

FLYCHEM INTERNATIONAL

Leading Manufacture of Active
Pharmaceutical Ingredients
(API's)



FLYCHEM
INTERNATIONAL

About Us

We are Leading Manufacturer & Exporter of **Paracetamol (Acetaminophen)** & other Active Pharmaceutical Ingredients (Bulk Drugs).



WELCOME TO FLYCHEM INTERNATIONAL

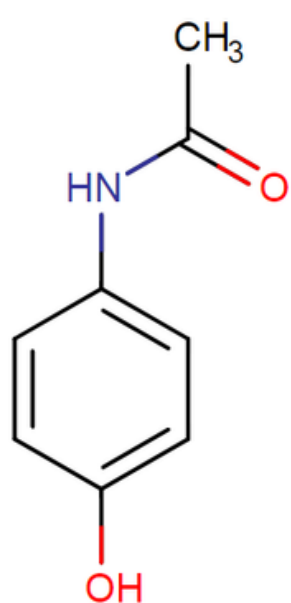
Backed by more than 12 years of industry experience, we have gained immense reputation in the manufacturing and exporting of a variety of Active Pharmaceutical Ingredients (Bulk Drugs). Our association with leading and quality conscious manufacturers of pharmaceutical products allows us to successfully handle the emerging product demands in the domestic market. Catering to the variegated requirements of our global clients, we are delivering our quality products in the market which are at par with international quality standards. Timely delivery, cost - effectiveness and state of the art facilities are some of the key factors that enable us to offer qualitative range in stipulated time frame. Further, the team of quality analysts strictly monitor each stage of production procedure to ensure flawless range.

The complete product range offered by us includes Paracetamol (Acetaminophen), Fluconazole, Sitagliptin Phosphate & Hydrochloride, Pregabalin, Cefixime Trihydrate, Lidocaine Base (Lignocaine Base), Lidocaine Hydrochloride (Lignocaine HCl), Piroxicam, Meloxicam and many others.

Product

Paracetamol (Acetaminophen)

N-(4-hydroxyphenyl) acetamide



CAS NO :- 103-90-2

Grade :- IP/USP/BP/EP

Empirical Formula :- C₈H₉NO₂

Molecular Weight :- 151.16 gm/mol

Packing Size :- 50 KG & As per customer convenience

Application :- Anti Pyretics & Analgesics

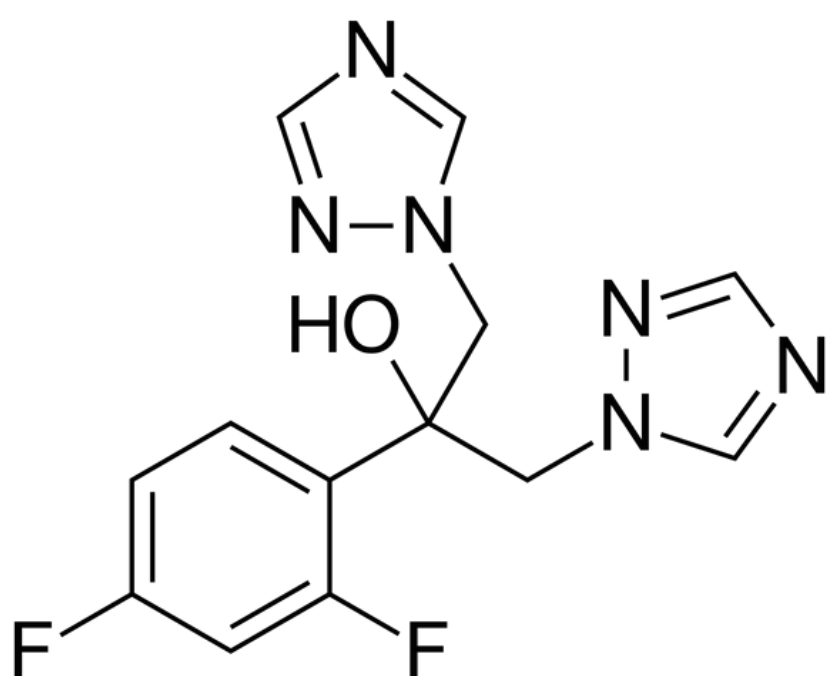
Specification:-

No.	Name of Test	IP	BP/EP	USP
1.	Description/Appearance	White Crystals or White Crystalline Powder	White, or almost white, Crystalline Powder	White, odorless, Crystalline Powder.
2.	Solubility	Sparingly soluble in Water	Sparingly soluble in Water	-
		Freely soluble in ethanol	Freely soluble in Ethanol (96%)	Freely soluble in Ethyl Alcohol
		Very slight soluble in Methylene chloride	Very slight soluble in Methylene chloride	-
		-	-	Soluble in Boiling Water and in 1N NaOH.
3.	Identification	(A) The absorbance at 249 nm is about 0.44(B) A violet color develops which does not turn to red.(C) Gives the reaction of acetyl groups.(D) The Infrared absorption spectrum of substance being examined must be concordant with the IR spectrum obtained from Paracetamol working standard.	(A)Result-AMelting Point - 168°C to 172°C.Result-BThe absolute difference between the melting point mixture and the value obtained in Determination A (Result-A) is not greater than 2°C(B) The Infrared absorption spectrum of substance being examined must be concordant with the IR spectrum obtained from Paracetamol working standard.	(A)By IR:The Infrared absorption spectrum of substance being examined must be concordant with the IR spectrum obtained from Acetaminophen working standard.(B) By HPLC:The retention time of the major peak obtained in sample solution corresponds to that obtained in the standard solution, as described in the test of assay.
		Related Substance		
	Impurity J	Max. 10 ppm	Max. 10 ppm	-
	Impurity K	Max. 50 ppm	Max. 50 ppm	-
	Impurity F	Max. 0.05 %	-	-
	Unspecified Impurity	-	Max. 0.05 %	Max. 0.05 %
	Total Impurities	Max. 0.1 %	Max. 0.2 %	NMT 0.1 %
	Any other Impurity	Max. 0.05 %	-	-
	Organic Impurities			
	Acetaminophen Related Compound B	-	-	NMT 0.05%
	Acetaminophen Related Compound C	-	-	NMT 0.05%
	Acetaminophen Related Compound B	-	-	NMT 0.05%
	Acetaminophen Related Compound J	-	-	NMT 0.001%
4.	Free 4-Aminophenol	-	-	NMT 0.005%
5.	Loss on Drying (at 105°C)	Maximum 0.5% w/w	Maximum 0.5 % w/w	Maximum 0.5% w/w
6.	Residue on Ignition	-	-	NMT 0.1%
7.	Heavy Metals	NMT 10 ppm	-	-
8.	Sulphated Ash	NMT 0.1 % w/w	NMT 0.1 % w/w	-
9.	Assay	99.0 % To 101.0 % w/w C ₈ H ₉ NO ₂ (On dried basis)	99.0 % To 101.0 % w/w C ₈ H ₉ NO ₂ (On dried basis)	98.0% To 102.0% w/w C ₈ H ₉ NO ₂ (on the dried basis)

Product

Fluconazole

2-(2,4-Difluorophenyl)-1,3-bis(1H-1,2,4-triazol-1-yl)propan-2-ol



CAS NO :- 86386-73-4

Grade :- IP/USP/BP/EP

Empirical Formula :- C₁₃H₁₂F₂N₆O

Molecular Weight :- 306.271 g/mol

Packing Size :- 25 KG HDPE Drum &

As per customer convenience

Application :- Antifungal

Specification:-

No.	Name of Test	IP	USP	EP
1	Description/Appearance	White or almost white, crystalline powder	White or almost white, crystalline powder	White or almost white, crystalline powder
2	Solubility	Slightly soluble in water.	Freely soluble in methanol; soluble in alcohol and in acetone; sparingly soluble in isopropanol and in chloroform; slightly soluble in water; very slightly soluble in toluene.	Freely soluble in methanol, soluble in acetone and slightly soluble in water.
3		A 5% w/v solution in methanol, the solution is clear and colorless.	A 5% w/v solution in methanol, the solution is clear and colorless.	A 5% w/v solution in methanol, the solution is clear and colorless.
4	Identification	(A) By IR :- The infrared absorption spectrum of the test substance exhibits maximum at the same wave-length as that of a similar preparation of Fluconazole working reference standard.	(A) By IR: - The infrared absorption spectrum of the test substance exhibits maximum at the same wave-length as that of a similar preparation of Fluconazole working reference standard.	(A) By IR :- The infrared absorbance spectrum of the test substance is concordant spectrum obtained from similar preparation of Fluconazole working reference Standard.
5		(B) By UV :- The UV absorption spectrum of 0.025% w/v of Fluconazole test solution in methanol in the range of 200 nm to 350 nm should shows absorption maxima at about 266 nm and 261 nm.	(B) By UV :- The UV absorption spectrum of 200 µg/ml of Fluconazole test solution and Fluconazole standard solution in alcohol should be exhibit maxima at a same wavelength.	
6	Loss on drying	NMT 0.5%	NMT 0.5%	NMT 0.5%
7	Sulphated ash	NMT 0.1%	NMT 0.1%	NMT 0.1%
8	Iron	NMT 20 ppm	NMT 20 ppm	NMT 20 ppm
9	Related substances By HPLC	(A) Individual known impurity : Compound A: NMT 0.2% Compound B: NMT 0.1% Compound C: NMT 0.2% (B) Impurity at about RRT 0.6: NMT 1.0% (C) Any single maximum unknown impurities: NMT 0.1% (D) Total Impurities: NMT 1.5%	(A) Individual known impurity : Compound A: NMT 0.2% Compound B: NMT 0.1% Compound C: NMT 0.2% (B) Impurity at about RRT 0.6: NMT 1.0% (C) Any single maximum unknown impurities: NMT 0.1% (D) Total Impurities: NMT 1.5% (E) Total Unknown Impurities: NMT 0.3%	(A) Individual known impurity : Compound A: NMT 0.4% Compound B: NMT 0.3% Compound C: NMT 0.1% (B) Any single maximum unknown impurities: NMT 0.1% (C) Total Impurities: NMT 0.6%
10	Assay	98.5% To 101.5% w/w C ₁₃ H ₁₂ F ₂ N ₆ O (On the dried basis)	98.0% To 102.0% w/w C ₁₃ H ₁₂ F ₂ N ₆ O (On the dried basis)	99.0% To 101.0% w/w C ₁₃ H ₁₂ F ₂ N ₆ O (On the dried basis)

Other Product




PRODUCT NAME	CAS NO.	GRADE	APPLICATION
Sitagliptin Hydrochloride	486459-71-6	IP/BP/EP/USP	Anti-diabetic
Sitagliptin Phosphate	654671-78-0	IP/BP/EP/USP	Anti-diabetic
Metformin Hydrochloride	1115-70-4	IP/BP/EP/USP	Anti-diabetic, Biguanides
Pregabalin	148553-50-8	IP/USP	Anti-Inflammatory
Cefixime Trihydrate	125110-14-7	IP/BP/EP/USP	Antibiotic
Lidocaine Base	137-58-6	IP/BP/EP/USP	Anesthetic
Lidocaine Hydrochloride	73-78-9	IP/BP/EP/USP	Anesthetic
Piroxicam	36322-90-4	IP/BP/EP/USP	Anti-Inflammatory
Meloxicam	71125-38-7	IP/BP/EP/USP	Anti-Inflammatory

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