow to yellow powder or crystals
Identification by IR	IR spectrum of sample is concordant with that of reference/working standard.	IR spectrum of sample is concordant with that of reference/working standard.
pH	3.9 to 4.6	3.9 to 4.6
Specific Rotation	-125º to -138º	-125.00º to -138.00º
Sulphated Ash	Not More Than 0.1% w/w	Not More Than 0.1% w/w
Related Substances by HPLC	As per EP Monogram	As per USP Monogram
Water Content	NMT 4.50%	NMT 4.50%
Assay by HPLC (Anhydrous basis)	98.0 % to 102 %	98.0 % to 102 %

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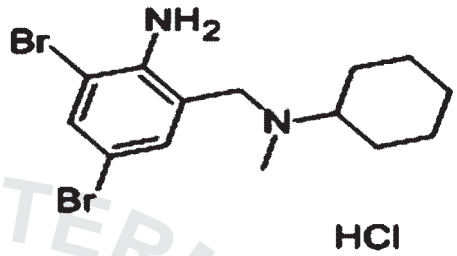
BROMHEXINE HYDROCHLORIDE

Structre	
Product Name	BROMHEXINE HYDROCHLORIDE
Grade	IP / EP
CAS No.	611 – 75 – 6
Molecular Weight	412.59
Molecular Formula	$C_{14}H_{21}Br_2ClN_2$
Specifications	**EP**
Appearance	White or almost white crystalline powder.
Identification by IR	IR Absorption spectrum Compare the spectrum obtained with Bromhexine hydrochloride CRS.
Appearance of solution	Solution should be clear and not more intensely coloured than reference solution *Y6*
Sulphated Ash	Max. 0.1 %.
Related Substances by HPLC	As per EP Monogram
Loss On Drying	Max. 1.0 %.
Assay by Potentiometry (dried basis)	98.5% to 101.5%

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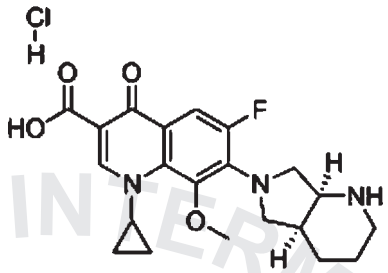
TELMISARTAN

Structre		
Product Name	TELMISARTAN	
Grade	BP/USP/IP	
CAS No.	144701-48-4	
Molecular Weight	514.62	
Molecular Formula	$C_{33}H_{30}N_4O_2$	
Specifications	**EP**	**USP**
Appearance	White or slightly yellowish, crystalline powder.	A white or slightly yellowish crystalline powder.
Identification by IR	The infrared absorption spectrum of the sample should concordant with that of Telmisartan working standard.	The infrared absorption spectrum of the sample should concordant with that of Telmisartan working standard.
Sulphated Ash	Not More Than 0.1% w/w	Not More Than 0.1% w/w
Related Substances by HPLC	As per EP Monogram	As per USP Monogram
Loss On Drying	Not More Than 0.5% w/w	Not More Than 1.5% w/w
Assay	**By Potentiometry :** NLT 99.0% and not more than 101.0%	**By Titration :** NLT 98.0% & not more than 101.0% w/w

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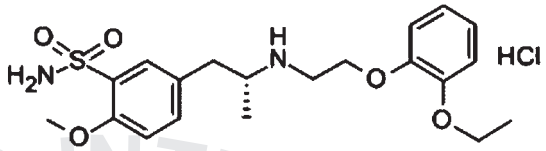
TAMSULOSIN HYDROCHLORIDE

Structre	
Product Name	TAMSULOSIN HYDROCHLORIDE
Grade	IP/EP
CAS No.	106463-17-6
Molecular Weight	444.97
Molecular Formula	$C_{20}H_{29}ClN_2O_5S$
Specifications	**EP**
Description	White to off white crystalline powder.
Identification by IR	The IR spectrum obtained from the sample should be concordant with the spectrum obtained from the working standard.
Test for chlorides	Positive test for chlorides
Specific optical rotation	-17.5° to -20.5° dried basis
Sulphated Ash	Max. 0.1 %.
Related Substances by HPLC	As per EP Monogram
Loss on drying	Not more than 0.5%
Heavy Metals	Not more than 20 ppm
Assay by titrimetry (on dried basis)	NLT 98.5 % to 101.0 % w/w.

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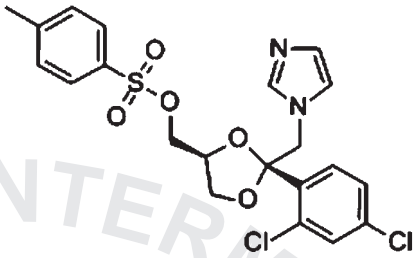
CIS-TOSYLATE

Structre	
Product Name	**Cis –Tosylate**
Grade	In – house
CAS No.	134071-44-6
Molecular Weight	483.12
Molecular Formula	$C_{21}H_{20}Cl_2N_2O_5S$
Specifications	In – House
Description	White to off white crystalline powder.
Melting Point	Between 118°C to 126°C
Moisture Content by KF	Not more than 0.5 % w/w.
By HPLC	Single maximum impurity – NMT 0.5% Total impurities – NMT 1%
Assay by titrimetry(on dried basis)	NLT - 98.0% w/w

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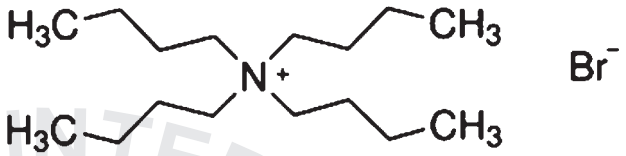
TETRA BUTYL AMMONIUM BROMIDE

Structre	
Product Name	**Tetra Butyl Ammonium Bromide**
Grade	In-house
CAS No.	1643-19-2
Molecular Weight	322.37
Molecular Formula	$C_{16}H_{36}BrN$
Specifications	**IN-HOUSE**
Description	White to cream colour crystalline powder.
Melting Point	Between 106°C to 110°C
Moisture Content by KF	Not more than 0.5 % w/w.
Assay by titrimetry(on dried basis)	Not less than 99.0% w/w.

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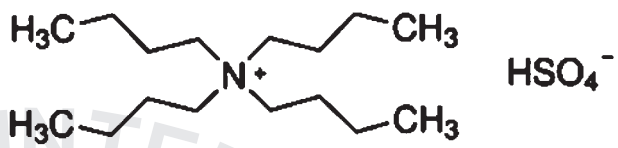
TETRA BUTYL AMMONIUM HYDROGEN SULPHATE

	
Product Name	**Tetra Butyl Ammonium Hydrogen Sulphate**
Grade	In-house
CAS No.	32503-27-8
Molecular Weight	339.53
Molecular Formula	$C_{16}H_{37}NO_4S$
Specifications	**IN-HOUSE**
Description	White to off white crystalline powder.
Melting Point	Between 164°C to 172°C
LOD	Not more than 0.5 % w/w.
pH (10% water)	Max 2.0
Sulphated ash	Max 0.3 %
Assay by titrimetry(on dried basis)	Not less than 99.0% w/w.

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