National Agency for Food & Drug Administration & Control (NAFDAC)

Registration & Regulatory Affairs (R & R) Directorate

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC) CIPROVEN TABLET 500MG

Summary of Product Characteristics (SmPC)

1.3.1 Summary of Product Characteristics (SmPC)

1.3.1.1 Name of the product： Ciprofloxacin tablets 500mg

1.3.1.2 Qualitative and quantitative composition

Each tablet contains: Ciprofloxacin Hydrochloride equivalent to 500mg of Ciprofloxacin.

1.3.1.3 Pharmaceutical form

Tablet for Oral.

1.3.1.4 Clinical particulars

PHARMACOLOGICAL ACTION:

As a fluoroquinolone antibacterial agent, the bactericidal action of ciprofloxacin results from the inhibition of both type II topoisomerase (DNA-gyrase) and topoisomerase IV, required for bacterial DNA replication, transcription, repair and recombination.

1.3.1.5 Pharmacological properties

Route of administration: orally

Dose and Administration: 500mg

Fasting:

Following an overnight fasting (at least 10 hours), the subjects were administrated 500mg of ciprofloxacin hydrochloride tablet together with 240ml of water or 500mg of reference preparation together with 240ml of water, in the next morning as per the dosage regimen. And then all the subjects have standard breakfast, lunch and supper after 2h (±30min), 4h

(±30min), 10h (±30min) of administration, light diet is required during the trial. After 7 days of wash-out, begin the secondary periodic test on 8th day. According to trial protocol, the subjects crosswise accept the other preparation and dosage regimen is the same with the 1st period.

Postprandial:

Following an overnight fasting (at least 10 hours), the subjects receive standard meal 30mins before the administration of drug. Then, the subjects were administrated 500mg of ciprofloxacin hydrochloride tablet together with 240ml of water or 500mg of reference preparation together with 240ml of water. After 7 days of wash-out, begin the secondary periodic test on 8th day. According to trial protocol, the subjects crosswise accept the other preparation and dosage regimen is the same with the 1st period.

1.3.1.6 Pharmaceutical particulars

1.3.1.6.1 List of excipients

Excipients for Ciprofloxacin tablets & 500mg

Ingredient	Function	Quantity/unit mg	Standard
Excipients			
Sodium Starch Glycolate	Disintegrant	48.0	Ch.P2020
Corn Starch	Diluent	96.0	Ch.P2020
Corn Starch (for 7% starch solution)	Adhesive	18.0	Ch.P2020
Magnesium stearate	Lubricant	10.8	Ch.P2020
Gastric soluble film coating premix agent	Coating agent	About 16	Local FDA standard
Remark: the composition of coating premix is as follows: Hypromellose (46%), Polyethylene glycol 6000 (18%), Talcum powder (20%), Titanium dioxide (16%).			

1.3.1.6.2 Incompatibilities

Not applicable.

1.3.1.6.3 Shelf life

36 months

1.3.1.6.4 Special precautions for storage

Store in a cool and dry place below 30℃. Protect from light and moisture.

Keep all medicines out of reach of children.

1.3.1.6.5 Nature and contents of container

We select medicinal PVC hard sheet and Aluminum foil as the primary package material, which is the same as the branded drug. PVC blister and Aluminum foil are well used in pharmaceutical industry, they have applicable compatibility with drug

product. The long-term and accelerated stability also demonstrate the compatibility of this package is qualified.

1.3.1.6.6 Special precautions for disposal and other handling

NA