ACCENT PHARMACEUTICALS & DIAGNOSTICS
FOREST ROAD SOLAN, H.P. (INDIA)
QUALITY CONTROL DEPARTMENT
STANDARD TESTING PROCEDURE

Material/ Generic Name	**Diclofenac Potassium, Paracetamol & Chlorzoxazone Tablets**		
STP No.	**APD/STP/GT/140-FG**	**Revision No.**	**05**
Supersedes No.	**04**	**Sample Quantity**	**140 Tablets**
Reference	**IHS**	**Review Date**	16/05/2025
Effective Date	17/05/2023		
Label Claim	**Each Film coated Tablet Contains:** **Chlorzoxazone USP 250 mg** **Diclofenac Potassium USP 50 mg** **Paracetamol BP 325 mg** **Excipients q.s.**		

1. STANDARD TEST PROCEDURE:

S. No.	TEST	REFERENCE	PROCEDURE
1.	**Description (By Visual Method)**	IHS	Take 20 tablets in a petri plate. Examine visually for colour, general appearance and any physical defect. Tablets should be Pink coloured, round shaped, biconvex, film coated tablets.
2.	**Identification**		
	By HPLC	IHS	In the assay, the principal peak in the chromatogram obtained with test solution corresponds to the principal peak in the chromatogram obtained with reference solution.
3.	**Average weight (By Analytical Balance)**	IHS	Take 20 tablets and weigh, note the weight of 20 tablets and divide the total weight by 20 **(Limit: 724.0 mg ± 2%)**
4.	**Uniformity of weight (By Analytical Balance)**	BP	Take 20 tablets and follow the SOP of balance & weigh accurately every tablet, record the minimum weight and maximum weight of the tablets. Find the uniformity of weight of the tablets as follows:- Minimum uniformity of weight (in %) = $\{(W_2 - W_1) \div W_1\} \times 100$ Maximum uniformity of weight (in %) = $\{(W_3 - W_1) \div W_1\} \times 100$ Where: W_1 = Average weight of tablets W_2 = Minimum weight of tablet W_3 = Maximum weight of tablet **(Limits: ±5.0% of Average weight)**
5.	**Thickness (By Vernier caliper & Five Parameter test**	IHS	Take 10 tablets and follow the SOP of vernier caliper & five parameter measure carefully the thickness of every tablet.

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Department	**Quality Control**	**Quality Control**	**Quality Assurance**

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S. No.	TEST	REFERENCE	PROCEDURE
	Apparatus)		**(Limit: 5.35 mm± 0.2 mm)**
6.	**Disintegration time**	BP	Take 6 tablets and follow the SOP of Disintegration Test Apparatus & observe the disintegration time of the tablets. **(Limit: Not More Than 30.0 minutes)**
7.	**Assay: (By HPLC) Each Film coated Tablet Contains:**		
	Chlorzoxazone USP 250 mg **Diclofenac Potassium USP 50 mg** **Paracetamol BP 325 mg**	IHS	**Buffer solution:** 1 ml orthophosphoric acid in 950 ml of water and Dilute with water to 1000 ml. **Mobile Phase:** 700 ml Acetonitrile and 300 ml buffer solution **Chromatographic condition:** **Column:** A stainless steel column 25 cm x 4.6 mm, packed with octadecylsilane bonded to porous silica (5µm), **Flow rate.** 1.5 ml per minute, **Spectrophotometer:** set at 220 nm, **Injection volume.** 20µl **Column temperature:** Ambient **Standard solution:** Accurately weigh of 162.5 mg of Paracetamol,125 mg of Chlorzoxazone and 25 mg of Diclofenac Potassium working standard in to a 100 ml volumetric flask add 40 ml of mobile phase, shake and sonicate to dissolve and dilute to volume with Solvent mixture up to the mark. Take 5 ml of this solution in 50 ml volumetric flask and dilute to with mobile phase Filter through 0.22µm membrane syringe filter. **Test solution.** Weigh and powder 20 tablets. Weigh a quantity of the powder containing 25 mg of Diclofenac

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UNCONTROLLED Issued By: Sign & Date: (QA/06) 05/08/2023

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FOREST ROAD SOLAN, H.P. (INDIA)
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S. No.	TEST	REFERENCE	PROCEDURE
			Potassium in to a 100 ml volumetric flask add 40 ml of mobile phase, shake and sonicate to dissolve and dilute to volume with Solvent mixture up to the mark. Take 5 ml of this solution in 50 ml volumetric flask and dilute to with mobile phase Filter through 0.22 µm membrane syringe filter. **Calculations for Paracetamol :** Standard solution and sample solution calculate the percentage of paracetamol Assay in mg per tablet of the label claim. $\frac{A_t}{A_s} \times \frac{Ws}{100} \times \frac{5}{50} \times \frac{100}{T_w} \times \frac{50}{5} \times \frac{P}{100} \times A_w$ = Paraetamol (in mg) Where At :Area of the peak test solution As :Area of the peak standard solution Ws :Weight of working standard T_w :Weight of the sample for analysis(powdered tablets in mg) P : potency of working standard as such basis. **(Limit: 90.0% to 110.0%)** **Calculations for Diclofenac Potassium:** Standard solution and sample solution calculate the percentage of Diclofenac Potassium Assay in mg per tablet of the label claim. $\frac{A_t}{A_s} \times \frac{Ws}{100} \times \frac{5}{50} \times \frac{100}{T_w} \times \frac{50}{5} \times \frac{P}{100} \times A_w$

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Supersedes No.	**04**	**Sample Quantity**	**140 Tablets**
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Effective Date	17/05/2028		
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S. No.	TEST	REFERENCE	PROCEDURE
			= Diclofenac Potassium (in mg) Where At :Area of the peak test solution As :Area of the peak standard solution Ws :Weight of working standard T_w :Weight of the sample for analysis(powdered tablets in mg) P : potency of working standard as such basis. **(Limit: 90.0% to 110.0%)** **Calculations for Chlorzoxazone:** Standard solution and sample solution calculate the percentage of Chlorzoxazone Assay in mg per tablet of the label claim. $\frac{A_t}{A_s} \times \frac{Ws}{100} \times \frac{5}{50} \times \frac{100}{T_w} \times \frac{50}{5} \times \frac{P}{100} \times A_w$ = Chlorzoxazone (in mg) Where At :Area of the peak test solution As :Area of the peak standard solution Ws :Weight of working standard T_w :Weight of the sample for analysis(powdered tablets in mg) P : potency of working standard as such basis. **(Limit: 90.0% to 110.0%)**
8.	**Microbial Limit Test: (By Plate Count Method)**		
	Total aerobic microbial count (TAMC) & Total	**BP**	Take 1 ml sample from pretreated sample in to sterile Petri dish.Pour 15-20 ml Soyabean Casein Digest Agar for bacteria and Sabour and Dextrose Agar with antibiotic

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	yeast and mould count (TYMC)		for fungus at not more than 45 °C. Close the lid and mix the plate gently by rotating the plates on smooth flat surface in "8" shape.Prepared at least two such plate using the same dilution. After solidify, incubate the plates of Soyabean Casein Digest Agar in inverted position at 30-35°C for 3-5 days. Similarly incubate the plate of Sabouraud dextrose agar at20-25 °C for 5-7 Days. Calculate the mean count on each medium and from that calculate the number of cfu/g/ml. **Calculation:** **$\frac{\text{Count of 1}^{st}\text{ plate + Count of 2}^{nd}\text{ plate}}{2}$ = Average cfu/ml** **Total aerobic microbial count = Average cfu/ml × Dilution factor** **(Limit: Not More Than 10^3 cfu/gm (TAMC) & Not Mor Than 10^2 cfu/gm (TYMC))**
	Presumptive Test: (By Direct Inoculation Method)		
	Escherichia Coli	BP	**Pretreatment of Sample:** Take 10 g or 10 ml of sample and transfer Into 100 ml or 90 ml of SCDM respectively. Incubate the sample in bacteriological incubator at 30-.35°C temperature for 24 hrs. If there is evidence of microbial growth (in term of turbidity) after 24 hours. Proceed for detection of pathogens as per the following procedures After incubation of pretreated sample shake the broth and transfer 1 ml to100 ml of Mac-Conkey Broth (MB). Incubate at 42-44 °C for 24-48 hours Examine the growth in terms of turbidity; if turbidity occurs carry out secondary test by sub culturing on a

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S. No.	TEST	REFERENCE	PROCEDURE
			plate of Mac-Conkey Agar (MA) and incubate at 30-35 °C for 18-72 hours, growth of brick red, non-mucoid colonies surrounded with precipitated bile indicates the possible presence of Escherichia coli, carry out confirmatory test-growth on Eosin Methylene Blue Agar (EMB) agar or Indole test. Subculture the suspected colony from Mac-Conkey Agar on EMB plate and incubate at 30-35 °C for 24-48 hours, check for colony with metallic sheen. For Indole testsubculture suspected colony from Mac-Conkey Agar into 5 ml of peptone water and incubate it at 30-35 °C for 18-24 hours, after completion of incubation add 0.5 ml ofKovac's reagent, shake well and stand for 1 minutes, red colour ring formation confirms presence of E-coli. Keep positive & Negative Controls also. **(Limit: Should be absent/gm)**

Note: *Microbiological analysis shall be performed for first three batches and then every tenth batch, after that every first & every tenth batch of years per SOP.: APD/QAD/028 "Procedure for In-Process and finished product sampling."

2. REVISION HISTORY:

REVISION NO.	EFFECTIVE DATE	DETAILS OF REVISION	CHANGE CONTROL NO.	REASON FOR REVISION
00	10 MAY 2018	NA	NA	New STP
01	20/12/2019	Old format no. APD/QC/020/02/05 to new Format no.	APD/CC/1932	System up gradation

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		APD/QCD/020/F01-06		
02	22/08/2020	In header add Generic name & Label Claim	C/20QCD/80/005	System up gradation
03	17/01/2021	➢ Remove Generic name column ➢ Add Generic name instead of product name Annexure I & II	C/21QCD/01/001	System up gradation
04	18/05/2021	Remove product/Material code & packing Information in Header	C21/QCD/05/003	System up gradation
05	17/05/2023	Microbial test to be performed as per pharmacopoeia	C22/QCD/06/002	System up gradation

3. ABBREVIATIONS:

- **3.1.** STP -Standard Test Procedure
- **3.2.** QA -Quality Assurance
- **3.3.** QC -Quality control
- **3.4.** NA -Not Applicable
- **3.5.** No. -Number
- **3.6.** IHS - In House Specification
- **3.7.** BP -British Pharmacopoeia

END OF STP

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